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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Parts 30, 32, and 35

**[NRC–2014–0030]**

**RIN 3150–AI63**

### Medical Use of Byproduct Material—Medical Event; Definitions and Training and Experience

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final guidance; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing a final guidance document entitled, ''Final Guidance for the Rule 'Medical Use of Byproduct Material—Medical Events Definitions, Training and Experience, and Clarifying Amendments.' '' This guidance document addresses implementation of the NRC's final rule amending its medical use of byproduct material regulations which is being published concurrently in Separate Part IV of this issue of the **Federal Register**.

**DATES:** The guidance document is available on July 16, 2018.

**ADDRESSES:** Please refer to Docket ID NRC–2014–0030 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0030. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The final guidance document is available in ADAMS under Accession No. ML18176A377.
- *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:** Donna-Beth Howe, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5441; email: *Donna-Beth.Howe@nrc.gov.*

**SUPPLEMENTARY INFORMATION:** The NRC published the draft guidance document in the **Federal Register** on July 21, 2014 (79 FR 42224). The NRC received seven comments on the draft guidance. The NRC's response to the public comments received can be found in the fourth section of the final guidance. The guidance document is for use by applicants, licensees, Agreement States, and the NRC staff. This guidance document (ADAMS Accession No. ML18176A377) has four parts: the first two are revisions to existing information in the NUREG–1556, ''Consolidated Guidance About Materials Licenses,'' series of volumes for medical uses (Volume 9) and commercial nuclear pharmacies (Volume 13); the third part is a series of questions and answers to assist applicants and licensees in understanding and implementing the new regulatory changes; and the fourth is the comments received on the proposed guidance during the public comment period, and the NRC's responses. The current NUREG–1556 documents provide guidance to applicants for the completion and submission of materials license applications to the NRC. The documents also include model procedures that an applicant may consider when developing its radiation safety program. The guidance document can be found on the NRC's Medical Uses Licensee Toolkit website (*http://www.nrc.gov/materials/miau/med-use-toolkit.html*).

The NRC is publishing concurrently with this guidance document the final rule, ''Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments'' (RIN 3150–AI63, NRC–2008–0175) in Separate Part IV of this issue of the **Federal Register**. In conjunction with the final rule, the NRC developed this final guidance document which provides guidance to licensees and applicants for implementing the revisions in the final rule.

Dated at Rockville, Maryland, this 3rd day of July 2018.

For the Nuclear Regulatory Commission.

**Daniel S. Collins,**

*Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2018–14853 Filed 7–13–18; 8:45 am]

**BILLING CODE 7590–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 25

**[Docket No. FAA–2015–0310; Special Conditions No. 25–732–SC]**

### Special Conditions: Gulfstream Aerospace Corporation Model GVII–G500 Series Airplanes; Flight Envelope Protection—High Incidence Protection System

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

**ACTION:** Final special conditions.

**SUMMARY:** These special conditions are issued for the Gulfstream Aerospace Corporation (Gulfstream) Model GVII–G500 series airplanes. This airplane will have a novel or unusual design feature when compared to the state of technology and design envisioned in the airworthiness standards for transport category airplanes. This design feature is a high incidence protection system that limits the angle of attack at which the airplane can be flown during normal low speed operation. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level

of safety equivalent to that established by the existing airworthiness standards.

**DATES:** This action is effective on July 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** Joe Jacobsen, Airframe & Flight Crew Interface Section, AIR–671, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3158; email *Joe.Jacobsen@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

## Background

On June 30, 2013, Gulfstream Aerospace Corporation (Gulfstream) applied for a type certificate for its new Model GVII–G500 series airplane. The Gulfstream Model GVII–G500 series airplane will be a business jet with seating for up to 19 passengers. It will incorporate a low, swept-wing design with a T-tail. The powerplant will consist of two aft-fuselage-mounted turbofan engines. The Gulfstream Model GVII–G500 series airplane's maximum takeoff weight will be approximately 79,600 pounds.

The high incidence protection system prevents the airplane from stalling at low speeds and, therefore, a stall warning system is not needed during normal flight conditions.

## Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.17, Gulfstream must show that the Model GVII–G500 series airplane meets the applicable provisions of 14 CFR part 25, as amended by amendments 25–1 through 25–137.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Gulfstream Model GVII–G500 series airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Gulfstream Model GVII–G500 series airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

## Novel or Unusual Design Features

The Gulfstream Model GVII–G500 series airplane will incorporate the following novel or unusual design feature:

A high incidence protection system, which limits the angle of attack at which the airplane can be flown during normal low speed operation, prohibits the airplane from stalling, and cannot be overridden by the flightcrew. The application of this angle of attack limit influences the stall speed determination, stall characteristics, stall warning demonstration, and longitudinal handling characteristics of the airplane. Existing airworthiness regulations do not contain adequate standards to address this feature.

## Discussion

The high incidence protection system prevents the airplane from stalling at low speeds and, therefore, a stall warning system is not needed during normal flight conditions. However, during failures, which are not shown to be extremely improbable, the requirements of §§ 25.203 and 25.207 apply, although slightly modified by these conditions. If there are failures of the high incidence protection system that are not shown to be extremely improbable, the flight characteristics at the angle of attack for $C_{LMAX}$ must be suitable in the traditional sense, and stall warning must be provided in a conventional manner.

Part I of the special conditions is in lieu of §§ 25.21(b), 25.103, 25.145(a), 25.145(b)(6), 25.175(c) and (d), 25.201, 25.203, 25.207, and 25.1323(d). Part II is in lieu of §§ 25.21(g)(1), 25.105(a)(2)(i), 25.107(c) and (g), 25.121(b)(2)(ii)(A), 25.121(c)(2)(ii)(A), 25.121(d)(2)(ii), 25.123(b)(2)(i), 25.125(b)(2)(ii)(B), and 25.143(j).

These special conditions address this novel or unusual design feature on the Gulfstream Model GVII–G500 series airplane, and contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

These special conditions are different from special conditions previously issued on this topic. In Part I, sections 3.b.iv, 3.b.vi, 3.e.vi, 5.a.i.1, 5.a.i.4, 5.a.i.6, 5.a.i.7, 5.c.i.4, 5.c.i.5, 5.c.i.6, 5.c.ii.4, and 5.c.ii.5, previously used verbiage was updated to reflect language recommended in the Aviation Rulemaking Advisory Committee (ARAC) Flight Test Harmonization Working Group (FTHWG) Phase 2 report. This language more accurately describes the actions required and formulas to be used to obtain the required result. In Part I, sections 3.b.ii and 5.a.ii.4, the ARAC FTHWG language was adapted to reflect specific Gulfstream design features.

In several previous special conditions on this subject, we used the nomenclature $V_{CLMAX}$. To avoid confusion with previous Gulfstream special conditions, we have changed the nomenclature to $V_{CLMAX\ Demo}$ to highlight a difference. The difference is not significant, but the change in nomenclature was considered clarifying and therefore was adopted in this instance.

## Discussion of Comments

The FAA issued Notice of Proposed Special Conditions No. 25–18–02–SC for the Gulfstream Model GVII–G500 series airplane, which was published in the **Federal Register** on May 14, 2018 (83 FR 22214). The FAA received one comment that was not relevant to the subject of these special conditions. Therefore, the special conditions are adopted as proposed.

## Applicability

As discussed above, these special conditions are applicable to the Gulfstream Model GVII–G500 series airplane. Should Gulfstream apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**. However, as the certification date for the Gulfstream Model GVII–G500 series airplane is imminent, the FAA finds that good cause exists to make these special conditions effective upon publication.

## Conclusion

This action affects only certain novel or unusual design features on Gulfstream Model GVII–G500 series of airplanes. It is not a rule of general applicability.

## List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

**Authority Citation**

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

**The Special Conditions**

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream Model GVII–G500 series airplanes.

**Part I: Stall Protection and Scheduled Operating Speeds**

In the following sections, ''in icing conditions,'' means with ice accretions (relative to the relevant flight phase) as defined in appendix C to part 25, at amendment 25–121.

1. Definitions

These special conditions use terminology that does not appear in 14 CFR part 25. For the purpose of these special conditions, the following terms describe certain aspects of this novel or unusual design feature:

*High-Incidence Protection System*

A system that operates directly and automatically on the airplane's flight controls to limit the maximum angle of attack that can be attained to a value below that at which an aerodynamic stall would occur.

*Alpha-Limit*

The maximum angle of attack at which an airplane stabilizes with the high incidence protection system operating and the longitudinal control held on its aft stop.

$V_{MIN}$

The minimum steady flight speed in the airplane's configuration under consideration with the high incidence protection system operating. See Part I, Section 3, ''Minimum Steady Flight Speed and Reference Stall Speed,'' of these special conditions.

$V_{MIN1g}$

$V_{MIN}$ corrected to 1g acceleration of gravity conditions. See Part I, Section 3, ''Minimum Steady Flight Speed and Reference Stall Speed,'' of these special conditions. This is the minimum calibrated airspeed at which the airplane can develop a lift force normal to the flight path and equal to its weight when at an angle of attack not greater than that determined for $V_{MIN}$.

2. Capability and Reliability of the High Incidence Protection System

The applicant must establish the capability and reliability of the high incidence protection system. The applicant may establish this capability and reliability by flight testing, simulation, or analysis as appropriate. The capability and reliability required are:

a. It must not be possible to encounter a stall during the pilot-induced maneuvers required by Part I, section 5(a), ''High Incidence Handling Demonstrations,'' and the handling characteristics must be acceptable as required by Part I, section 5(b), ''Characteristics in High Incidence Maneuvers'' of these special conditions;

b. The airplane must be protected against stalling due to the effects of wind shears and gusts at low speeds as required by Section 6, ''Atmospheric Disturbances'' of these special conditions;

c. The ability of the high incidence protection system to accommodate any reduction in stalling incidence must be verified in icing conditions;

d. The high incidence protection system must be provided in each abnormal configuration of the high lift devices that is likely to be used in flight following system failures; and

e. The reliability of the system and the effects of failures must be acceptable in accordance with § 25.1309.

3. Minimum Steady Flight Speed and Reference Stall Speed

In lieu of § 25.103, ''Stall speed,'' the following applies:

a. The minimum steady flight speed, $V_{MIN}$, is the final, stabilized, calibrated airspeed obtained when an airplane is decelerated until the longitudinal control is on its stop in such a way that the entry rate does not exceed 1 knot per second.

b. The minimum steady flight speed, $V_{MIN}$, must be determined in icing and non-icing conditions with:

i. The high incidence protection system operating normally;

ii. Idle thrust;

iii. All combinations of flap settings and landing gear positions for which $V_{MIN}$ is required to be determined;

iv. The weight used when the reference stall speed, $V_{SR}$, is used as a factor to determine compliance with a required performance standard;

v. The most unfavorable center of gravity (CG) allowable; and

vi. The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 $V_{SR}$ and not greater than 1.3 $V_{SR}$.

c. The 1g minimum steady flight speed, $V_{MIN1g}$, is the minimum calibrated airspeed at which an airplane can develop a lift force (normal to the flight path) equal to its weight, while at an angle of attack not greater than that at which the minimum steady flight speed referenced in section 3(a) of this special condition is determined. These minimum calibrated airspeeds must be determined for both icing and non-icing conditions.

d. The reference stall speed, $V_{SR}$, is a calibrated airspeed defined by the applicant. $V_{SR}$ may not be less than a 1g stall speed. $V_{SR}$ must be determined in non-icing conditions and expressed as:

$$V_{SR} \geq \frac{V_{\text{CLMAX Demo}}}{\sqrt{n_{ZW}}}$$

Where:

$V_{CLMAX\ Demo}$ = Demonstrated calibrated airspeed obtained when the corrected lift coefficient of the load factor

$$\left(\frac{n_{ZW}W}{qS}\right)$$

is first a maximum during the maneuver prescribed in section 3(e)(viii) of this special condition.

$n_{ZW}$ = Load factor normal to the flight path at $V_{CLMAX\ Demo}$

W = Airplane gross weight;

S = Aerodynamic reference wing area; and

q = Dynamic pressure.

e. $V_{CLMAX\ Demo}$ is determined in non-icing conditions with:

i. Engines idling, or, if that resultant thrust causes an appreciable decrease in stall speed, not more than zero thrust at the stall speed;

ii. The airplane in other respects (such as flaps and landing gear) in the condition existing in the test or performance standard in which $V_{SR}$ is being used;

iii. The weight used when $V_{SR}$ is being used as a factor to determine compliance with a required performance standard;

iv. The CG position that results in the highest value of the reference stall speed;

v. The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 $V_{SR}$ and not greater than 1.3 $V_{SR}$;

vi. At the option of the applicant, the high incidence protection system can be disabled or adjusted to allow full development of the maneuver to the angle of attack corresponding to $V_{SR}$; and

vii. Starting from the stabilized trim condition, with an application of the longitudinal control to decelerate the airplane so that the speed reduction does not exceed 1 knot per second.

4. Stall Warning

In lieu of § 25.207, the following apply:

a. Normal Operation

If the design meets all conditions of Part I, section 2 of these special conditions, then the airplane need not provide stall warning during normal operation. The conditions of Part I, section 2 provide a level of safety equal to the intent of § 25.207, ''Stall warning,'' so the provision of an additional, unique warning device for normal operations is not required.

b. High Incidence Protection System Failure

For any failures of the high incidence protection system that the applicant cannot show to be extremely improbable, and that result in the capability of the system no longer satisfying any part of sections 2(a), (b), and (c) of Part I of these special conditions: The design must provide stall warning that protects against encountering unacceptable characteristics and against encountering stall.

i. This stall warning, with the flaps and landing gear in any normal position, must be clear and distinctive to the pilot, and must meet the requirements specified in sections 4(b)(iv) and 4(b)(v) of Part I of these special conditions.

ii. The design must also provide this stall warning in each abnormal configuration of the high lift devices that is likely to be used in flight following system failures.

iii. The design may furnish this stall warning either through the inherent aerodynamic qualities of the airplane or by a device that will provide clearly distinguishable indications to the flightcrew under all expected conditions of flight. However, a visual stall warning device that requires the attention of the flightcrew within the flight deck is not acceptable by itself. If a warning device is used, it must provide a warning in each of the airplane configurations prescribed in section 4(b)(i), above, and for the conditions prescribed in sections 4(b)(iv) and 4(b)(v) of part I of these special conditions.

iv. In non-icing conditions, the stall warning must provide sufficient margin to prevent encountering unacceptable characteristics and encountering stall in the following conditions:

1. In power-off straight deceleration not exceeding 1 knot per second to a speed of 5 knots or 5 percent calibrated airspeed (CAS), whichever is greater, below the warning onset; and

2. In turning flight, stall deceleration at entry rates up to 3 knots per second when recovery is initiated not less than 1 second after the warning onset.

v. In icing conditions, the stall warning must provide sufficient margin to prevent encountering unacceptable characteristics and encountering stall in power-off straight and turning flight decelerations not exceeding 1 knot per second, when the pilot starts a recovery maneuver not less than three seconds after the onset of stall warning.

vi. An airplane is considered stalled when the behavior of the airplane gives the pilot a clear, distinctive, and acceptable indication that the airplane is stalled. Acceptable indications of a stall, occurring either individually or in combination, are:

1. A nose-down pitch that cannot be readily arrested;

2. Buffeting of a magnitude and severity that is strong and thereby an effective deterrent to further speed reduction; or

3. The pitch control reaches the aft stop, and no further increase in pitch attitude occurs when the control is held full aft for a short time before recovery is initiated.

vii. An airplane exhibits unacceptable characteristics during straight or turning flight decelerations if it is not always possible to produce and to correct roll and yaw by unreversed use of aileron and rudder controls, or abnormal nose-up pitching occurs.

5. Handling Characteristics at High Incidence

a. High Incidence Handling Demonstrations

In lieu of § 25.201, ''Stall demonstration,'' the following is required:

i. Maneuvers to the limit of the longitudinal control, in the nose-up sense, must be demonstrated in straight flight and in 30-degree banked turns with:

1. The high incidence protection system operating normally;

2. Initial power conditions of:

a. Power off; and

b. Power necessary to maintain level flight at 1.5 $V_{SR1}$, where $V_{SR1}$ is the reference stall speed with flaps in approach position, landing gear retracted, and maximum landing weight;

3. None;

4. Flaps, landing gear, and deceleration devices in any likely combination of positions not prohibited by the airplane flight manual (AFM);

5. Representative weights within the range for which certification is requested;

6. The most adverse CG for recovery; and

7. The airplane trimmed for straight flight at the speed prescribed in section 3(e)(v) of these special conditions.

ii. The following procedures must be used to show compliance in non-icing and icing conditions:

1. Starting at a speed sufficiently above the minimum steady flight speed to ensure that a steady rate of speed reduction can be established, apply the longitudinal control so that the speed reduction does not exceed 1 knot per second until the control reaches the stop.

2. The longitudinal control must be maintained at the stop until the airplane has reached a stabilized flight condition, and must then be recovered by normal recovery techniques.

3. Maneuvers with increased deceleration rates:

a. In non-icing conditions, the requirements must also be met with increased rates of entry to the incidence limit, up to the maximum rate achievable.

b. In icing conditions, with the anti-ice system working normally, the requirements must also be met with increased rates of entry to the incidence limit, up to three knots per second.

4. Maneuvers with ice accretion prior to normal operation of the ice protection system:

For flight in icing conditions before the ice protection system has been activated and is performing its intended function, the handling demonstration requirements identified in section 5(a)(i) must be satisfied using the procedures specified in sections 5(a)(ii)(1) and 5(a)(ii)(2) of these special conditions. The airplane configurations required to be tested must be in accordance with the limitations and procedures for operating the ice protection system provided in the AFM, per § 25.21(g)(1), as modified by and Part II of these special conditions.

b. Characteristics in High Incidence Maneuvers

In lieu of § 25.203, ''Stall characteristics,'' the following apply:

i. Throughout maneuvers with a rate of deceleration of not more than 1 knot per second, both in straight flight and in 30-degree banked turns, the airplane's characteristics must be as follows:

1. There must not be any abnormal nose-up pitching;

2. There must not be any uncommanded nose-down pitching, which would be indicative of stall. However, reasonable attitude changes associated with stabilizing the incidence at Alpha limit, as the longitudinal

control reaches the stop would be acceptable;

3. There must not be any uncommanded lateral or directional motion, and the pilot must retain good lateral and directional control by conventional use of the controls throughout the maneuver; and

4. The airplane must not exhibit buffeting of a magnitude and severity that would act as a deterrent from completing the maneuver specified in section 5(a)(i) of these special conditions.

ii. In maneuvers with increased rates of deceleration, some degradation of characteristics is acceptable, associated with a transient excursion beyond the stabilized Alpha limit. However, the airplane must not exhibit dangerous characteristics or characteristics that would deter the pilot from holding the longitudinal control on the stop for a period of time appropriate to the maneuver.

iii. It must always be possible for flightcrew to reduce incidence by conventional use of the controls.

iv. The rate at which the airplane can be maneuvered from trim speeds, associated with scheduled operating speeds such as $V_2$ and $V_{REF}$ up to Alpha limit, must not be unduly damped or be significantly slower than can be achieved on conventionally controlled transport airplanes.

c. Characteristics up to the Maximum Lift Angle of Attack

In addition to the requirements in section 5(b) of this special condition, the following requirements apply:

i. In non-icing conditions, maneuvers with a rate of deceleration of not more than 1 knot per second, up to the angle of attack corresponding to $V_{SR}$ obtained using sections 3(d) and (e) of this special condition, must be demonstrated in straight flight and in 30-degree banked turns in the following configurations:

1. The high incidence protection system deactivated or adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system;

2. Automatic-thrust-increase system inhibited (if applicable);

3. Engines idling;

4. Flaps, landing gear, and deceleration devices in any likely combination of positions not prohibited by the AFM;

5. The most adverse CG for recovery; and

6. The airplane trimmed for straight flight at the speed prescribed in section 3(e)(v) of this special condition.

ii. In icing conditions, maneuvers with a rate of deceleration of not more than 1 knot per second up to the maximum angle of attack reached during maneuvers from section 5(a)(ii)(3)(b) must be demonstrated in straight flight with:

1. The high incidence protection system deactivated or adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system;

2. Automatic-thrust-increase system inhibited (if applicable);

3. Engines idling;

4. Flaps, landing gear, and deceleration devices in any likely combination of positions not prohibited by the AFM;

5. The most adverse CG for recovery; and

6. The airplane trimmed for straight flight at the speed prescribed in section 3(e)(v) of this special condition.

iii. During the maneuvers used to show compliance with sections 5(c)(i) and 5(c)(ii) of Part I of these special conditions, the airplane must not exhibit dangerous characteristics and it must always be possible for flightcrew to reduce angle of attack by conventional use of the controls. The pilot must retain good lateral and directional control, by conventional use of the controls, throughout the maneuver.

6. Atmospheric Disturbances

Operation of the high incidence protection system must not adversely affect airplane control during expected levels of atmospheric disturbances, nor impede the application of recovery procedures in case of wind shear. This must be demonstrated in non-icing and icing conditions.

7. None

8. Proof of Compliance

Add the following requirement to that of § 25.21:

(b) The flying qualities will be evaluated at the most unfavorable CG position.

9. The Design Must Meet the Following Modified Requirements

| 14 CFR section | Change |
|---|---|
| 25.145(a) | "$V_{MIN}$" in lieu of "stall identification." |
| 25.145(b)(6) | "$V_{MIN}$" in lieu of "$V_{SW}$." |
| 25.175(c) and (d). | "$V_{MIN}$" in lieu of "$V_{SW}$." |
| 25.1323(d) | "From 1.23 $V_{SR}$ to $V_{MIN}$" in lieu of "From 1.23 $V_{SR}$ to the speed at which stall warning begins;" and "speeds below $V_{MIN}$" in lieu of "speeds below stall warning speed." |

**Part II: Credit for Robust Envelope Protection in Icing Conditions**

1. In lieu of § 25.21(g)(1), the following applies:

(g) The requirements of this subpart associated with icing conditions apply only if certification for flight in icing conditions is desired. If certification for flight in icing conditions is desired, the following requirements also apply (see AC 25–25):

(1) Each requirement of this subpart, except §§ 25.121(a), 25.123(c), 25.143(b)(1) and (b)(2), 25.149, 25.201(c)(2), 25.207(c) and (d), and 25.251(b) through (e), must be met in icing conditions. Compliance must be shown using the ice accretions defined in appendix C to part 25, assuming normal operation of the airplane and its ice protection system in accordance with the operating limitations and operating procedures established by the applicant and provided in the airplane flight manual.

2. In lieu of § 25.103, "Stall speed," define the stall speed as provided in Special Conditions Part I, section 3, "*Minimum Steady Flight Speed and Reference Stall Speed.*"

3. In lieu of § 25.105(a)(2)(i) to read as follows:

(2) In icing conditions, if in the configuration of § 25.121(b) with the "Takeoff Ice" accretion defined in appendix C to part 25:

(i) The V2 speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the takeoff configuration, or

4. In lieu of § 25.107(c) and (g), the following apply, with additional sections (c') and (g'):

(c) In non-icing conditions, $V_2$, in terms of calibrated airspeed, must be selected by the applicant to provide at least the gradient of climb required by § 25.121(b) but may not be less than—

1. $V_{2MIN}$;

2. $V_R$ plus the speed increment attained (in accordance with § 25.111(c)(2)) before reaching a height of 35 feet above the takeoff surface; and

3. A speed that provides the maneuvering capability specified in § 25.143(h).

(c') In icing conditions with the "Takeoff Ice" accretion defined in appendix C to part 25, $V_2$ may not be less than—

1. The $V_2$ speed determined in non-icing conditions.

2. A speed that provides the maneuvering capability specified in § 25.143(h).

(g) In non-icing conditions, $V_{FTO}$, in terms of calibrated airspeed, must be

selected by the applicant to provide at least the gradient of climb required by § 25.121(c), but may not be less than—

1. 1.18 $V_{SR}$; and

2. A speed that provides the maneuvering capability specified in § 25.143(h).

(g') In icing conditions with the ''Final Takeoff Ice'' accretion defined in appendix C to part 25, $V_{FTO}$ may not be less than—

1. The $V_{FTO}$ speed determined in non-icing conditions.

2. A speed that provides the maneuvering capability specified in § 25.143(h).

5. In lieu of §§ 25.121(b)(2)(ii)(A), 25.121(c)(2)(ii)(A), and 25.121(d)(2)(ii), the following apply:

*§ 25.121 Climb: one-engine inoperative:*

(b) Takeoff; landing gear retracted. In the takeoff configuration existing at the point of the flight path at which the landing gear is fully retracted, and in the configuration used in § 25.111, but without ground effect,

* * * * *

2. The requirements of subparagraph (b)(1) of this section must be met:

* * * * *

(ii) In icing conditions with the ''Takeoff Ice'' accretion defined in appendix C of part 25, if in the configuration of § 25.121(b) with the ''Takeoff Ice'' accretion:

(A) The $V_2$ speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the takeoff configuration; or

(c) Final takeoff. In the en route configuration at the end of the takeoff path determined in accordance with § 25.111:

* * * * *

2. The requirements of subparagraph (c)(1) of this section must be met:

* * * * *

(ii) In icing conditions with the ''Final Takeoff Ice'' accretion defined in appendix C of part 25, if:

(A) The $V_{FTO}$ speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the en route configuration; or

(d) Approach. In a configuration corresponding to the normal all-engines operating procedure in which $V_{SR}$ for this configuration does not exceed 110 percent of the $V_{SR}$ for the related all-engines-operating landing configuration:

* * * * *

2. The requirements of sub-paragraph (d)(1) of this section must be met:

* * * * *

(ii) In icing conditions with the ''Approach Ice'' accretion defined in appendix C to part 25, in a configuration corresponding to the normal all-engines-operating procedure in which $V_{MIN1g}$ for this configuration does not exceed 110% of the $V_{MIN1g}$ for the related all engines-operating landing configuration in icing, with a climb speed established with normal landing procedures, but not more than 1.4 $V_{SR}$ ($V_{SR}$ determined in non-icing conditions).

6. In lieu of § 25.123 (b)(2)(i), the following applies:

*§ 25.123 En route flight paths:*

(b) The one-engine-inoperative net flight path data must represent the actual climb performance diminished by a gradient of climb of 1.1 percent for two-engine airplanes, 1.4 percent for three-engine airplanes, and 1.6 percent for four-engine airplanes.

* * * * *

2. In icing conditions with the ''En route Ice'' accretion defined in appendix C to part 25 if:

(i) The minimum en route speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the en route configuration, or

7. In lieu of § 25.125(b)(2)(ii)(B) and § 25.125(b)(2)(ii)(C), the following applies:

*§ 25.125 Landing*

(b) In determining the distance in (a):

* * * * *

2. A stabilized approach, with a calibrated airspeed of not less than $V_{REF}$, must be maintained down to the 50-foot height.

* * * * *

(ii) In icing conditions, $V_{REF}$ may not be less than:

(A) The speed determined in sub-paragraph (b)(2)(i) of this section;

(B) A speed that provides the maneuvering capability specified in § 25.143(h) with the ''Landing Ice'' accretion defined in appendix C to part 25.

8. In lieu of § 25.143(j), the following applies:

*§ 25.143 General*

(j) For flight in icing conditions—before the ice protection system has been activated and is performing its intended function—the following requirements apply:

(1) If activating the ice protection system depends on the pilot seeing a specified ice accretion on a reference surface (not just the first indication of icing), the requirements of § 25.143 apply with the ice accretion defined in part II(e) of appendix C to part 25.

(2) For other means of activating the ice protection system, it must be demonstrated in flight with the ice accretion defined in part II(e) of appendix C to part 25 that:

(i) The airplane is controllable in a pull-up maneuver up to 1.5 g load factor or lower if limited by AOA protection; and

(ii) There is no reversal of pitch control force during a pushover maneuver down to 0.5 g load factor.

9. In lieu of § 25.207, ''Stall warning,'' to read as the requirements defined in Part I of these special conditions.

Issued in Des Moines, Washington, on July 9, 2018.

**Victor Wicklund,**

*Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.*

[FR Doc. 2018–15071 Filed 7–13–18; 8:45 am]

**BILLING CODE 4910–13–P**

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 97

**[Docket No. 31203; Amdt. No. 3808]**

## Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective July 16, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 16, 2018.

**ADDRESSES:** Availability of matter incorporated by reference in the amendment is as follows:

**For Examination**

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;
2. The FAA Air Traffic Organization Service Area in which the affected airport is located;
3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,
4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

**Availability**

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. Nichols, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

**SUPPLEMENTARY INFORMATION:** This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

**Availability and Summary of Material Incorporated by Reference**

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

**The Rule**

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 97**

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on June 29, 2018.

**John S. Duncan,**

*Executive Director, Flight Standards Service.*

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

## PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

**§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]**

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * Effective Upon Publication*

| AIRAC date | State | City | Airport | FDC No. | FDC date | Subject |
|---|---|---|---|---|---|---|
| 16–Aug–18 | AZ | Fort Huachuca Sierra Vista. | Sierra Vista Muni-Libby AAF | 8/5934 | 6/20/18 | RNAV (GPS) RWY 8, Amdt 1B. |
| 16–Aug–18 | IA | Audubon | Audubon County | 8/7524 | 6/20/18 | RNAV (GPS) RWY 32, Orig. |
| 16–Aug–18 | CT | Danbury | Danbury Muni | 8/8657 | 6/20/18 | RNAV (GPS)–A, Orig. |
| 16–Aug–18 | CT | Danbury | Danbury Muni | 8/8664 | 6/20/18 | LOC RWY 8, Amdt 6. |

[FR Doc. 2018–15058 Filed 7–13–18; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 97

**[Docket No. 31202; Amdt. No. 3807]**

## Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective July 16, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 16, 2018.

**ADDRESSES:** Availability of matters incorporated by reference in the amendment is as follows:

### For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

### Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. Nichols, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

**SUPPLEMENTARY INFORMATION:** This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

### Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

### The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and

ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 97**

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on June 29, 2018.

**John S. Duncan,**

*Executive Director, Flight Standards Service.*

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

## PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

**Effective 16 August 2018**

Deland, FL, Deland Muni-Sidney H Taylor Field, RNAV (GPS) RWY 5, Orig-B
Deland, FL, Deland Muni-Sidney H Taylor Field, RNAV (GPS) RWY 12, Orig-A
Deland, FL, Deland Muni-Sidney H Taylor Field, RNAV (GPS) RWY 23, Orig-A
Deland, FL, Deland Muni-Sidney H Taylor Field, RNAV (GPS) RWY 30, Orig-A
Easton, MD, Easton/Newnam Field, ILS OR LOC RWY 4, Amdt 2B
Easton, MD, Easton/Newnam Field, RNAV (GPS) RWY 15, Orig-B
Easton, MD, Easton/Newnam Field, RNAV (GPS) RWY 33, Orig-B
Dayton, OH, James M Cox Dayton Intl, RNAV (RNP) Y RWY 24R, Orig-C
Norwalk, OH, Norwalk-Huron County, RNAV (GPS) RWY 28, Orig-B
Martin, SD, Martin Muni, RNAV (GPS) RWY 32, Amdt 1

**Effective 13 September 2018**

Ambler, AK, Ambler, RNAV (GPS) RWY 1, Amdt 1A
Galena, AK, Edward G Pitka SR, RNAV (GPS) RWY 8, Amdt 3
Galena, AK, Edward G Pitka SR, RNAV (GPS) RWY 26, Amdt 3
Galena, AK, Edward G Pitka SR, Takeoff Minimums and Obstacle DP, Amdt 1
Golovin, AK, Golovin NOME TWO, Graphic DP
Golovin, AK, Golovin, RNAV (GPS) RWY 3, Amdt 1
Golovin, AK, Golovin, RNAV (GPS)-A, Amdt 1
Golovin, AK, Golovin, Takeoff Minimums and Obstacle DP, Amdt 1
Flippin, AR, Marion County Rgnl, VOR–A, Amdt 15, CANCELED
Pocahontas, AR, Pocahontas Muni, RNAV (GPS) RWY 18, Orig
Pocahontas, AR, Pocahontas Muni, RNAV (GPS) RWY 36, Orig
Pocahontas, AR, Pocahontas Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Pocahontas, AR, Pocahontas Muni, VOR OR GPS RWY 36, Amdt 6, CANCELED
Fort Huachuca/Sierra Vista, AZ, Sierra Vista Muni-Libby AAF, NDB RWY 26, Amdt 4, CANCELED
San Bernardino, CA, San Bernardino Intl, ILS OR LOC Z RWY 6, Amdt 3
San Bernardino, CA, San Bernardino Intl, LOC Y RWY 6, Amdt 1
San Bernardino, CA, San Bernardino Intl, RNAV (GPS) Y RWY 6, Amdt 1
San Bernardino, CA, San Bernardino Intl, RNAV (GPS) Z RWY 6, Amdt 1
Sterling, CO, Sterling Muni, NDB RWY 33, Amdt 3B, CANCELED
DeFuniak Springs, FL, DeFuniak Springs, RNAV (GPS) RWY 9, Amdt 1A
Immokalee, FL, Immokalee Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2A
Albany, GA, Southwest Georgia Rgnl, ILS OR LOC RWY 4, Amdt 13A
West Union, IA, George L Scott Muni, VOR/DME–A, Amdt 4, CANCELED
Champaign/Urbana, IL, University of Illinois-Willard, VOR RWY 4, Amdt 12A
Champaign/Urbana, IL, University of Illinois-Willard, VOR RWY 14L, Orig-B
Champaign/Urbana, IL, University of Illinois-Willard, VOR RWY 22, Amdt 8A
Chicago, IL, Chicago O'Hare Intl, Takeoff Minimums and Obstacle DP, Amdt 20D
Lawrenceville, IL, Lawrenceville-Vincennes Intl, VOR RWY 36, Amdt 1C, CANCELED
Mount Carmel, IL, Mount Carmel Muni, VOR/DME RWY 22, Amdt 10A, CANCELED
Anderson, IN, Anderson Muni-Darlington Field, NDB RWY 30, Amdt 8A
Fort Wayne, IN, Fort Wayne Intl, ILS OR LOC RWY 32, Amdt 31A
Huntington, IN, Huntington Muni, NDB RWY 9, Amdt 2, CANCELED
Jeffersonville, IN, Clark Rgnl, ILS OR LOC RWY 18, Amdt 4
Jeffersonville, IN, Clark Rgnl, NDB RWY 18, Amdt 3
Jeffersonville, IN, Clark Rgnl, RNAV (GPS) RWY 18, Amdt 1
Jeffersonville, IN, Clark Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3
Richmond, IN, Richmond Muni, VOR RWY 6, Amdt 12A, CANCELED
Shelbyville, IN, Shelbyville Muni, RNAV (GPS) RWY 19, Amdt 1C
Winchester, IN, Randolph County, RNAV (GPS) RWY 8, Amdt 2
Winchester, IN, Randolph County, VOR–A, Amdt 10
Wellington, KS, Wellington Muni, RNAV (GPS) RWY 18, Amdt 2
Wellington, KS, Wellington Muni, RNAV (GPS) RWY 36, Amdt 2
Wellington, KS, Wellington Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Wellington, KS, Wellington Muni, VOR RWY 18, Amdt 3
Galliano, LA, South Lafourche Leonard Miller Jr, RNAV (GPS) RWY 18, Amdt 2B
Pittsfield, ME, Pittsfield Muni, RNAV (GPS) RWY 18, Amdt 1
Pittsfield, ME, Pittsfield Muni, RNAV (GPS) RWY 36, Amdt 1
Escanaba, MI, Delta County, RNAV (GPS) RWY 1, Orig-C
Escanaba, MI, Delta County, Takeoff Minimums and Obstacle DP, Amdt 1
Escanaba, MI, Delta County, VOR RWY 1, Orig-D
Lapeer, MI, DuPont-Lapeer, VOR–A, Amdt 1
Newberry, MI, Luce County, VOR RWY 29, Amdt 12, CANCELED
Fredericktown, MO, A Paul Vance Fredericktown Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1A
Vicksburg, MS, Vicksburg Muni, RNAV (GPS) RWY 1, Amdt 1B
Vicksburg, MS, Vicksburg Muni, RNAV (GPS) RWY 19, Orig-B
Asheville, NC, Asheville Rgnl, ILS OR LOC RWY 35, Orig
Asheville, NC, Asheville Rgnl, ILS OR LOC RWY 35, Orig, CANCELED
Asheville, NC, Asheville Rgnl, LOC RWY 17, Orig
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 17, Orig
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 17, Orig, CANCELED
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 35, Orig
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 35, Orig, CANCELED
Asheville, NC, Asheville Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
Tioga, ND, Tioga Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Kimball, NE, Kimball Muni/Robert E Arraj Field, RNAV (GPS) RWY 28, Amdt 1C
Gallup, NM, Gallup Muni, RNAV (GPS) RWY 24, Orig-A
Buffalo, NY, Buffalo Niagara Intl, RNAV (RNP) Z RWY 23, Orig-B
New York, NY, Long Island Mac Arthur, Takeoff Minimums and Obstacle DP, Amdt 5A

Wellsville, NY, Wellsville Muni Arpt, Tarantine Fld, VOR–A, Amdt 6, CANCELED
Columbus, OH, John Glenn Columbus Intl, RNAV (RNP) Z RWY 10L, Amdt 1C
Columbus, OH, John Glenn Columbus Intl, RNAV (RNP) Z RWY 10R, Amdt 1C
Delaware, OH, Delaware Muni—Jim Moore Field, RNAV (GPS) RWY 10, Amdt 1A
Delaware, OH, Delaware Muni—Jim Moore Field, RNAV (GPS) RWY 28, Amdt 1A
London, OH, Madison County, RNAV (GPS) RWY 9, Orig-A
London, OH, Madison County, RNAV (GPS) RWY 27, Orig-A
Mount Vernon, OH, Knox County, RNAV (GPS) RWY 28, Amdt 1C
New Philadelphia, OH, Harry Clever Field, RNAV (GPS) RWY 15, Amdt 1
New Philadelphia, OH, Harry Clever Field, RNAV (GPS) RWY 33, Orig
New Philadelphia, OH, Harry Clever Field, VOR–A, Amdt 2B
Sidney, OH, Sidney Muni, RNAV (GPS) RWY 28, Amdt 1A
Steubenville, OH, Jefferson County Airpark, RNAV (GPS) RWY 32, Amdt 1A
Willard, OH, Willard, Takeoff Minimums and Obstacle DP, Amdt 2
Fairview, OK, Fairview Muni, Takeoff Minimums and Obstacle DP, Amdt 4
Tahlequah, OK, Tahlequah Muni, RNAV (GPS) RWY 35, Amdt 1A
Beaver Falls, PA, Beaver County, LOC RWY 10, Amdt 4C
St Marys, PA, St Marys Muni, LOC RWY 28, Amdt 4D
St Marys, PA, St Marys Muni, RNAV (GPS) RWY 28, Amdt 1D
St Marys, PA, St Marys Muni, Takeoff Minimums and Obstacle DP, Amdt 2A
Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 3, Amdt 2
Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 21, Amdt 2
Cleveland, TN, Cleveland Rgnl Jetport, Takeoff Minimums and Obstacle DP, Amdt 2
Austin, TX, Austin-Bergstrom Intl, ILS OR LOC RWY 35R, ILS RWY 35R SA CAT I, ILS RWY 35R SA CAT II, Amdt 4
Floydada, TX, Floydada Muni, RNAV (GPS) RWY 17, Amdt 1
Floydada, TX, Floydada Muni, RNAV (GPS) RWY 35, Amdt 1
Renton, WA, Renton Muni, Takeoff Minimums and Obstacle DP, Amdt 8A
Seattle, WA, Seattle-Tacoma Intl, Takeoff Minimums and Obstacle DP, Amdt 4B
Wheeling, WV, Wheeling Ohio Co, RNAV (GPS) RWY 34, Amdt 1A
Jackson, WY, Jackson Hole, RNAV (RNP) Y RWY 1, Amdt 1
Jackson, WY, Jackson Hole, RNAV (RNP) Y RWY 19, Amdt 2
Jackson, WY, Jackson Hole, RNAV (RNP) Z RWY 1, Amdt 1

[FR Doc. 2018–15059 Filed 7–13–18; 8:45 am]

BILLING CODE 4910–13–P

## FEDERAL TRADE COMMISSION

## 16 CFR Parts 801, 802, and 803

## Premerger Notification; Reporting and Waiting Period Requirements

**AGENCY:** Federal Trade Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is amending the Hart-Scott-Rodino (''HSR'') Premerger Notification Rules (the ''Rules'') that require the parties to certain mergers and acquisitions to file reports with the Federal Trade Commission (''the Commission'' or ''FTC'') and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (''the Assistant Attorney General'' or ''DOJ'') (together the ''Antitrust Agencies'' or ''Agencies'') and to wait a specified period of time before consummating such transactions. The Commission is amending the Rules to make them clearer and easier to apply. The Commission is also amending the Rules to allow for the use of email in certain circumstances. Finally, the Commission is adding updated Instructions to the Premerger Notification and Report Form which include amendments for clarity and to make several non-substantive changes.

**DATES:** Effective August 15, 2018.

**FOR FURTHER INFORMATION CONTACT:** Nora Whitehead, Attorney, Premerger Notification Office, Bureau of Competition, Room 5301, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024. Telephone: (202) 326–3100, Email: *nwhitehead@ftc.gov.*

**SUPPLEMENTARY INFORMATION:**

### Introduction

Section 7A of the Clayton Act (the ''Act'') requires the parties to certain mergers or acquisitions to file reports with the Commission and DOJ and wait a specified period before consummating the proposed transaction to allow the Agencies to conduct their initial review of the transaction's competitive impact. The reporting requirement and the waiting period that it triggers are intended to enable the Antitrust Agencies to determine whether a proposed merger or acquisition may violate the antitrust laws if consummated and, when appropriate, to seek a preliminary injunction in federal court to prevent consummation.

Section 7A(d)(1) of the Act, 15 U.S.C. 18a(d)(1), directs the Commission, with the concurrence of the Assistant Attorney General, in accordance with the Administrative Procedure Act, 5 U.S.C. 553, to require that premerger notification be in such form and contain such information and documentary material as may be necessary and appropriate to determine whether the proposed transaction may, if consummated, violate the antitrust laws. Section 7A(d)(2) of the Act, 15 U.S.C.

18a(d)(2), grants the Commission, with the concurrence of the Assistant Attorney General, in accordance with 5 U.S.C. 553, the authority to define the terms used in the Act and prescribe such other rules as may be necessary and appropriate to carry out the purposes of section 7A of the Act.

Pursuant to that authority, the Commission, with the concurrence of the Assistant Attorney General, developed the Rules, codified in 16 CFR parts 801, 802, and 803, and the Premerger Notification and Report Form (''Form'') and its associated Instructions, codified in the appendix to part 803, to govern the form of premerger notification to be provided by merging parties.

Potential filing parties rely on the Rules to determine whether they must file under the Act and often consult the Premerger Notification Office to better understand how to apply the Rules. These changes to the Rules and Instructions address many of the questions received.

### Amendments to the Rules

The Commission is amending the Rules, as described below, in order to clarify them and make them easier for potential filing parties to apply. The Commission is also amending the Rules to allow for the use of email in sending notice letters pursuant to 16 CFR 801.30, granting early termination, withdrawing a filing pursuant to 16 CFR 803.12, and issuing requests for additional information or documentary material (''Second Requests'').

*A. Control of a Trust*

The Commission is amending § 801.1(b)(2) to clarify the term ''control'' as it pertains to trusts. This change explains that a person or entity is deemed to control a trust if that person or entity has the contractual power to designate 50 percent or more of the trust's trustees, where the trust is also irrevocable and/or the settlor does not retain a reversionary interest. This revision does not alter the substance of the test, but merely aims to eliminate confusion that arises from the text as currently written.

*B. Exemption for Goods Acquired in the Ordinary Course of Business*

The Commission is amending § 802.1 to remove ''realty'' from the heading and introductory paragraph of the rule. Although section 7A(c)(1) of the Act exempts from the reporting requirement both goods and realty transferred in the ordinary course of business, § 802.1 addresses only the exemption of goods, and the reference to realty in the heading and introductory paragraph is misleading and confusing. Prior to 1996, § 802.1 paralleled the language of the statute, which allowed for a broad ordinary course exemption but contained no guidance on specifics. In 1996, the FTC revised and clarified the ''ordinary course of business'' exemption with four new rules—§ 802.1 through§ 802.3 and § 802.5. With this change, § 802.1 was amended to address only the acquisition of goods in the ordinary course of business. The removal of the term ''realty'' from § 802.1does not affect the treatment of acquisitions of realty, which are addressed in the other regulations noted above.

In addition, the Commission is amending example 4 to § 802.1 to clarify that the acquisition described could be exempt pursuant to § 802.2.

*C. Intraperson Transactions*

The Commission is amending § 802.30(c) to add ''non-corporate interests'' after assets and voting securities. This change clarifies that, in the context of a formation pursuant to § 801.40 or § 801.50, the contribution of non-corporate interests by the acquiring person to the newly formed entity, like the contribution of assets and voting securities, is exempt from the requirements of the Act as to that contributing acquiring person. This change corrects an oversight in the non-corporate rulemaking.[1]

*D. Entity Formation*

The Commission is amending § 802.41, Example 1, to replace the word ''cash'' with ''assets.'' In its current form, the example is confusing and misleading because the acquisition of an entity that holds only cash is not subject to notification requirements.

*E. Affidavits*

The Commission is amending § 803.5(a)(1) to clarify that the provision applies to acquisitions of non-corporate interests as well as acquisitions of voting securities. With this amendment, the Commission brings § 803.5(a)(1) into accord with the language in the rest of § 803.5 regarding the applicability of the rule to acquisitions of non-corporate interests.

*F. Withdraw and Refile Notification*

The Commission is amending § 803.12(c) to clarify that the process for withdrawing an HSR filing and resubmitting it without incurring a new filing fee is available only during the initial waiting period. Although a filing may be withdrawn at any time while the waiting period is open, pursuant to § 803.12(a), a party may refile without paying a new fee only prior to the expiration or early termination of the initial waiting period and prior to the issuance of a Second Request. This revision eliminates confusion about the availability of the withdraw and refile process.

*G. Use of Email*

The Commission makes the following amendments to allow for the use of email.

- Section 803.5(a)(1) is amended to allow notice letters required by § 801.30 to be sent via email. The PNO has permitted notice letters to be sent via email for many years, and the Commission now formally authorizes the use of email to send notice letters pursuant to § 801.30. The Commission is also amending § 803.5(a)(1) to clarify that notice letters sent via email must be sent to the email address of an officer within the acquired issuer, such as the Chief Executive Officer, General Counsel or Secretary, or in the case of an unincorporated entity, persons exercising similar functions. Allowing notice letters to be sent via email to an appropriate person at the acquired entity will make the process of providing and receiving the notice letter required by § 801.30 more efficient for filing parties.
- Section 803.11(c) is amended to provide that grants of early termination will become effective upon notice to the filing persons transmitted by either telephone or email. Notice by email will also serve as written confirmation. Allowing for notice of grants of early termination by email eliminates the time-intensive and inefficient process of calling each party individually and then following-up with a hard copy letter, instead combining notice and confirmation into one step.
- Section 803.12(a) and (b) are amended to provide that a party's notification to the Agencies of its withdrawal of its premerger notification may be delivered in writing by email or mail to the Agencies.
- Section 803.20(b) is amended to provide that a Second Request may be delivered in writing by email. Current Agency practice is to send notice via mail as well as to email the parties a Second Request within the original waiting period. In addition, the section is amended to eliminate the requirement that the full text of a Second Request will be read upon request. This amendment makes clear that email confirmation of the Second Request within the original waiting period is sufficient for the Second Request to be effective, and that email is a valid means of communication during the waiting period.

These amendments will make the Rules easier to apply for both filing parties and the Agencies. Further, amending the Rules to allow for the use of email in sending notice letters pursuant to § 801.30, granting early termination, withdrawing a filing, and issuing Second Requests will make these processes more efficient.

**Revisions to the Instructions to the Form**

The Commission is adding updated Instructions to the Form with amendments as follows.

- Page I of the Instructions now provides an email address for the Premerger Notification Office, an updated address for DOJ's Premerger and Division Statistics Unit, and a reminder that affidavits and certifications submitted with DVD filings should be in searchable PDF format.
- Page I of the Instructions is also edited to clarify how the terms ''documentary attachments,'' ''person filing,'' ''filing person,'' and ''ultimate parent entity'' are used in the Instructions.
- Page II of the Instructions is edited to clarify that filing parties should continue to use 6- and 10-digit 2012 NAICS codes when responding to certain items in the Form, until further announcement by the Premerger Notification Office.
- Page II of the Instructions is further edited to clarify that the limitation on the acquired person's response applies to Items 5–7 of the Form.
- Page III of the Instructions is edited to indicate that there are now specific, limited criteria for fee payment via certified check.
- Page IV of the Instructions is edited to remove references to fax numbers.
- Page V of the Instructions is edited to clarify that it is not necessary to list all subsidiaries wholly owned by the acquired entity in Item 3(a), and to require filing parties to provide an index of any coded names used to refer to the parties in any transaction document(s).

[1] 70 FR 11502 (Mar. 8, 2005).

▪ Page V of the Instructions is also edited to include a list of the most common mistakes when completing the HSR Form.

▪ Page VI of the Instructions is edited to include additional instructions regarding the numbering and cross-referencing of Item 4(c) and 4(d) documents.

▪ Page VI of the Instructions is further clarified to note that any privilege log(s) should contain the names of inside and outside counsel providing privileged legal advice.

▪ Page IX of the Instructions is edited to note that if the acquiring person reports an associate overlap only, the acquired person need not respond to Item 7.

▪ Page XI of the Instructions is edited to cross-reference the regulation setting civil penalties for consummation of a reportable transaction without providing complete and proper notification.

▪ The footer on each page of the Instructions has been updated to reflect the date of the latest revision.

These amendments to the Instructions, which provide additional clarity, will benefit filing parties in the preparation of the Form.

**Administrative Procedure Act**

The Commission finds good cause to adopt these changes without prior public comment. Under the Administrative Procedure Act (''APA''), notice and comment are not required ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(3)(B).

The Commission is amending the Rules to make them clearer and easier to apply. The Commission is also amending the Rules to allow for the use of email in certain circumstances. Finally, the Commission is amending the Instructions to the Form for clarity and to make several non-substantive changes. These amendments fall within the category of rules covering agency procedure and practice that are exempt from the notice-and-comment requirements of the APA. *See* 5 U.S.C. 553(b)(A). Because the amendments are not substantive in nature, they are also not subject to the delayed effective date provisions of the APA. *See* 5 U.S.C. 553(d) (substantive rules may take effect no sooner than 30 days after publication). For these reasons, the Commission finds that there is good cause for adopting this final rule as effective on August 15, 2018 without prior public comment.

**Regulatory Flexibility Act**

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that the agency conduct an initial and final regulatory analysis of the anticipated economic impact of the proposed amendments on small businesses, except where the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605. The Regulatory Flexibility Act requirements apply, however, only to rules or amendments that are subject to the notice-and-comment requirements of the APA. *See* 5 U.S.C. 603, 604. Because these amendments are exempt from those APA requirements, as noted earlier, they are also exempt from the Regulatory Flexibility Act requirements. In any event, because of the size of the transactions necessary to invoke an HSR Filing, the premerger notification rules rarely, if ever, affect small businesses. Indeed, amendments to the Act in 2001 were intended to reduce the burden of the premerger notification program by exempting all transactions valued at less than $50 million (as adjusted annually). Further, none of the proposed rule amendments expands the coverage of the premerger notification rules in a way that would affect small business. Accordingly, to the extent, if any, that the Regulatory Flexibility Act applies, the Commission certifies that these proposed rules will not have a significant economic impact on a substantial number of small entities. This document serves as notice of this certification to the Small Business Administration.

**Paperwork Reduction Act**

These changes do not contain any record maintenance, reporting or disclosure requirements that would constitute agency ''collections of information'' that would have to be submitted for clearance and approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

**List of Subjects in 16 CFR Parts 801, 802, and 803**

Antitrust.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

For the reasons stated above, the Federal Trade Commission amends 16 CFR parts 801, 802, and 803 as set forth below:

## PART 801—COVERAGE RULES

■ 1. The authority citation for part 801 continues to read as follows:

**Authority:** 15 U.S.C. 18a(d).

■ 2. Amend § 801.1 by revising the introductory text of paragraph (b)(2) to read as follows:

### § 801.1 Definitions.

* * * * *

(b) * * *

(2) Having the contractual power presently to designate 50 percent or more of the directors of a for-profit or not-for-profit corporation, or 50 percent or more of the trustees in the case of trusts that are irrevocable and/or in which the settlor does not retain a reversionary interest.

* * * * *

## PART 802—EXEMPTION RULES

■ 3. The authority citation for part 802 continues to read as follows:

**Authority:** 15 U.S.C. 18a(d).

■ 4. Amend § 802.1 by revising the section heading, introductory text, and Example 4 of paragraph (d)(4) to read as follows:

### § 802.1 Acquisitions of goods in the ordinary course of business.

Pursuant to section 7A(c)(1) of the Clayton Act (the ''Act''), acquisitions of goods transferred in the ordinary course of business are exempt from the notification requirements of the Act. This section identifies certain acquisitions of goods that are exempt as transfers in the ordinary course of business. This section also identifies certain acquisitions of goods that are not in the ordinary course of business and, therefore, do not qualify for the exemption.

* * * * *

(d) * * *

(4) * * *

*Examples:* * * *

4. ''A,'' a national producer of canned fruit, preserves, jams and jellies, agrees to purchase from ''B'' for in excess of $50 million (as adjusted) a total of 20,000 acres of orchards and vineyards in several locations throughout the U.S. ''A'' plans to harvest the fruit from the acreage for use in its canning operations. The acquisition is not exempt under this section because orchards and vineyards are real property, not ''goods.'' If, on the other hand, ''A'' had contracted to acquire from ''B'' the fruit and grapes harvested from the orchards and vineyards, the acquisition would qualify for the exemption as an acquisition of current supplies under paragraph (c)(3) of this section. Although the transfer of orchards and vineyards is not exempt under this

section, the acquisition could be exempt under § 802.2(g) as an acquisition of agricultural property.

* * * * *

■ 5. Amend § 802.30 by revising the introductory text of paragraph (c) to read as follows:

**§ 802.30 Intraperson transactions.**

* * * * *

(c) For purposes of applying § 802.4(a) to an acquisition that may be reportable under § 801.40 or § 801.50, assets, voting securities, or non-corporate interests contributed by the acquiring person to a new entity upon its formation are assets, voting securities, or non- corporate interests whose acquisition by that acquiring person is exempt from the requirements of the Act.

* * * * *

■ 6. Amend § 802.41 by revising Example 1 to read as follows:

**§ 802.41 Corporations or unincorporated entities at time of formation.**

* * * * *

*Examples:* 1. Corporations A and B, each having sales of in excess of $100 million (as adjusted), each propose to contribute in excess of $50 million (as adjusted) in assets in exchange for 50 percent of the voting securities of a new corporation, N. Under this section, the new corporation need not file notification, although both A and B must do so and observe the waiting period prior to receiving any voting securities of N.

* * * * *

## PART 803—TRANSMITTAL RULES

■ 7. The authority citation for part 803 continues to read as follows:

**Authority:** 15 U.S.C. 18a(d).

■ 8. Amend § 803.5 by:

■ a. Revising the introductory text of paragraph (a)(1);

■ b. Adding an example in paragraph (a)(1)(vi); and

■ c. In paragraph (a)(2), removing ''*Example:*'' and adding in its place ''*Examples to paragraph (a)(2):*''.

The revisions and addition read as follows:

**§ 803.5 Affidavits Required.**

(a)(1) *Section 801.30 acquisitions.* For acquisitions to which § 801.30 applies, the notification required by the Act from each acquiring person shall contain an affidavit, attached to the front of the notification, or with the DVD submission, attesting that the issuer or unincorporated entity whose voting securities or non-corporate interests are to be acquired has received written notice delivered to an officer (or a person exercising similar functions in the case of an entity without officers) by email, certified or registered mail, wire, or hand delivery, at its principal executive offices, of:

* * * * *

(vi) * * *

*Example to paragraph (a)(1)(vi):* 1. Company A intends to acquire voting securities of Company B. ''A'' sends, via email, a notice letter to a general email account, *information@CompanyB.com.* ''A'' has not provided sufficient notice. Alternatively, ''A'' sends, via email, a notice letter to ''B's'' President, Jane Doe, at *Jane.Doe@CompanyB.com.* ''A'' has provided email notice to a specific officer of ''B.''

* * * * *

■ 9. Amend § 803.11 by revising paragraph (c) to read as follows:

**§ 803.11 Termination of waiting period.**

* * * * *

(c) The Federal Trade Commission and the Assistant Attorney General may, in their discretion, terminate a waiting period upon the written request of any person filing notification or, notwithstanding paragraph (a) of this section, sua sponte. A request for termination of the waiting period shall be sent to the offices designated in § 803.10(c). Termination shall be effective upon notice to any requesting person by either email or telephone, and such notice shall be given as soon as possible. Such notice shall be made to each person which has filed notification, and notice of termination shall be published in the **Federal Register** in accordance with section 7A(b)(2) of the Clayton Act (the ''act''). The Federal Trade Commission and the Assistant Attorney General also may use other means to make the termination public, prior to publication in the **Federal Register** in a manner that will make the information equally accessible to all members of the public.

■ 10. Amend § 803.12 by revising paragraphs (a), (b), and (c)(1) to read as follows:

**§ 803.12 Withdraw and refile notification.**

(a) *Voluntary.* An acquiring person, and in the case of an acquisition to which § 801.30 does not apply, an acquired person, may withdraw its notification by notifying the Federal Trade Commission and the Antitrust Division in writing by email or mail of such withdrawal.

(b) *Upon public announcement of termination.* An acquiring person's notification or, in the case of an acquisition to which § 801.30 of this chapter does not apply, an acquiring or an acquired person's notification, will be deemed to have been withdrawn if any filing that publicly announces the expiration, termination or withdrawal of a tender offer or the termination of an agreement or letter of intent is made by the acquiring person or the acquired person with the U.S. Securities and Exchange Commission (''SEC'') under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) and rules promulgated under that act. The acquiring person or acquired person must notify the Federal Trade Commission and the Antitrust Division in writing by email or mail that such filing has been made with the SEC and the withdrawal shall be deemed effective on the date of the SEC filing. Withdrawal of the HSR notification(s) shall occur even if statements are made in the SEC filing indicating a desire to recommence the tender offer or enter into a new or amended agreement or letter of intent. This paragraph is inapplicable if the initial 15-day or 30-day waiting period has expired without issuance of a request for additional information or documentary material and without an agreement in place with the Agencies to delay closing of the transaction (''a timing agreement''); or early termination of that waiting period has been granted, without a timing agreement in place; or if a request for additional information or documentary material has been issued and the Agencies have either granted early termination or allowed the extended waiting period to expire following certification of compliance without a timing agreement in place.

(c) *Resubmission without a new filing fee.* (1) An acquiring person whose notification has been voluntarily withdrawn pursuant to paragraph (a) of this section, or an acquiring person whose notification is deemed to have been automatically withdrawn under paragraph (b) of this section, may resubmit its notification, thereby initiating a new waiting period for the same transaction without an additional filing fee pursuant to § 803.9(f). This procedure may be used only one time, and only under the following circumstances:

(i) The notification is withdrawn prior to the expiration or early termination of the waiting period and prior to the issuance of a request for additional information pursuant to § 803.20 and section 7A(e) of the act;

(ii) The proposed acquisition does not change in any material way;

(iii) The resubmitted notification is recertified, and the submission, as it relates to Items 4(a), 4(b), 4(c), and 4(d) of the Notification and Report Form, is updated to the date of the resubmission;

(iv) A new executed affidavit is provided with the resubmitted HSR filing; and

(v) The resubmitted notification is refiled prior to the close of the second business day after withdrawal.

* * * * *

■ 11. Amend § 803.20 by revising paragraphs (b)(2)(ii) and (b)(3) and the example in paragraph (b)(3) to read as follows:

**§ 803.20 Requests for additional information or documentary material.**

* * * * *

(b) * * *

(2) * * *

(ii) In the case of a written request, upon notice of the issuance of such request to the person to which it is directed within the original 30-day (or, in the case of a cash tender offer or of an acquisition covered by 11 U.S.C. 363(b), 15-day) waiting period (or, if § 802.23 applies, such other period as that section provides), provided that written confirmation of the request is emailed or mailed to the person to which the request is directed within the original 30-day (or, in the case of a cash tender offer or of an acquisition covered by 11 U.S.C. 363(b), 15-day) waiting period (or, if § 802.23 applies, such other period as that section provides). Notice to the person to which the request is directed may be given by email, telephone or in person. The person filing notification shall keep a designated individual reasonably available during normal business hours throughout the waiting period at the email or telephone number supplied in the Notification and Report Form. Notice of a request for additional information or documentary material need be given by email or telephone only to that individual or to the individual designated in accordance with paragraph (b)(2)(iii) of this section. The written confirmation of the request shall be emailed or mailed to the ultimate parent entity of the person filing notification, or if another entity within the person filed notification pursuant to § 803.2(a), then to such entity.

* * * * *

(3) *Requests to natural persons.* A request addressed to an individual, requiring that he or she submit additional information or documentary material, shall be transmitted to the person filing notification of which the individual is an ultimate parent entity, officer, director, partner, agent or employee, and shall be effective as to that individual when effective as to the person filing notification pursuant to paragraph (b)(2) of this section. A written copy of the request shall also be delivered to the individual by email, by hand, or by registered or certified mail at his or her home or business address.

*Example:* A designee of the Federal Trade Commission sends, by email, a written request for additional information to the CEO of corporation W, the ultimate parent entity within a person that filed notification. The request is effective under paragraph (b)(2)(i) of this section. If the email also addressed a request for documentary material to the Secretary of corporation W, a named individual, under this paragraph (b)(3), the request would likewise be effective as to the individual upon receipt of the email by corporation W. In the latter case, the Federal Trade Commission also would send a copy of the request to the Secretary of the corporation at his or her home or business address, or email.

* * * * *

## Appendix to Part 803 [Redesignated as Appendix A to Part 803]

■ 12. Redesignate the appendix to part 803 as appendix A to part 803.

■ 13. Add appendix B to part 803 to read as follows:

## Appendix B to Part 803—Instructions to the Notification and Report Form for Certain Mergers and Acquisitions

BILLING CODE 6750–01–P

CMXCV

# ANTITRUST IMPROVEMENTS ACT NOTIFICATION AND REPORT FORM for Certain Mergers and Acquisitions

**INSTRUCTIONS** **OMB: 3084-0005**

## GENERAL

The Notification and Report Form ("the Form") is required to be submitted pursuant to § 803.1(a) of the premerger notification rules, 16 CFR Parts 801-803 ("the Rules"). These instructions specify the information that must be provided in response to the items on the Form.

**Information**
The central office for information and assistance concerning the Form and the Rules is:

Premerger Notification Office
Federal Trade Commission, Room #5301
400 7th Street, S.W.
Washington, D.C. 20024
Phone: (202) 326-3100
E-mail: HSRhelp@ftc.gov

Copies of the Form, Instructions and Rules as well as information to assist in completing the Form are available at the PNO website.

**Definitions**
The definitions used in this Form are set forth in the Rules. See Statute, Rules and Formal Interpretations for copies of the Hart-Scott-Rodino Act ("the Act"), the Rules, and the Federal Register Notices issuing the Rules and Rule amendments ("Statements of Basis and Purpose").

The term "documentary attachments" refers only to materials submitted in response to Item 3(b), Item 4 and to submissions pursuant to § 803.1(b) of the Rules.

The terms "person filing" or "filing person" mean the ultimate parent entity ("UPE"). (See § 801.1(a)(3)). The terms are used herein interchangeably.

**Filing**
Parties should file the completed Form, together with all documentary attachments, with the Premerger Notification Office ("PNO") of the Federal Trade Commission ("FTC") and the Premerger Unit of the Antitrust Division of the Department of Justice ("DOJ") (together, "the Agencies"). Filers have the option of submitting a DVD filing or a paper filing. Filings should be submitted to:

Premerger Notification Office
Federal Trade Commission, Room #5301
400 7th Street, S.W.
Washington, D.C. 20024

and

Department of Justice
Antitrust Division
Premerger and Division Statistics Unit
450 Fifth Street, N.W., Suite 1100
Washington, D.C. 20530

If one or both delivery sites are unavailable, the Agencies may announce alternate sites for delivery through the media and, if possible, at the PNO website.

**If submitting a DVD filing**

1) Provide the FTC with:

   **TWO** (2) DVDs, each containing the Form, affidavit, certification and all documentary attachments, along with the original hard copies of the cover letter, certification and affidavit.

2) Provide DOJ with:

   **TWO** (2) DVDs containing the same content as above, along with **THREE** (3) hard copies of the cover letter.

The Form must be a searchable PDF document. All other files must be in searchable PDF or MS Excel spreadsheet format and saved in color, if applicable. This includes the affidavit and certification.

Label each DVD with the name of the person filing, the name of a contact person and that person's phone number. Leave space on the DVD for the Agencies to write the assigned transaction number and date of receipt.

If the DVD or files contain viruses, passwords, or are not readable, the filing will not be accepted and the waiting period will not start.

For further instructions on DVD filing and specific DVD requirements, go to HSR Resources on the PNO website.

**If submitting a paper filing**

1) Provide the FTC with:

   **ONE** (1) original and **ONE** (1) copy of the Form, certification page and affidavit, along with an original cover letter and **ONE** (1) set of documentary attachments.

2) Provide DOJ with:

   **TWO** (2) copies of the Form, certification page and affidavit, along with **THREE** (3) copies of the cover letter, and **ONE** (1) set of documentary attachments.

**Affidavits**
Affidavit(s) are required by § 803.5 and must attest to the good faith of the persons filing to complete the transaction. Affidavits must be notarized or use the language found in 28 U.S.C. § 1746 relating to unsworn declarations under penalty of perjury. If an entity is filing on behalf of the acquiring or acquired person, the affidavit must still attest to the good faith of the UPE.

**In non-§ 801.30 transactions**, the affidavit(s) (submitted by both persons filing) must attest that a contract, agreement in principle or letter of intent to merge or acquire has been executed, and further attest to the good faith intention of the person filing notification to complete the transaction. (See § 803.5(b)).

**In § 801.30 transactions**, the affidavit (submitted only by the acquiring person) must attest:

1) that the issuer whose voting securities or the unincorporated entity whose non-corporate interests are to be acquired has received notice, as described below, from the acquiring person;

2) in the case of a tender offer, that the intention to make the tender offer has been publicly announced; and

3) the good faith intention of the person filing notification to complete the transaction.

Acquiring persons in § 801.30 transactions are required to submit a copy of the notice received by the acquired person pursuant to § 803.5(a)(3) along with the filing. This notice must include:

1) the identity of the acquiring person and the fact that the acquiring person intends to acquire voting securities of the issuer or non-corporate interests of the unincorporated entity;

2) the specific notification threshold that the acquiring person intends to meet or exceed in an acquisition of voting securities;

3) the fact that the acquisition may be subject to the Act, and that the acquiring person will file notification under the Act;

4) the anticipated date of receipt of such notification by the Agencies; and

5) the fact that the person within which the issuer or unincorporated entity is included may be required to file notification under the Act. (See § 803.5(a)).

**Responses**
Enter the name of the person filing notification in Item 1(a) on page 1 of the Form, and enter the same name and the date on which the Form is completed at the top of each page of the Form.

If there is insufficient room on the Form for a response to a particular item, attach "additional pages" behind that item on the Form. Filers must submit a complete set of additional pages within each copy of the Form.

Each additional page should identify, at the top of the page, the name of the person filing notification, the date on which the Form is completed and the item to which it is addressed.

Voluntary submissions pursuant to § 803.1(b) should be identified as V-1, V-2, etc.

If unable to answer any item fully, provide such information as is available and a statement of reasons for non-compliance as required by § 803.3. If exact answers to any item cannot be given, enter best estimates and indicate the source or basis of such estimates. Add an endnote with the notation "est." to any item where data are estimated.

All financial information should be expressed in millions of dollars rounded to the nearest one-tenth of a million dollars.

**Limited Response**
The acquired person should limit its response in Items 5-7:

1) in the case of an acquisition of assets, to the assets being acquired;

2) in the case of an acquisition of voting securities, to the issuer(s) whose voting securities are being acquired and all entities controlled by such acquired entities; and

3) in the case of an acquisition of non-corporate interests, to the unincorporated entity(s) whose non-corporate interests are being acquired and all entities controlled by such acquired entities.

Separate responses may be required where a person is both acquiring and acquired. (See § 803.2(b)).

Information need not be supplied regarding assets, voting securities or non-corporate interests currently being acquired when their acquisition is exempt under the Act or Rules. (See § 803.2(c)).

**Year**
All references to "year" refer to calendar year. If data are not available on a calendar year basis, supply the requested data for the fiscal year reporting period that most nearly corresponds to the calendar year specified. References to "most recent year" mean the most recent calendar or fiscal year for which the requested information is available.

**North American Industry Classification System (NAICS) Data**
The Form requests "dollar revenues" categorized by NAICS codes for non-manufactured and manufactured products with respect to operations conducted within the United States, and for products manufactured outside of the United States and sold into the United States. (See § 803.2(d)). Filing persons must submit data at the 6-digit NAICS national industry code level to reflect non-manufacturing dollar revenues. To the extent that dollar revenues are derived from manufacturing operations (NAICS Sectors 31-33), filing persons must only submit data at the 10-digit NAICS product code levels, not the 6-digit level. (See Item 5 below).

In reporting information by 6-digit NAICS industry code, refer to the 2012 *North American Industry Classification System - United States* published by the Executive Office of the President, Office of Management and Budget. In reporting information by 10-digit NAICS product code, refer to the 2012 *Numerical List of Manufactured and Mineral Products* published by the Bureau of the Census. Information regarding NAICS is available at www.census.gov. This site also provides assistance in choosing the proper code(s) for reporting in Item 5 of the Form.

Filers should continue to use 6- and 10-digit 2012 NAICS codes when filling out Items 5, 7, and 8 of the Form. The U.S. Census Bureau is transitioning to a new classification system and the PNO will wait until that system is fully functional before switching. Please monitor the PNO's website for further announcements on this topic.

**Thresholds**
Filing fee and notification thresholds are adjusted annually pursuant to 15 U.S.C. § 18A(a)(2)(A) based on the change in gross national product, in accordance with 15 U.S.C. § 19(a)(5). The current threshold values can be found at Current Filing Thresholds.

END OF GENERAL SECTION

Online Style Sheet for the Form

Online Tips for the Form

## THE FORM - ITEM BY ITEM

**Fee Information**
The fee for filing the Form is based on the aggregate total value of assets, voting securities and controlling non-corporate interests to be held as a result of the acquisition:

| Value of assets, voting securities and controlling non-corporate interests to be held | Fee Amount |
|---|---|
| greater than $50 million (as adjusted) but less than $100 million (as adjusted) | $45,000 |
| $100 million (as adjusted) or greater but less than $500 million (as adjusted) | $125,000 |
| $500 million or greater (as adjusted) | $280,000 |

For current thresholds and fee information, see the PNO website.

**Amount Paid**
Indicate the amount of the filing fee paid. This amount should be net of any banking or financial institution charges.

**Payer Identification**
Provide the payer's name and 9-digit Taxpayer Identification Number (TIN). If the payer is a natural person with no TIN, provide the natural person's social security number.

**Method of Payment**
The preferred method of payment is by electronic wire transfer (EWT). For EWT payments, provide the EWT confirmation number and the name of the financial institution from which the EWT is being sent. If the EWT confirmation number is not available at the time of filing, provide this information to the PNO within two business days of filing.

In order for the FTC to track payment, the payer must provide information required by the Fedwire Instructions to the financial institution initiating the EWT. A template of the Fedwire Instructions is available at the PNO website on the Filing Fee Information page.

There are now specific, limited criteria for paying by certified check. Please see the Filing Fee Information page for details.

**Corrective Filings**
Put an X in the appropriate box to indicate whether the notification is a corrective filing (i.e., an acquisition that has already taken place without filing, in violation of the statute). See Procedures for Submitting Post-Consummation Filings for more information on how to proceed in the case of a corrective filing.

**Cash Tender Offer**
Put an X in the appropriate box to indicate whether the acquisition is a cash tender offer.

**Bankruptcy**
Put an X in the appropriate box to indicate whether the acquired person's filing is being made by a trustee in bankruptcy or by a debtor-in-possession for a transaction that is subject to Section 363(b) of the Bankruptcy Code (11 U.S.C. § 363).

**Early Termination**
Put an X in the "yes" box to request early termination of the waiting period. Notification of each grant of early termination will be published in the Federal Register, as required by 15 U.S.C. § 18A(b)(2), and on the PNO website. Note that if either party in any transaction requests early termination, it may be granted and published.

**Transactions Subject to International Antitrust Notification**
If, to the knowledge or belief of the filing person at the time of filing, a non-U.S. antitrust or competition authority has been or will be notified of the proposed transaction, list the name of each such authority. Response to this item is voluntary.

**Index of Hyperlinks in these Instructions:**

PNO website: https://www.ftc.gov/enforcement/premerger-notification-program

Statute, Rules and Formal Interpretations: https://www.ftc.gov/enforcement/premerger-notification-program/statute-rules-formal-interpretations

HSR Resources: https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources

Current Filing Thresholds: https://www.ftc.gov/enforcement/premerger-notification-program/current-thresholds

Online Style Sheet for the Form: https://www.ftc.gov/enforcement/premerger-notification-program/form-instructions/style-sheet

Online Tips for the Form: https://www.ftc.gov/system/files/attachments/form-instructions/hsr_form_tip_sheet_1.0.5.pdf

Filing Fee Information: https://www.ftc.gov/enforcement/premerger-notification-program/filing-fee-information

Procedures for Submitting Post-Consummation Filings: https://www.ftc.gov/enforcement/premerger-notification-program/post-consummation-filings-hsr-violations

Online Tips for Item 4(c): https://www.ftc.gov/sites/default/files/attachments/hsr-resources/4ctipsheet.pdf

Online Tips for Item 4(d): https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources/pno-guidance-item-4d

Online Tips for Item 5: https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources/reporting-revenues-item-5

Online Tips for Item 6: https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources/tips-completing-item-6-hsr-form

Online Tips for Item 7: https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources/tips-completing-item-7-hsr-form

## ITEM 1

**Item 1(a)**
Provide the name, headquarters address and website (if one exists) of the person filing notification. The name of the person filing is the name of the UPE. (See § 801.1(a)(3)).

**Item 1(b)**
Indicate whether the person filing notification is an acquiring person, an acquired person, or both an acquiring and acquired person. (See § 801.2).

**Item 1(c)**
Put an X in the appropriate box to indicate whether the person in Item 1(a) is a corporation, unincorporated entity, natural person, or other (specify). (See § 801.1).

**Item 1(d)**
Put an X in the appropriate box to indicate whether data furnished in Item 5 is by calendar year or fiscal year. If fiscal year, specify the time period.

**Item 1(e)**
Put an X in the appropriate box to indicate if the Form is being filed on behalf of the UPE by another entity within the same person authorized by it to file notification on its behalf pursuant to § 803.2(a), or if the Form is being filed pursuant to § 803.4 on behalf of a foreign person. Then provide the name and mailing address of the entity filing notification on behalf of the filing person named in Item 1(a) of the Form.

**Item 1(f)**
For the acquiring person, if an entity other than the UPE listed in Item 1(a) is making the acquisition, provide the name and mailing address of that entity and the percentage of its voting securities or non-corporate interests held directly or indirectly by the person named in Item 1(a) above.

For the acquired person, if the assets, voting securities or non-corporate interests of an entity other than the UPE listed in Item 1(a) are being acquired, provide the name and mailing address of that entity and the percentage of its voting securities or non-corporate interests held directly or indirectly by the person named in Item 1(a) above.`

**Item 1(g)**
Provide the name and title, firm name, address, telephone number, and e-mail address of the primary and secondary individuals to contact regarding the Form. A second contact person is required. (See § 803.20(b)(2)(ii)).

**Item 1(h)**
Foreign filing persons must provide the name, firm name, address, telephone number, and e-mail address of an individual located in the United States designated for the limited purpose of receiving notice of the issuance of a request for additional information or documentary material. (See § 803.20(b)(2)(iii)).

Note: The Form has fields for fax numbers in Item 1. Providing fax numbers is no longer necessary. The fields will be deleted during the next update of the HSR Form.

END OF ITEM 1

## ITEM 2

**Item 2(a)**
Provide the names of all UPEs of acquiring and acquired persons that are parties to the transaction, whether or not they are required to file notification. If a person is not required to file, check the non-reportable box.

**Item 2(b)**
Put an X in all the boxes that apply to the transaction.

**Item 2(c)**
**This item should only be completed by the acquiring person where voting securities are being acquired.** If more than voting securities are being acquired, respond to this item only regarding voting securities. Put an X in the box to indicate the highest applicable threshold for which notification is being filed: $50 million (as adjusted), $100 million (as adjusted), $500 million (as adjusted), 25% (if the value of voting securities to be held is greater than $1 billion, as adjusted), or 50%. (See § 801.1(h)).

Note that the 50% notification threshold is the highest threshold and should be used for any acquisition of 50% or more of the voting securities of an issuer, regardless of the value of the voting securities. For instance, an acquisition of 100% of the voting securities of an issuer, valued in excess of $500 million (as adjusted) would cross the 50% notification threshold, not the $500 million (as adjusted) threshold.

**Item 2(d)**
Provide the requested information on assets, voting securities and non-corporate interests. If a combination of assets, voting securities and/or non-corporate interests are being acquired and allocation is not possible, note such information in an endnote.

For determining percentage of voting securities, evaluate total voting power per § 801.12.

For determining percentage of non-corporate interests, evaluate the economic interests per § 801.1(b)(1)(ii).

**Item 2(d)(i)**
State the value of voting securities already held. (See § 801.10).

**Item 2(d)(ii)**
State the percentage of voting securities already held. (See § 801.12).

**Item 2(d)(iii)**
State the total value of voting securities to be held as a result of the acquisition. (See § 801.10).

**Item 2(d)(iv)**
State the total percentage of voting securities to be held as a result of the acquisition. (See § 801.12).

**Item 2(d)(v)**
State the value of non-corporate interests already held. (See § 801.10).

**Item 2(d)(vi)**
State the percentage of non-corporate interests already held. (See § 801.1(b)(1)(ii)).

**Item 2(d)(vii)**
State the total value of non-corporate interests to be held as a result of the acquisition. (See § 801.10).

## ITEM 2 cont.

**Item 2(d)(viii)**
State the total percentage of non-corporate interests to be held as a result of the acquisition. (See §§ 801.10 and 801.1(b)(1)(ii)).

**Item 2(d)(ix)**
State the value of assets to be held as a result of the acquisition. (See § 801.10).

**Item 2(d)(x)**
State the aggregate total value of assets, voting securities and non-corporate interests of the acquired person to be held as a result of the acquisition. (See §§ 801.10, 801.12, 801.13 and 801.14).

END OF ITEM 2

**Most Common Mistakes When Completing the HSR Form**

- Noncompliant affidavit
- Missing contact information in Item 1(g)
- Failure to describe target in Item 3(a)
- Incomplete privilege log
- Failure to properly identify authors and recipients of Item 4c/4d documents
- Failure to properly round revenues in Item 5 to nearest tenth of a million and failure to list in ascending order
- Failure to provide required geographic information (e.g., state, county, and city

## ITEM 3

**Item 3(a)**
At the top of Item 3(a), list the name and mailing address of each acquiring and acquired person, and acquiring and acquired entity, whether or not required to file notification. It is not necessary to list every subsidiary wholly-owned owned by an acquired entity.

In the Transaction Description section, briefly describe the transaction, indicating whether assets, voting securities or non-corporate interests (or some combination) are to be acquired. Describe the business operation(s) being acquired. If assets, describe the assets and whether they comprise a business operation. Also, indicate what consideration will be received by each party and the scheduled consummation date of the transaction.

If any attached transaction documents use coded names to refer to the parties, please provide an index identifying the codes.

If there are additional filings, such as shareholder backside filings, associated with the transaction, identify those. Also, identify any special circumstances that apply to the filing, such as whether part of the transaction is exempt under one of the exemptions found in Part 802.

**Item 3(b)**
Furnish copies of all documents that constitute the agreement(s) among the acquiring person(s) and the person(s) whose assets, voting securities or non-corporate interests are to be acquired. Also furnish agreements not to compete and other agreements between the parties. Do not submit schedules and the like unless they contain agreements not to compete, other agreements between the parties, or other important terms of the transaction. For purposes of Item 3(b), responsive documents must be submitted; identifying an internet address or providing a link is not sufficient.

Documents that constitute the agreement(s) (e.g., a Letter of Intent, Merger Agreement, Purchase and Sale Agreement) must be executed, while agreements not to compete may be provided in draft form if that is the most recent version.

If parties are filing on an executed Letter of Intent, they may also submit a draft of the definitive agreement, if one exists.

Note that transactions subject to § 801.30 and bankruptcies under 11 U.S.C. § 363 do not require an executed agreement or letter of intent. For bankruptcies, provide the order from the bankruptcy court.

END OF ITEM 3

M

## ITEM 4

**Item 4(a)**
Provide the names of all entities within the person filing notification, including the UPE, that file annual reports (Form 10-K or Form 20-F) with the United States Securities and Exchange Commission, and provide the Central Index Key (CIK) number for each entity.

**Item 4(b)**
Provide the most recent annual reports and/or annual audit reports (or, if audited is unavailable, unaudited) of the person filing notification.

The acquiring person should also provide the most recent reports of the acquiring entity(s) and any controlled entity whose dollar revenues contribute to an overlap reported in Item 7.

The acquired person should also provide the most recent reports of the acquired entity(s).

Natural persons need only provide the most recent reports for the highest level entity(s) they control. Do not provide personal balance sheets or tax returns.

If the most recent reports do not show sales or assets sufficient to meet the size of person test, and the size of person test is relevant given the size of the transaction, the filing person must stipulate in Item 4(b) that it meets the test.

Note that the person filing notification may incorporate a document by reference to an internet address directly linking to the document. (See § 803.2(e)).

**Items 4(c) and 4(d)**
For each document responsive to Items 4(c) and 4(d), provide the:

1) document's title;
2) date of preparation; and
3) name and title of each individual who prepared the document.

If a specific date is not available, indicate the month and year the document was prepared.

If a large group of people prepared the document, list all the authors and their titles, identifying the principal authors.

Alternatively, it is acceptable to indicate that the document was prepared under the supervision of the lead author and to provide the name and title of that author. If a third party prepared the document, the date of preparation and the name of the third party will suffice.

**Numbering**
Number each document provided in response to Items 4(c) and 4(d). Number 4(c) documents 4(c)-1, 4(c)-2, 4(c)-3, etc. Likewise, number 4(d) documents 4(d)-1, 4(d)-2, 4(d)-3, etc., regardless of the three sub-categories within Item 4(d). If providing only one document, identify it as 4(c)-1 or 4(d)-1.

When submitting a document responsive to both 4(c) and 4(d), list it only once, under 4(c) or 4(d). If a document is responsive to both 4(c) and 4(d), do not cross-reference.

**Privilege**
Note that if the filing person withholds or redacts portions of any document responsive to Items 4(c) and 4(d) based on a claim of privilege, the person must provide a statement of reasons for non-compliance (a "privilege log") detailing the claim of privilege for each withheld or redacted document. (See § 803.3(d)).

For each document, include the:

1) title of the document;
2) its author;
3) author's title/position;
4) addressee;
5) addressee's title/position;
6) date;
7) subject matter;
8) all recipients of the original and any copies;
9) recipients' titles/positions;
10) document's present location; and
11) who has control over it.

Additionally, the filing person must state the factual basis supporting the privilege claim in sufficient detail to enable staff to assess the validity of the claim for each document without disclosing the protected information.

If a privileged document was circulated to a group, such as the Board or an investment committee, the name of the group is sufficient, but the filing person should be prepared to disclose the names and titles/positions of the individual group members, if requested. If the claim of privilege is based on advice from inside and/or outside counsel, the name of the inside and/or outside counsel providing the advice (and the law firm, if applicable) must be provided. If several lawyers participated in providing advice, identifying lead counsel is sufficient. In identifying who controls a document, the name of the law firm is sufficient.

When creating a privilege log, use a separate numbering system for withheld documents, such as P-1, P-2, etc. Redacted documents should also be listed in a separate log that complies with § 803.3(d).

**Item 4(c)**
Provide all studies, surveys, analyses and reports which were prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) for the purpose of evaluating or analyzing the acquisition with respect to market shares, competition, competitors, markets, potential for sales growth or expansion into product or geographic markets.

**Item 4(d)**
**Item 4(d)(i)**
Provide all Confidential Information Memoranda prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) of the UPE of the acquiring or acquired person or of the acquiring or acquired entity(s) that specifically relate to the sale of the acquired entity(s)

**ITEM 4 cont.**

or assets. If no such Confidential Information Memorandum exists, submit any document(s) given to any officer(s) or director(s) of the buyer meant to serve the function of a Confidential Information Memorandum. This does not include ordinary course documents and/or financial data shared in the course of due diligence, except to the extent that such materials served the purpose of a Confidential Information Memorandum when no such Confidential Information Memorandum exists. Documents responsive to this item are limited to those produced up to one year before the date of filing.

**Item 4(d)(ii)**
Provide all studies, surveys, analyses and reports prepared by investment bankers, consultants or other third party advisors ("third party advisors") for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) of the UPE of the acquiring or acquired person or of the acquiring or acquired entity(s) for the purpose of evaluating or analyzing market shares, competition, competitors, markets, potential for sales growth or expansion into product or geographic markets that specifically relate to the sale of the acquired entity(s) or assets. This item requires only materials developed by third party advisors during an engagement or for the purpose of seeking an engagement. Documents responsive to this item are limited to those produced up to one year before the date of filing.

**Item 4(d)(iii)**
Provide all studies, surveys, analyses and reports evaluating or analyzing synergies and/or efficiencies prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) for the purpose of evaluating or analyzing the acquisition. Financial models without stated assumptions need not be provided in response to this item.

END OF ITEM 4

**Tip for Item 4**
If there is insufficient room on the Form for a response, attach "additional pages" behind that item on the Form. (See Responses on page II).

Online Tips for Item 4(c)

Online Tips for Item 4(d)

**ITEMS 5 THROUGH 7**

**Limited response for acquired person.** For Items 5 through 7, the acquired person should limit its response in the case of an acquisition of:

1) assets, to the assets to be acquired;

2) voting securities, to the issuer(s) whose voting securities are being acquired and all entities controlled by such issuer; and/or

3) non-corporate interests, to the unincorporated entity(s) being acquired and all entities controlled by such unincorporated entity(s).

A person filing as both acquiring and acquired persons may be required to provide a separate response to Items 5 through 7 in each capacity so that it can properly limit its response as an acquired person. (See §§ 803.2(b) and (c)).

**ITEM 5**

This item requests revenue information by NAICS code regarding dollar revenues. (See NAICS Data section on page II). All persons must submit data on non-manufacturing dollar revenues at the 6-digit NAICS industry code level. To the extent that dollar revenues are derived from manufacturing operations (NAICS Sectors 31-33), only submit data at the 10-digit product code level (NAICS-based codes).

List all NAICS codes in ascending order.

Persons filing notification should include the total dollar revenues for all entities included within the person filing notification at the time the Form is prepared. If no dollar revenues are reported, check the "None" box and provide a brief explanation.

**Item 5(a)**
Provide 6-digit NAICS industry data concerning the aggregate U.S. operations of the person filing notification for the most recent year in all non-manufacturing NAICS Sectors in which the person engaged. If the dollar revenues for a non-manufacturing NAICS code totaled less than one million dollars in the most recent year, that code may be omitted from Item 5(a).

Provide 10-digit NAICS product code data for each product code within all manufacturing NAICS Sectors (31-33) in which the person engaged in the U.S., including dollar revenues for each product manufactured outside the U.S. but sold into the U.S. Sales of any manufactured product should be reported in a manufacturing code only, even if sold through a separate warehouse or retail establishment.

If such data have not been compiled for the most recent year, estimates of dollar revenues by 6-digit NAICS industry codes and 10-digit NAICS product codes may be provided.

Check the Overlap box for a NAICS code if both parties to the transaction generate dollar revenues in that NAICS code. If there is only a 6-digit overlap in a manufacturing code in Item 7, do not check the Overlap box for a related 10-digit code in Item 5.

ITEM 5 cont.

**Item 5(b)**
**Complete only if the acquisition is the formation of a joint venture corporation or unincorporated entity.** (See §§ 801.40 and 801.50). If the acquisition is not the formation of a joint venture, check the "Not Applicable" box.

**Item 5(b)(i)**
List the contributions that each person forming the joint venture corporation or unincorporated entity has agreed to make, specifying when each contribution is to be made and the value of the contribution as agreed by the contributors.

**Item 5(b)(ii)**
Describe fully the consideration that each person forming the joint venture corporation or unincorporated entity will receive in exchange for its contribution(s).

**Item 5(b)(iii)**
Describe generally the business in which the joint venture corporation or unincorporated entity will engage, including its principal types of products or activities, and the geographic areas in which it will do business.

**Item 5(b)(iv)**
Identify each 6-digit NAICS industry code in which the joint venture corporation or unincorporated entity will derive dollar revenues. If the joint venture corporation or unincorporated entity will be engaged in manufacturing, also specify each 10-digit NAICS product code in which it will derive dollar revenues.

END OF ITEM 5

**Tip for Item 5**
Remember, all financial information should be expressed in millions of dollars, rounded to the nearest one-tenth of a million dollars.

Online Tips for Item 5

ITEM 6

**An acquired person does not complete Item 6 if the transaction involves only the acquisition of assets.** If the transaction involves a mix of assets along with voting securities and/or non-corporate interests, the acquired person must complete Item 6 as related to the voting securities and non-corporate interests.

**Item 6(a)**
**Subsidiaries of filing person**. List the name, city and state/country of all U.S. entities, and all foreign entities that have sales in or into the U.S., that are included within the person filing notification. Entities with total assets of less than $10 million may be omitted. Alternatively, the filing person may report all entities within it.

**Item 6(b)**
**Minority shareholders**. For the acquired entity(s) and for the acquiring entity(s) and its UPE or, in the case of natural persons, the top-level corporate or unincorporated entity(s) within that UPE, list the name and headquarters mailing address of each shareholder that holds 5% or more but less than 50% of the outstanding voting securities or non-corporate interests of the entity, and the percentage of voting securities or non-corporate interests held by that person. (See § 801.1(c))

For limited partnerships, only the general partner(s), regardless of percentage held, should be listed.

**Item 6(c)**
**Minority holdings**. Item 6(c) requires the disclosure of holdings of 5% or more but less than 50%, of any entity(s) that derives dollar revenues in any 6-digit NAICS code reported by the other person filing notification. Holdings in those entities that have total assets of less than $10 million may be omitted.

The acquiring person may rely on its regularly prepared financials that list its investments, and those of its associates that list their investments, to respond to Items 6(c)(i) and (ii), provided the financials are no more than three months old.

If NAICS codes are unavailable, holdings in entities that have operations in the same industry, based on the knowledge or belief of the acquiring person, should be listed. In responding to Items 6(c)(i) and 6(c)(ii), it is permissible for the acquiring person to list all entities in which it or its associate(s) holds 5% or more but less than 50% of the voting securities of any issuer or non-corporate interests of any unincorporated entity. Holdings in those entities that have total assets of less than $10 million may be omitted.

**Item 6(c)(i)**
**Minority holdings of filing person**. If the person filing notification holds 5% or more but less than 50% of the voting securities of any issuer or non-corporate interests of any unincorporated entity, list the issuer and percentage of voting securities held, or in the case of an unincorporated entity, list the unincorporated entity and the percentage of non-corporate interests held.

The acquiring person should limit its response, based on its knowledge or belief, to entities that derived dollar revenues in the most recent year from operations in industries within any 6-digit NAICS industry code in which the acquired entity(s) or assets also derived dollar revenues in the most recent year.

The acquired person should limit its response, based on its knowledge or belief, to entities that derive dollar revenues in the

**ITEM 6 cont.**

same 6-digit NAICS industry code as the acquiring person.

**Item 6(c)(ii)**
**Minority holdings of associates**.
**This item should only be completed by the acquiring person.**
Based on the knowledge or belief of the acquiring person, for each associate (see § 801.1(d)(2)) of the acquiring person holding:

1) 5% or more but less than 50% of the voting securities or non-corporate interests of the acquired entity(s); and/or

2) 5% or more but less than 50% of the voting securities of any issuer or non-corporate interests of any unincorporated entity that derived dollar revenues in the most recent year from operations in industries within any 6-digit NAICS industry code in which the acquired entity(s) or assets also derived dollar revenues in the most recent year;

list the associate, the issuer or unincorporated entity and the percentage held.

END OF ITEM 6

**Tip for Item 6(c)**
Remember, if NAICS codes are unavailable, holdings in entities that have operations in the same industry, based on the knowledge or belief of the acquiring person, should be listed.

Online Tips for Item 6

**ITEM 7**

If, to the knowledge or belief of the person filing notification, the acquiring person, or any associate (see § 801.1(d)(2)) of the acquiring person, derived any amount of dollar revenues (even if omitted from Item 5) in the most recent year from operations:

1) in industries within any 6-digit NAICS industry code in which any acquired entity that is a party to the acquisition also derived any amount of dollar revenues in the most recent year; or

2) in which a joint venture corporation or unincorporated entity will derive dollar revenues;

then for each such 6-digit NAICS industry code follow the instructions below for this section.

Note that if the acquired entity is a joint venture, the only overlaps that should be reported are those between the assets to be held by the joint venture and any assets of the acquiring person or its associates not contributed to the joint venture.

Also, if the acquiring person reports an associate overlap only, the acquired person does not need to respond to Item 7.

**Item 7(a)**
**Industry Code Overlap Information**
Provide the 6-digit NAICS industry code and description for the industry, and indicate whether the overlap is from the person, an associate or both.

**Item 7(b)**
**Item 7(b)(i)**
If the UPE of the other person(s) filing notification derived dollar revenues in the same 6-digit industry code(s) listed in Item 7(a), list the name of that UPE and the name of the entity(s) within that UPE that actually derived those dollar revenues, if different from the entity(s) listed in Item 3(a).

**Item 7(b)(ii)**
**This item should only be completed by the acquiring person.**
List the name of each associate of the acquiring person that also derived dollar revenues through a controlled operating company(s) in the 6-digit industry and, if different, the name of the entity(s) that actually derived those dollar revenues.

**Item 7(c)**
**Geographic Market Information**
Use the 2-digit postal codes for states and territories and provide the total number of states and territories at the end of the response.

Note that except in the case of those NAICS industries in the Sectors and Subsectors mentioned in Item 7(c)(iv)(b), the person filing notification may respond with the word "national" if business is conducted in all 50 states.

**Item 7(c)(i)**
*NAICS Sectors 31-33*
For each 6-digit NAICS industry code within NAICS Sectors 31-33 (manufacturing industries) listed in Item 7(a), list the relevant geographic information in which, to the knowledge or belief of the person filing the notification, the products in that 6-digit NAICS industry code produced by the person filing notification are sold without a significant change in their form (whether they are sold by the person filing notification or by others to whom such products have been sold or resold). Except for industries covered

**ITEM 7 cont.**

by Item 7(c)(iv)(b), the relevant geographic information is all states or, if desired, portions thereof.

**Item 7(c)(ii)**
*NAICS Sector 42*
For each 6-digit NAICS industry code within NAICS Sector 42 (wholesale trade) listed in Item 7(a), list the states or, if desired, portions thereof in which the customers of the person filing notification are located.

**Item 7(c)(iii)**
*NAICS Industry Group 5241*
For each 6-digit NAICS industry code within NAICS Industry Group 5241 (insurance carriers) listed in Item 7(a), list the state(s) in which the person filing notification is licensed to write insurance.

**Item 7(c)(iv)(a)**
*Other NAICS Sectors*
For each 6-digit NAICS industry code listed in item 7(a) within the NAICS Sectors or Subsectors below, list the states or, if desired, portions thereof in which the person filing notification conducts such operations.

| | |
|---|---|
| 11 | agriculture, forestry, fishing and hunting |
| 21 | mining |
| 22 | utilities |
| 23 | construction |
| 48-49 | transportation and warehousing |
| 511 | publishing industries |
| 515 | broadcasting |
| 517 | telecommunications |
| 71 | arts, entertainment and recreation |

**Item 7(c)(iv)(b)**
For each 6-digit NAICS industry code listed in item 7(a) within the NAICS Sectors or Subsectors below, provide the address, arranged by state, county and city or town, of each establishment from which dollar revenues were derived in the most recent year by the person filing notification.

| | |
|---|---|
| 2123 | nonmetallic mineral mining and quarrying |
| 32512 | industrial gases |
| 32732 | concrete |
| 32733 | concrete products |
| 44-45 | retail trade, except 442 (furniture and home furnishings stores), and 443 (electronics and appliance stores) |
| 512 | motion picture and sound recording industries |
| 521 | monetary authorities - central bank |
| 522 | credit intermediation and related activities |
| 532 | rental and leasing services |
| 62 | health care and social assistance |
| 72 | accommodations and food services, except 7212 (recreational vehicle parks and recreational camps), and 7213 (rooming and boarding houses) |
| 811 | repair and maintenance, except 8114 (personal and household goods repair and maintenance) |
| 812 | personal and laundry services |

**Item 7(c)(iv)(c)**
For each 6-digit NAICS industry code listed in item 7(a) within the NAICS Sectors or Subsectors below, list the states or, if desired, portions thereof in which the person filing notification conducts such operations.

| | |
|---|---|
| 442 | furniture and home furnishings stores |
| 443 | electronics and appliance stores |
| 516 | internet publishing & broadcasting |
| 518 | internet service providers |
| 519 | other information services |
| 523 | securities, commodity contracts and other financial investments and related activities |
| 5242 | insurance agencies and brokerages, and other insurance related activities |
| 525 | funds, trusts and other financial vehicles |
| 53 | real estate and rental and leasing |
| 54 | professional, scientific and technical services |
| 55 | management of companies and enterprises |
| 56 | administrative and support and waste management and remediation services |
| 61 | educational services |
| 7212 | recreational vehicle parks and recreational camps |
| 7213 | rooming and boarding houses |
| 813 | religious, grantmaking, civic, professional, and similar organizations |
| 8114 | personal and household goods repair and maintenance |

**Item 7(d)**
**This item should only be completed by the acquiring person.** Use the geographic markets listed in Items 7(c)(i) through 7(c)(iv) to respond to this item, providing the information for associates of the acquiring person. Provide separate responses for each associate of the acquiring person and, if different, the controlled operating company(s) that actually derived the dollar revenues.

END OF ITEM 7

Online Tips for Item 7

MV

## ITEM 8

**This item should only be completed by the acquiring person.** Determine each 6-digit NAICS industry code listed in Item 7(a), in which the acquiring person derived dollar revenues of $1 million or more in the most recent year and in which either:

1) the acquired entity derived dollar revenues of $1 million or more in the recent year (or in the case of the formation of a joint venture corporation or unincorporated entity, the joint venture corporation or unincorporated entity reasonably can be expected to derive dollar revenues of $1 million or more); or

2) in the case of acquired assets, to which dollar revenues of $1 million or more were attributable in the most recent year.

For each such 6-digit NAICS industry code, list all acquisitions of entities or assets deriving dollar revenues in that 6-digit NAICS industry code made by the acquiring person in the five years prior to the date of the instant filing, even if the transaction was non-reportable. List only acquisitions of 50% or more of the voting securities of an issuer or 50% or more of non-corporate interests of an unincorporated entity that had annual net sales or total assets greater than $10 million in the year prior to the acquisition, and any acquisitions of assets valued at or above the statutory size-of-transaction test at the time of their acquisition.

This item pertains only to acquisitions of U.S. entities/assets and foreign entities/assets with sales in or into the U.S., i.e., with dollar revenues that would be reported in Item 5.

For each such acquisition, supply:

1) the 6-digit NAICS industry code (by number and description) identified above in which the acquired entity derived dollar revenues;

2) the name of the entity from which the assets, voting securities or non-corporate interests were acquired;

3) the headquarters address of that entity prior to the acquisition;

4) whether assets, voting securities or non-corporate interests were acquired; and

5) the consummation date of the acquisition.

END OF ITEM 8

## CERTIFICATION

See § 803.6 for requirements.

The certification must be notarized or use the language found in 28 U.S.C. § 1746 relating to unsworn declarations under penalty of perjury.

## *PRIVACY ACT STATEMENT*

Section 18a(a) of Title 15 of the U.S. Code authorizes the collection of this information. Our authority to collect Social Security numbers is 31 U.S.C. § 7701. The primary use of information submitted on this Form is to determine whether the reported merger or acquisition may violate the antitrust laws. Taxpayer information is collected, used, and may be shared with other agencies and contractors for payment processing, debt collection and reporting purposes. Furnishing the information on the Form is voluntary. Consummation of an acquisition required to be reported by the statute cited above without having provided this information may, however, render a person liable to civil penalties up to the amount listed in 16 C.F.R. §1.98(a) per day.

We also may be unable to process the Form unless you provide all of the requested information.

## DISCLOSURE NOTICE

Public reporting burden for this report is estimated to vary from 8 to 160 hours per response, with an average of 37 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this report, including suggestions for reducing this burden to:

Premerger Notification Office
Federal Trade Commission, Room #5301
400 7th Street, S.W.
Washington, D.C. 20024

and

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Under the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The operative OMB control number, 3084-0005, appears within the Notification and Report Form and these Instructions.

END OF FORM INSTRUCTIONS

[FR Doc. 2018–14378 Filed 7–13–18; 8:45 am]
**BILLING CODE 6750–01–C**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1303

**[Docket No. DEA–480]**

**RIN 1117–AB48**

## Controlled Substances Quotas

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is publishing this final rule to strengthen the process for setting controls over diversion of controlled substances and make other improvements in the quota management regulatory system for the production, manufacturing, and procurement of controlled substances.

**DATES:** This final rule is effective August 15, 2018.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–8953.

**SUPPLEMENTARY INFORMATION:**

### Legal Authority

Provisions of the Controlled Substances Act, 21 U.S.C. 801 *et seq.,* authorize the Attorney General to issue rules and regulations relating to registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals. 21 U.S.C. 821. Pursuant to this authority, the Attorney General, through the Drug Enforcement Administration (DEA), has issued and administers regulations setting aggregate production quotas for each basic class of controlled substances in schedules I and II, manufacturing quotas for individual manufacturers, and procurement quotas for manufacturers to produce other controlled substances or to convert the substances into dosage form. *See* 21 CFR part 1303.

The current regulations, issued initially in 1971, need to be updated to reflect changes in the manufacture of controlled substances, changing patterns of substance abuse and markets in illicit drugs, and the challenges presented by the current national crisis of controlled substance abuse. This final rule modifies the regulations to strengthen controls over diversion—that is, the redirection of controlled substances which may have lawful uses into illicit channels—and makes other improvements in the controlled substance regulatory quota system.

The quota process, in general terms, is a critical element of the Controlled Substances Act's regulatory system that seeks to prevent or limit diversion by preventing the accumulation of controlled substances in amounts exceeding legitimate need. The measures the final rule adopts to strengthen the system include authorizing the requisition from quota applicants of additional information helpful in detecting and preventing diversion, and ensuring that DEA's determinations regarding the appropriate quotas are adequately informed by input from other federal agencies, from the states, and from quota applicants.

### Section-by-Section Analysis

The DEA is finalizing the rule as proposed without changes. Below are summaries of provisions contained in the final rule.

*Section 1303.11—Aggregate Production Quotas*

Section 1303.11 currently directs the Administrator of DEA to determine the total quantity of each basic class of controlled substance listed in schedule I or II needed in the calendar year for the medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Section 1303.11(b)(1) through (4) identifies a number of factors that are categorically to be considered in determining aggregate production quotas—relating to total net disposal, net disposal trends, inventories and inventory trends, and demand—followed by a final catchall factor, (5), regarding factors to be considered as the Administrator finds relevant.

The final rule makes two additions to the list of factors that must regularly be considered in setting the aggregate production quotas because of their importance. First, it adds to the list the extent of any diversion of the controlled substance in the class, which will ensure that the allowed aggregate production quota is limited to that needed to provide adequate supplies for the United States' legitimate needs. Second, the final rule amends the list of factors to be considered in establishing these quotas to include relevant information from the Department of Health and Human Services (HHS) and its components, including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), as well as relevant information obtained from the states. The amendment will ensure that information will be requested from the relevant HHS components and will be considered in setting the aggregate production quotas.

The final rule provides that the Administrator will consider information from the states in setting the aggregate production quotas and make additional changes enhancing their role in § 1303.11(c). The states are critically situated to provide information about the extent of legitimate and illegitimate use of controlled substances because of their responsibilities for drug enforcement within their jurisdictions, including through the Prescription Drug Monitoring Programs (PDMP), their responsibilities for administration of their health care systems, and their responsibilities for dealing with the human and social costs of drug abuse and diversion. States may have relevant information indicating that individual procurement quota requests reflect quantities which will in fact be diverted to illicit use, which may in turn yield an exaggerated picture of the aggregate production quotas needed for legitimate purposes.

The final rule accordingly includes amendments to § 1303.11(c) which provide for (i) transmitting notices of proposed aggregate production quotas, and final aggregate production quota orders, to the state attorney general, and (ii) holding a hearing if necessary to resolve an issue of material fact raised by a state's objection to a proposed aggregate production quota as excessive in relation to legitimate United States need.

*Section 1303.12—Procurement Quotas*

Section 1303.12 currently directs the Administrator to issue procurement quotas for manufacturers that use controlled substances to put them into dosage form or to make other substances. The section requires applicants for procurement quotas to state what basic class of controlled substance is needed, the purpose or purposes for which the class is desired, the quantity desired for each purpose during the next calendar year, and the quantities used and estimated to be used for each purpose during the current and preceding two calendar years. If the applicant's purpose is to manufacture another basic class of controlled substance, the applicant also must state the quantity of the other basic class that the applicant has applied to

manufacture, and the quantity of the first basic class necessary to manufacture a specified quantity of the second basic class.

The final rule amends § 1303.12(b) to clarify that the Administrator may require additional information from applicants that may help to detect or prevent diversion, including customer identities and amounts of the controlled substance sold to each customer.

*Section 1303.13—Adjustments of Aggregate Production Quotas*

Section 1303.13 authorizes the Administrator, at any time, to increase or reduce the aggregate production quotas for basic classes of controlled substances that were previously fixed pursuant to § 1303.11. The final rule in § 1303.13 parallels some of the amendments made to § 1303.11. Specifically, it includes changes in the extent of any diversion of the controlled substance among the factors to be considered in adjusting the aggregate production quota, requires transmission of adjustment notices and final adjustment orders to the state attorneys general, and provides for a hearing if necessary to resolve an issue of material fact raised by a state's objection to a proposed adjusted quota as excessive for legitimate United States need.

*Section 1303.22—Procedure for Applying for Individual Manufacturing Quotas*

The final rules amends § 1303.22 to clarify that the Administrator may require additional information from individual manufacturing quota applicants that may help to detect or prevent diversion, including customer identities and amounts of the controlled substance sold to each customer.

*Section 1303.23—Procedures for Fixing Individual Manufacturing Quotas*

The final rule amends § 1303.23 to provide that the factors the Administrator may deem relevant in fixing individual manufacturing quotas include the extent and risk of diversion of controlled substances.

*Section 1303.32—Purpose of Hearing*

The final rule includes an amendment relating to hearings in § 1303.32(a), conforming to the amendments to §§ 1303.11(c) and 1303.13(c) concerning hearings based on state objections.

*Other Matters*

In addition to the significant changes discussed above, the final rule corrects a number of typographic errors in the current regulations.

**Notice of Proposed Rulemaking**

On April 19, 2018, the DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register**, which provided an opportunity for comment on the proposed rule. The comment period closed on May 4, 2018. 83 FR 17329. The DEA specifically sought comments on the provisions regarding the factors the Administrator should consider when adjusting the aggregate production quotas (21 CFR 1303.13(b)(1)), and the additional information the Administrator may require from applicants (21 CFR 1303.12(b) and 21 CFR 1303.22).

**Discussion of Comments**

DEA received a total of 1,561 written and electronic comments on the NPRM. In the NPRM, the DEA stated that some of the proposed rule's provisions relating to seeking information from other federal agencies and the states (21 CFR 1303.11(b)(6)) and those relating to the holding of hearings based on state objections (21 CFR 1303.11(c), 21 CFR 1303.13(c), and 21 CFR 1303.32(a)) were exempt from the notice and comment requirements of the Administrative Procedure Act as ''rules of agency organization, procedure, or practice.'' 5 U.S.C. 553(b)(A). However, many commenters still addressed these two issues. While the DEA appreciates the interest commenters have shown in these areas, because they were exempt from the notice and comment requirements of the APA, the DEA has not considered these comments in its promulgation of this final rule.

After a review of the comments, DEA noted that there were six main issues that commenters raised, and that many commenters raised multiple issues in their comments. Each issue is summarized below, along with the DEA's responses. The DEA has also summarized the remainder of the comments which did not fit into one of the six main issues.

*A. Causes for the Increase in Opioid Deaths*

*Issue:* Approximately 156 commenters raised the issue that the increase in opioid deaths was due to illicitly manufactured opioids coming in from Mexico and China and errors in reporting deaths involving multiple substances, not written prescriptions for controlled substances. Advocacy groups and the general public voiced concern about the accuracy of CDC death calculations that they believe led to more strict quotas on the pain pills they need to live, instead of focusing on the issue of illicitly manufactured substances like fentanyl and heroin.

One advocacy group noted that available data indicated that the large increase in overdose deaths was largely due to illicitly manufactured fentanyl, heroin, and synthetic opioids, not prescription opioids. The advocacy group stated that the data reinforced the need to address the growing threat posed by heroin, counterfeit fentanyl, and other counterfeit drugs.

An association representing physicians also noted that although the rate of prescription opioid mortality continues to rise, illicit fentanyl and heroin have become the main contributors to opioid-related mortality.

A coalition commented that a major issue with the proposed rule was that it would do nothing to solve the current opioid epidemic because illicit fentanyl and heroin cause most of the overdoses in the United States, not prescription opioids. The coalition referenced journal articles for statistics to support their argument. The coalition also noted that the vast majority of the illicit fentanyl that is arriving into the United States is coming from China through the U.S. Postal Service, and that the policies in the proposed rule would have no effect on the current number of overdose deaths.

One law firm noted that after a re-evaluation of CDC data and DEA's own analyses, it has become evident that the current opioid ''crisis'' is caused by illicit synthetic opioids, particularly fentanyl and deadlier fentanyl derivatives with no medical use.

*DEA Response:* This final rule does not establish specific quotas. Instead, this final rule revises and improves the process for DEA to follow in gathering information and taking other actions pertaining to quotas. The CDC has acknowledged that they have a new analysis confirming recent increases in drug overdose death,[1] however, as stated in the NPRM, the CDC's data will not be the only source of information the DEA will be considering. The DEA will also consider relevant information from other components of HHS, as well as relevant information from the States.

The DEA believes that the misuse of controlled prescription drugs (CPDs) is inextricably linked with the threat the United States faces from the trafficking of heroin and illicit fentanyl and fentanyl analogues. In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain

[1] *https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html.*

relievers within the past month.[2] Roughly 75 percent of heroin users reported nonmedical use of prescription opioids before using heroin (though the vast majority of individuals misusing opioid CPDs do not go on to use heroin).[3] Many stated that they first obtained these drugs for free from the family medicine cabinet or from friends[4] but then sought street or black market drugs to maintain their addiction. This illustrates the role that CPDs have played in the opioid epidemic and underscores the continued need for robust regulatory and enforcement measures to stop diversion of CPDs. Black-market sales for opioid CPDs are typically five to ten times their retail value, and DEA intelligence reveals the ''street'' cost of prescription opioids steadily increases with the relative strength of the drug.

*B. The Injectable Shortage and Adjusting the Quota Process*

*Issue:* The DEA received 23 comments concerning how manufacturing quotas may cause a shortage of injectable opioids. Commenters were concerned that injectable opioids that are used routinely for surgeries and cancer treatment, such as injectable morphine, hydromorphone, and fentanyl would not be available to hospitals and patients. Commenters attributed the perceived shortages of these drugs to manufacturing setbacks and a government effort to restrict the amount of opioids and other pain medicines to be manufactured. Commenters stated that due to the alleged shortage of these drugs, hospitals are having a difficult time treating patients and finding alternatives for pain management.

Many commenters stated that the DEA is focusing on the wrong issues. A majority asserted that synthetic drugs are the cause of most of the overdose opioid deaths, and that the government should focus on those synthetic drugs instead of creating regulations that they feel lead to a reduction in injectable opioids.

Comments received from organizations and associations asserted that there is no risk of diversion for injectables. It was stated numerous times that the DEA should consider adding drug shortage information as a factor when establishing and adjusting quotas. It was also recommended that the DEA add the intent to resolve drug shortages to the relevant factors considered in adjusting quotas.

*DEA Response:* The DEA is committed to ensuring that quotas are set in such a way as to grant manufacturers the ability to provide FDA-approved drug products to meet the demand of the legitimate medical, scientific, and export needs of the United States. As required in 21 U.S.C. 826(h), when there is a shortage, the DEA will ''increase the aggregate and individual production quotas and any ingredients therein to the level requested.'' When it is determined that the level requested is not necessary to address a shortage, the DEA provides a written response detailing the basis for the decision. 21 U.S.C. 826(h)(1)(B)(ii). Quotas granted to the dosage form manufacturers based on legitimate medical need will always be considered in the aggregate production quota. The DEA will always take into consideration any changes in market dynamics that may require allocation of individual manufacturers' quotas or revisions of the aggregate production quota. The DEA, however, cannot set quotas based on individual pharmaceutical dosage forms (21 U.S.C. 826(a)) nor can DEA compel manufacturers to manufacture specific individual pharmaceutical dosage forms even though the latter may lead to manufacturer induced shortages based on their internal business decisions. Thus, independent of DEA's adjustment of quotas, manufacturers' business decisions and manufacturing practices may lead to a shortage of certain individual pharmaceutical dosage forms, despite the adequacy of the applicable aggregate production quota.

*C. The DEA's Methodology for Quantifying Diversion*

*Issue:* The DEA received 16 comments regarding DEA's methodology for determining quantities of controlled substances being diverted. Three commenters recommended that the DEA obtain data from HHS, CDC, and CMS on topics such as patterns of drug abuse, and that such information be considered for calculating aggregate production quota. The same commenters suggested that the information from HHS, CDC, and CMS can contribute to appropriate methods for determining quantities of controlled substances being diverted. Another commenter stated that the DEA does not distinguish between diversion and abuse when considering the quota formula. Seven commenters stated that DEA does not have reliable measures to calculate diversion of controlled substances. One of these commenters stated that DEA did not provide any examples or explanations on how DEA will collect measureable data. Two commenters suggested that DEA obtain data from the FDA on controlled substances shortages (which can be broken down by dosage) to help the DEA quantify a clear picture of diversion risks by the specific dosage forms. Another commenter stated that DEA did not provide any scientific data that supports DEA claim that quota reductions decrease diversion of controlled substances.

One commenter suggested DEA work on anti-diversion legislation that will put requirements in place during the manufacturing process to prevent diversion of controlled substances so it will not affect quotas. Another commenter requested DEA to provide quantitative evidence to show the impact current reductions have had on diversion of controlled substances.

*DEA Response:* The DEA is committed to continuously developing sound and reliable methods for determining quantities of controlled substances being diverted. Currently, DEA's reliable method to measure the diversion of controlled substances occurs at the level of individual dosage manufacturers rather than at the aggregate production quota level. Selected opioid dispositions from these manufacturers are compared to known, completed regulatory and operation enforcement actions and counted toward diverted quantities for individual manufacturers and not the aggregate production quota itself.

Modifications to section 1303.11 would allow relevant information from appropriate HHS components to be considered in setting the aggregate production quota. HHS studies the use and misuse of controlled substances regarding the quantities of controlled substances necessary to support the medical needs in the United States pursuant to 42 U.S.C. 242(a). Furthermore, the CDC and the CMS may have relevant information related to the patterns of drug abuse and the diversion of controlled substances for illicit use which DEA will also consider when setting the aggregate production quota. The information collected from HHS

[2] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17–5044, NSDUH Series H–52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/.*

[3] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. (2014). The changing face of heroin use in the United States: A retrospective analysis of the past 50 years. JAMA Psychiatry.71(7):821–826.

[4] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17–5044, NSDUH Series H–52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/.*

through FDA, CDC, and CMS, and that collected from the states, will improve DEA's ability to distinguish diversion of controlled substances at a more geographically localized level. The information collected will enhance the DEA's ability to determine registrant's compliance with suspicious order monitoring regulations. The modifications to section 1303.22 will allow the Administrator to require additional information from manufacturing quota applicants that will assist the DEA in detecting or preventing diversion of controlled substances.

The Administrator of the DEA has the authority to determine the total quantity of each basic class of controlled substance listed in Schedule I or II needed in each calendar year for medical, scientific, research and industrial needs of the United States, for lawful export, and for the establishment and maintenance of reserve stocks. The DEA has observed a decline for certain prescriptions written for Schedule II opioids since 2014 which can be attributed to federal and state government activities and interventions, including the implementation of Prescription Drug Monitoring Programs, enforcement of current regulations, and guidance documents such as the CDC *Guideline for Prescribing Opioids for Chronic Pain*—United States March 2016.

*D. Trend in the Number of Prescriptions Written for Controlled Substances*

*Issue:* The DEA received 36 comments from commenters stating that prescription data shows that there has been a downward trend in the prescribing of controlled substances for the last several years, therefore prescription opioids are not responsible for the current opioid epidemic. As such, the commenters believed there was no need for the regulations to be updated. There were comments received from patients describing their inability to receive prescriptions for pain medications; they stated that their doctors had placed blame on the DEA.

*DEA Response:* The DEA acknowledges that prescriptions for opioid drug products have decreased over the last several years due to the stepped up civil, criminal, and regulatory enforcement efforts of the agency. However, while there is a downward trend in prescribing, these schedule II prescription opiates continue to have a high potential for abuse and dependence and require the annual assessment of quotas. These decreases can be attributed to DEA's 360 Strategy, which combines local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents, including the CDC *Guideline for Prescribing Opioids for Chronic Pain* released in March 2016. In addition, more states have enacted and are enforcing laws mandating the use of PDMPs by medical providers and pharmacists, which provides prescribers with valuable information to guide their medical decisions.[5] As such, this final rule will allow the downward trend to continue through the continued sharing of information from different HHS components and states.

*E. Fifteen Day Comment Period*

*Issue:* The DEA received 5 comments from commenters who felt the proposed rule's comment period was too short. One commenter suggested that the comment period remain open for 180 days because of the complex issues being addressed in the document. Two commenters voiced displeasure with the length of the comment period stating that it made it seem like the average citizens' opinion was not being valued.

One national organization noted that the comment period provided by the DEA was unusual in its brevity. The national organization referenced Executive Order 13563, as well as guidance from the Administrative Conference of the United States, to suggest that the DEA comment period should have at least been 30 days since it was a rulemaking that was not considered ''significant.'' The national organization stated that they were not certain that the additional 15 days necessary to achieve the 30-day period for review and input by experts outside of the agency would meaningfully ''impede putting into effect the diversion countermeasures [the proposal] authorizes.''

*DEA Response:* The APA does not specify a minimum time for submission of written comments. Agencies must provide the public with a ''meaningful opportunity'' to comment on a proposed notice. *Rural Cellular Ass'n* v. *FCC, 588 F.3d 1095* (D.C. Cir. 2009). While the length of the comment period is a factor in determining whether the public was afforded a ''meaningful opportunity'' to comment, courts have upheld comment periods of less than 30 days. *See, e.g. Omnipoint Corp.* v. *FCC, 78 F.3d 620* (D.C. Cir. 1996) (upholding 15-day comment period where there was ''urgent necessity for rapid administrative action under the circumstances'' and the public was not harmed).

Under Executive Order 13563, there is a presumption that a period of 60 days should be allotted for the comment period. The Administrative Conference of the United States' recommendations serve as guidance for the notice-and-comment period. While they recommend 30 to 60 days depending on the significance of a rule, they also recommend that agencies provide an explanation when they set a shorter comment period, as was done in the NPRM. 76 FR 48791 (Aug. 9, 2011).

Here, the DEA received more than 1,500 comments, many of which included a thoughtful and detailed analysis. Due to the opioid epidemic as expressed in the proposed rule and the urgent need to finalize this rule, the 15-day comment period was sufficient.

*F. Clarification of What Additional Data DEA May Seek From Registrants*

*Issue:* There were 11 comments received seeking clarification of what additional information the Administrator may require from registrants. The majority of the comments received were from industry and advocacy groups. While they agreed that steps need to be taken to address the current opioid epidemic, the views were not completely in support of the possibility of having to turn in additional information.

One company felt the proposed changes seemed to codify the current practice of considering ARCOS (Automated Reporting and Consolidated Orders System) data when setting quotas. Many comments under this issue suggested that the DEA clearly detail what information would be required. A trade group also explained that knowing what the DEA could request beforehand would allow manufacturers the ability to ensure that systems are in place to collect and provide relevant data in a timely manner. The group felt that the DEA should determine whether additional data should be required beyond what is already required for schedule II controlled substances by way of the DEA Form 222. The group also requested that the DEA make sure that any additional requested information not place an undue burden on manufacturers or delay the issuance of initial quotas. They argued that DEA needs to include adequate protection of proprietary and sensitive commercial and financial information provided by the manufacturers, because the

[5] *Challenges and Solutions in the Opioid Abuse Crisis: Hearing Before the H. Comm. On the Judiciary,* 115th Cong. 6,10 (2018) (statement of Robert W. Patterson, Acting Administrator, Drug Enforcement Administration).

additional data allowed for the collection of trade secrets or confidential commercial information. One association asked for the additional data to be used in a timely fashion to help anticipate and address potential shortages in the future. Another organization strongly objected to the proposed rule, because they did not see how the additional information could be useful in reducing opioid abuse and overdose when the main source of the problem is illicit drugs.

A pharmaceutical company requested that the DEA provide opportunities for companies to receive guidance and training on how to best satisfy the additional information requirements. Another pharmaceutical company stated they contract with Contract Manufacturing Organizations (CMO) for the manufacturing of their finished drug products, and that because of this the CMO would be the actual quota applicant but would not be equipped with the additional information to help in detecting and preventing diversion.

Two states commented on this issue and both applauded the DEA for taking action. West Virginia stated that obtaining additional information would be helpful because some of the legitimate demand may be double counted by way of multiple applicants relying on the same amounts of legitimate demand from the same customers. West Virginia's view was that the additional information will allow the DEA to prevent excess quota levels. Ohio also agreed with the proposed rule and encouraged the DEA to consider a more rigorous and information-driven quota application process.

*DEA Response:* The DEA acknowledges that the CSA's requirement for allotting quotas for manufacturers was enacted on the business model of a vertically integrated system. Since its enactment, manufacturers have determined new and innovative ways of conducting business, as a response to a more robust, competitive market. While the CSA allows for adequate domestic competition, it also limits this competition to the legitimate medical, scientific, and industrial needs of the United States. The DEA has always had the ability to request information to clarify and support a manufacturer's request for quota to ensure that any quota granted is limited to legitimate need. Detailed information about what may be requested for clarification or support cannot be provided because the request would be on a case-by-case basis. DEA does not provide a list of additional items needed to process quotas because they may not pertain to every registrant. Therefore, additional data will be determined in light of the information manufacturers provide to the DEA as justification for a quota.

Manufacturers of schedule I and II substances provide information needed to assist the DEA in making a quota determination. The information provided is based on their individual business activities. Regulations require manufacturers to utilize DEA Form 222 [6] to document purchase and disposition information between DEA registrations; similar information is also transmitted to ARCOS. A limitation of ARCOS can be the reporting period a company opts to report their data (monthly or quarterly) and the timeliness of corrections to any errors in the reported data. There is no undue burden or cost to supply this information because it is already being captured in some form by the company per CSA regulations and good business practices.

The DEA communicates with registrants who have pending quota applications via telephone or email when necessary, to request clarification or additional information required to process their applications in a timely manner. The DEA also maintains an email box that registrants may preemptively supply information and communicate concerns related to quota requirements. Appropriate safeguards are currently in place to protect confidential business information.

As stated above, requesting clarification or additional information is a current practice of DEA. The DEA provides training conferences annually, in strategic locations, to help registrants understand quota and reporting requirements. The agency also provides the presentations from the trainings on the DEA website. During these conferences, DEA explicitly states it never provides confidential and proprietary information supplied by registrants to outside sources. The additional information that may be requested is important and an integral part of the analysis as it helps DEA determine the amount of quota a manufacturer should be granted.

*G. Other Comments*

Approximately 1,300 comments were received from the general public expressing concerns about the proposed regulations affecting their ability to get their prescriptions, and the possibility of drug shortages being created because of the proposed rule. The DEA understands and appreciates the nature of the comments. It is not the DEA's intent to create shortages or prevent a patient with a legitimate need from getting their prescription. The purpose of the proposed rule is to improve the process of setting the annual quota while ensuring an adequate supply is available for the United States' legitimate needs.

[6] 21 CFR 1305.11–1305.19.

**Regulatory Flexibility Act**

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this final rule and by approving it certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The DEA estimates that 325 manufacturers may be affected by the final rule, of which 301 manufacturers (92.6% of the total) are small entities. There will not be a significant economic impact on a substantial number of these small entities or any others because, as the ensuing certifications discuss, any overall cost of the rule is not significant.

**Executive Orders 12866, 13563, and 13771—Regulatory Planning and Review, and Reducing Regulation and Controlling Regulatory Costs**

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), Principles of Regulation, and Executive Order 13563, ''Improving Regulation and Regulatory Review.'' The DEA has determined that this final rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f). The DEA analyzed the economic impact of each provision of this final rule. Section 1303.11 is amended to make two additions to the list of factors to be considered by the Administrator in setting the aggregate production quotas. First, it adds the extent of any diversion of the controlled substance in the class. Second, it adds relevant information from HHS and its components, as well as from the states. The DEA has always considered any information obtained from other federal and state government agencies when fixing the aggregate production quotas for a controlled substance. While the DEA may receive additional information that is valuable in detecting and preventing diversion, the DEA has no reason to believe that there will be adverse economic impact or other consequences sufficient to implicate Executive Order (E.O.) 12866.

Additionally, §§ 1303.11 and 1303.13 are amended to require the DEA to transmit copies of aggregate production quotas and any adjustments to those quotas published in the **Federal Register** directly to state attorneys

general. While the DEA anticipates some labor burden to transmit aggregate production quota notices and orders to each state attorney general, the DEA estimates that this activity will result in a minimal yearly cost to the DEA and that the DEA has sufficient resources to absorb this minimal cost.

Additionally, §§ 1303.11, 1303.13, and 1303.32 are amended to explicitly state that the DEA Administrator shall hold a hearing if he or she determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States need. The estimated yearly cost of this revision will be dependent on the number of hearings the DEA Administrator determines to be necessary to resolve an issue of material fact raised by a state regarding the aggregate production quota. Hearings regarding aggregate production quotas are infrequent and the DEA estimates that hearings of this type will continue to be infrequent under this final rule. For these reasons, the DEA does not expect a material increase in the number of hearings or in the associated costs to DEA or the states.

Sections 1303.12 and 1303.22 are amended to explicitly state that the Administrator may require additional information from an individual manufacturing or procurement quota applicant, including customer identities and amounts of controlled substances sold to each of their customers. Currently, the DEA can and does request additional information of this nature from quota applicants if deemed necessary. While affording the Administrator express regulatory authority to require such information may result in the receipt of additional information that is valuable in detecting and preventing diversion, it is not expected that the difference will have adverse economic impact or other consequences sufficient to implicate E.O. 12866.

Sections 1303.11, 1303.13, and 1303.23 are amended to add the requirement that the DEA consider diversion of a controlled substance when fixing aggregate production quotas, adjusting aggregate production quotas, and fixing individual manufacturing quotas. When fixing and adjusting the aggregate production quota, or fixing an individual manufacturing quota for a controlled substance, the DEA has always considered all available information regarding the diversion of that controlled substance. While the final rule's amendments, as discussed above, may result in the receipt and consideration of additional information relating to diversion, it is not expected that the difference will have adverse economic impact or other consequences sufficient to implicate E.O. 12866.

This final rule is not an E.O. 13771 regulatory action because this final rule is not significant under E.O. 12866.

**Executive Order 13132—Federalism**

This regulation will not have substantial direct effects on the states, on the relationship between the national Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

**Executive Order 12988—Civil Justice Reform**

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

**Paperwork Reduction Act**

This final rule codifies current agency practice under existing approved information collections, and does not impose new information collection requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

**Unfunded Mandates Reform Act of 1995**

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

**Congressional Review Act**

This rulemaking is not a major rule as defined by section 251 of the Congressional Review Act. 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

**List of Subjects in 21 CFR Part 1303**

Administrative practice and procedure, Drug traffic control.

Accordingly, for the reasons stated in the preamble, part 1303 of title 21 of the Code of Federal Regulations is amended as follows:

## PART 1303—QUOTAS

■ 1. The authority citation for part 1303 continues to read as follows:

**Authority:** 21 U.S.C. 821, 826, 871(b).

■ 2. In § 1303.11:
■ a. Remove the word ''and'' at the end of paragraph (b)(4).
■ b. Redesignate paragraph (b)(5) as paragraph (b)(7).
■ c. Add new paragraph (b)(5) and paragraph (b)(6).
■ d. Revise paragraph (c).

The additions and revision read as follows:

**§ 1303.11 Aggregate production quotas.**

* * * * *

(b) * * *

(5) The extent of any diversion of the controlled substance in the class;

(6) Relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services, and relevant information obtained from the states; and

* * * * *

(c) The Administrator shall, on or before May 1 of each year, publish in the **Federal Register**, general notice of an aggregate production quota for any basic class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the **Federal Register**, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 30 days after the

date of publication of the notice. After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the **Federal Register** his final order determining the aggregate production quota for the basic class of controlled substances. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

■ 3. In § 1303.12, paragraph (b), add after the fifth sentence a new sentence to read as follows:

**§ 1303.12 Procurement quotas.**

* * * * *

(b) * * * The Administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer. * * *

* * * * *

■ 4. In § 1303.13, revise paragraphs (b)(1) and (c) to read as follows:

**§ 1303.13 Adjustments of aggregate production quotas.**

* * * * *

(b) * * *

(1) Changes in the demand for that class, changes in the national rate of net disposal of the class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class;

* * * * *

(c) The Administrator in the event he determines to increase or reduce the aggregate production quota for a basic class of controlled substance, shall publish in the **Federal Register** general notice of an adjustment in the aggregate production quota for that class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed adjusted quota as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the **Federal Register**, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice. After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the **Federal Register** his final order determining the aggregate production for the basic class of controlled substance. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

**§ 1303.21 [Amended]**

■ 5. In § 1303.21, in paragraph (a), remove ''§§ '' in the second sentence and add in its place ''§ ''.

■ 6. In § 1303.22:

■ a. In paragraph (c)(2), remove the word ''econolic'' and add in its place the word ''economic''.

■ b. Add paragraph (d).

The addition reads as follows:

**§ 1303.22 Procedure for applying for individual manufacturing quotas.**

* * * * *

(d) The Administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer.

**§ 1303.23 [Amended]**

■ 7. In § 1303.23, add the phrase ''the extent of any diversion of the controlled substance,'' after ''strikes),'' in paragraph (a)(2), and add the phrase ''any risk of diversion of the controlled substance,'' after ''strikes),'' in paragraph (b)(2).

**§ 1303.32 [Amended]**

■ 8. In § 1303.32, in paragraph (a), add the phrase ''and shall, if determined by the Administrator to be necessary under § 1303.11(c) or 1303.13(c) based on objection by a state,'' before ''hold a hearing''.

Dated: July 11, 2018.

**Uttam Dhillon,**

*Acting Administrator.*

[FR Doc. 2018–15141 Filed 7–13–18; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Parts 28, 30, 87, 180, and 3282

**[Docket No. FR–6076–F–01]**

**RIN 2501–AD86**

## Adjustment of Civil Monetary Penalty Amounts for 2018

**AGENCY:** Office of the General Counsel, HUD.

**ACTION:** Final rule.

**SUMMARY:** This rule provides for 2018 inflation adjustments of civil monetary penalty amounts required by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

**DATES:** *Effective date for 2018 inflation adjustment:* August 15, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dane Narode, Associate General Counsel, Office of Program Enforcement, Department of Housing and Urban Development, 1250 Maryland Avenue SW, Suite 200, Washington, DC 20024; telephone number 202–245–4141 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Information Relay Service, toll-free, at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Pub. L. 114–74, Sec. 701), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), requires agencies to make annual adjustments to civil monetary penalty (CMP) amounts for inflation ''notwithstanding section 553 of title 5, United States Code.'' Section 553 refers to the Administrative Procedure Act, which might otherwise require a delay for advance notice and opportunity for public comment on future annual inflation adjustments. This annual adjustment is for 2018.

The annual adjustment is based on the percent change between the U.S.

Department of Labor's Consumer Price Index for All Urban Consumers (''CPI–U'') for the month of October preceding the date of the adjustment, and the CPI–U for October of the prior year (28 U.S.C. 2461 note, section (5)(b)(1)). Based on that formula, the cost-of-living adjustment multiplier for 2018 is 1.02041.[1] Pursuant to the 2015 Act, adjustments are rounded to the nearest dollar.[2]

## II. This Final Rule

This rule makes the required 2018 inflation adjustment. Since HUD is not applying these adjustments retroactively, the 2018 increases apply to violations occurring on or after this rule's effective date. For each component, HUD provides a table showing how the penalties are being adjusted for 2018 pursuant to the 2015 Act. In the first column (''Description''), HUD provides a description of the penalty. In the second column (''Statutory Citation''), HUD provides the United States Code statutory citation providing for the penalty. In the third column (''Regulatory Citation''), HUD provides the Code of Federal Regulations citation under Title 24 for the penalty. In the fourth column (''Previous Amount''), HUD provides the amount of the penalty pursuant to the rule implementing the 2017 adjustment (82 FR 24521, May 30, 2017). In the fifth column (''2018 Adjusted Amount''), HUD lists the penalty after applying the 2018 inflation adjustment.

| Description | Statutory citation | Regulatory citation (24 CFR) | Previous amount | 2018 Adjusted amount |
|---|---|---|---|---|
| False Claims & Statements | Omnibus Budget Reconciliation Act of 1986 (31 U.S.C. 3802(a)(1)). | 28.10 | $10,957 | $11,181. |
| Advance Disclosure of Funding | Department of Housing and Urban Development Act (42 U.S.C. 3537a(c)). | 30.20 | $19,246 | $19,639. |
| Disclosure of Subsidy Layering | Department of Housing and Urban Development Act (42 U.S.C. 3545(f)). | 30.25 | $19,246 | $19,639. |
| FHA Mortgagees and Lenders Violations. | HUD Reform Act of 1989 (12 U.S.C. 1735f–14(a)(2)). | 30.35 | Per Violation: $9,623<br>Per Year: $1,924,589 | Per Violation: $9,819.<br>Per Year: $1,963,870. |
| Other FHA Participants Violations. | HUD Reform Act of 1989 (12 U.S.C. 1735f–14(a)(2)). | 30.36 | Per Violation: $9,623<br>Per Year: $1,924,589 | Per Violation: $9,819.<br>Per Year: $1,963,870. |
| Indian Loan Mortgagees Violations. | Housing Community Development Act of 1992 (12 U.S.C. 1715z–13a(g)(2)). | 30.40 | Per Violation: $9,623<br>Per Year: $1,924,589 | Per Violation: $9,819.<br>Per Year: $1,963,870. |
| Multifamily & Section 202 or 811 Owners Violations. | HUD Reform Act of 1989 (12 U.S.C. 1735f–15(c)(2)). | 30.45 | $48,114 | $49,096. |
| Ginnie Mae Issuers & Custodians Violations. | HUD Reform Act of 1989 (12 U.S.C. 1723i(b)). | 30.50 | Per Violation: $9,623<br>Per Year: $1,924,589 | Per Violation: $9,819.<br>Per Year: $1,963,870. |
| Title I Broker & Dealers Violations. | HUD Reform Act of 1989 (12 U.S.C. 1703). | 30.60 | Per Violation: $9,623<br>Per Year: $1,924,589 | Per Violation: $9,819.<br>Per Year: $1,963,870. |
| Lead Disclosure Violation | Title X—Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4852d(b)(1)). | 30.65 | $17,047 | $17,395. |
| Section 8 Owners Violations | Multifamily Assisted Housing Reform and Affordability Act of 1997 (42 U.S.C. 1437z–1(b)(2)). | 30.68 | $37,396 | $38,159. |
| Lobbying Violation | The Lobbying Disclosure Act of 1995 (31 U.S.C. 1352). | 87.400 | Min: $19,246<br>Max: $192,459 | Min: $19,639.<br>Max: $196,387. |
| Fair Housing Act Civil Penalties | Fair Housing Amendments Act of 1988 (42 U.S.C. 3612(g)(3)). | 180.671(a) | No Priors: $20,111<br>One Prior: $50,276<br>Two or More Priors: $100,554 | No Priors: $20,521.<br>One Prior: $51,302.<br>Two or More Priors: $102,606. |
| Manufactured Housing Regulations Violation. | Housing Community Development Act of 1974 (42 U.S.C. 5410). | 3282.10 | Per Violation: $2,795<br>Per Year: $3,493,738 | Per Violation: $2,852.<br>Per Year: $3,565,045. |

## II. Justification for Final Rulemaking for the 2018 Adjustments

HUD generally publishes regulations for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advanced notice and public participation. The good cause requirement is satisfied when prior public procedure is ''impractical, unnecessary, or contrary to the public interest'' (see 24 CFR 10.1). As discussed, this rule makes the required 2018 inflation adjustment, which HUD does not have discretion to change. Moreover, the 2015 Act specifies that a delay in the effective date under the Administrative Procedure Act is not required for annual adjustments under the 2015 Act. HUD has determined,

[1] Office of Management and Budget, M–18–03, Memorandum for the Heads of Executive Departments and Agencies, Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. (*https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf*). (October 2017 CPI–U (246.663)/October 2016 CPI–U (241.729) = 1.02041.)

[2] 28 U.S.C. 2461 note.

therefore, that it is unnecessary to delay the effectiveness of the 2018 inflation adjustments to solicit prior public comments.

Section 7(o) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(o)) requires that any HUD regulation implementing any provision of the Department of Housing and Urban Development Reform Act of 1989 that authorizes the imposition of a civil money penalty may not become effective until after the expiration of a public comment period of not less than 60 days. This rule does not authorize the imposition of a civil money penalty—rather, it makes a standard inflation adjustment to penalties that were previously authorized. As noted above, the 2018 inflation adjustments are made in accordance with a statutorily prescribed formula that does not provide for agency discretion. Accordingly, a delay in the effectiveness of the 2018 inflation adjustments in order to provide the public with an opportunity to comment is unnecessary because the 2015 Act exempts the adjustments from the need for delay, the rule does not authorize the imposition of a civil money penalty, and, in any event, HUD would not have the discretion to make changes as a result of any comments.

## IV. Findings and Certifications

*Regulatory Review—Executive Orders 12866 and 13563*

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) requires that for every new regulation issued, at least two prior regulations be identified for removal, and that the cost of planned regulations be prudently managed and controlled through a budgeting process. As discussed above in this preamble, this final rule adjusts existing civil monetary penalties for inflation by a statutorily required amount.

As a result of this review, OMB determined that this rule was not significant under Executive Order 12866 and Executive Order 13563. Moreover, as this rule is not a significant regulatory action under Executive Order 12866, it is not considered an Executive Order 13771 regulatory action.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because HUD has determined that good cause exists to issue this rule without prior public comment, this rule is not subject to the requirement to publish an initial or final regulatory flexibility analysis under the RFA as part of such action.

*Unfunded Mandates Reform*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) [3] requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of UMRA also requires an agency to identity and consider a reasonable number of regulatory alternatives before promulgating a rule.[4] However, the UMRA applies only to rules for which an agency publishes a general notice of proposed rulemaking. As discussed above, HUD has determined, for good cause, that prior notice and public comment is not required on this rule and, therefore, the UMRA does not apply to this final rule.

*Executive Order 13132, Federalism*

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

*Environmental Review*

This interim final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern, or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this final rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

**List of Subjects**

*24 CFR Part 28*

Administrative practice and procedure, Claims, Fraud, Penalties.

*24 CFR Part 30*

Administrative practice and procedure, Grant programs-housing and community development, Loan programs-housing and community development, Mortgage insurance, Penalties.

*24 CFR Part 87*

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

*24 CFR Part 180*

Administrative practice and procedure, Aged, Civil rights, Fair housing, Individuals with disabilities, Investigations, Mortgages, Penalties, Reporting and recordkeeping requirements.

*24 CFR Part 3282*

Administrative practice and procedure, Consumer protection, Intergovernmental relations, Manufactured homes, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD amends 24 CFR parts 28, 30, 87, 180, and 3282 to read as follows:

## PART 28—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

■ 1. The authority citation for part 28 continues to read as follows:

[3] 2 U.S.C. 1532.

[4] 2 U.S.C. 1534.

**Authority:** 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812; 42 U.S.C. 3535(d).

■ 2. In § 28.10, revise paragraphs (a)(1) introductory text and (b)(1) introductory text to read as follows:

**§ 28.10 Basis for civil penalties and assessments.**

(a) *Claims.* (1) A civil penalty of not more than $11,181 may be imposed upon any person who makes, presents, or submits, or causes to be made, presented, or submitted, a claim that the person knows or has reason to know:

* * * * *

(b) *Statements.* (1) A civil penalty of not more than $11,181 may be imposed upon any person who makes, presents, or submits, or causes to be made, presented, or submitted, a written statement that:

* * * * *

## PART 30—CIVIL MONEY PENALTIES: CERTAIN PROHIBITED CONDUCT

■ 3. The authority citation for part 30 continues to read as follows:

**Authority:** 12 U.S.C. 1701q–1, 1703, 1723i, 1735f–14, and 1735f–15; 15 U.S.C. 1717a; 28 U.S.C. 1 note and 2461 note; 42 U.S.C. 1437z–1 and 3535(d).

■ 4. In § 30.20, revise paragraph (b) to read as follows:

**§ 30.20 Ethical violations by HUD employees.**

* * * * *

(b) *Maximum penalty.* The maximum penalty is $19,639 for each violation.

■ 5. In § 30.25, revise paragraph (b) to read as follows:

**§ 30.25 Violations by applicants for assistance.**

* * * * *

(b) *Maximum penalty.* The maximum penalty is $19,639 for each violation.

■ 6. In § 30.35, revise the first sentence in paragraph (c)(1) to read as follows:

**§ 30.35 Mortgagees and lenders.**

* * * * *

(c)(1) * * * The maximum penalty is $9,819 for each violation, up to a limit of $1,963,870 for all violations committed during any one-year period. * * *

* * * * *

■ 7. In § 30.36, revise the first sentence in paragraph (c) to read as follows:

**§ 30.36 Other participants in FHA programs.**

* * * * *

(c) * * * The maximum penalty is $9,819 for each violation, up to a limit of $1,963,870 for all violations committed during any one-year period. * * *

■ 8. In § 30.40, revise the first sentence in paragraph (c) to read as follows:

**§ 30.40 Loan guarantees for Indian housing.**

* * * * *

(c) * * * The maximum penalty is $9,819 for each violation, up to a limit of $1,963,870 for all violations committed during any one-year period. * * *

■ 9. In § 30.45, revise paragraph (g) to read as follows:

**§ 30.45 Multifamily and section 202 or 811 mortgagors.**

* * * * *

(g) *Maximum penalty.* The maximum penalty for each violation under paragraphs (c) and (f) of this section is $49,096.

* * * * *

■ 10. In § 30.50, revise the first sentence in paragraph (c) to read as follows:

**§ 30.50 GNMA issuers and custodians.**

* * * * *

(c) * * * The maximum penalty is $9,819 for each violation, up to a limit of $1,963,870 during any one-year period. * * *

■ 11. In § 30.60, revise paragraph (c) to read as follows:

**§ 30.60 Dealers or sponsored third-party originators.**

* * * * *

(c) *Amount of penalty.* The maximum penalty is $9,819 for each violation, up to a limit for any particular person of $1,963,870 during any one-year period.

■ 12. In § 30.65, revise paragraph (b) to read as follows:

**§ 30.65 Failure to disclose lead-based paint hazards.**

* * * * *

(b) *Amount of penalty.* The maximum penalty is $17,395 for each violation.

■ 13. In § 30.68, revise paragraph (c) to read as follows:

**§ 30.68 Section 8 owners.**

* * * * *

(c) *Maximum penalty.* The maximum penalty for each violation under this section is $38,159.

* * * * *

## PART 87—NEW RESTRICTIONS ON LOBBYING

■ 14. The authority citation for part 87 continues to read as follows:

**Authority:** 28 U.S.C. 1 note; 31 U.S.C. 1352; 42 U.S.C. 3535(d).

■ 15. In § 87.400, revise paragraphs (a), (b), and (e) to read as follows:

**§ 87.400 Penalties.**

(a) Any person who makes an expenditure prohibited herein shall be subject to a civil penalty of not less than $19,639 and not more than $196,387 for each such expenditure.

(b) Any person who fails to file or amend the disclosure form (see appendix B) to be filed or amended if required herein, shall be subject to a civil penalty of not less than $19,639 and not more than $196,387 for each such failure.

* * * * *

(e) First offenders under paragraph (a) or (b) of this section shall be subject to a civil penalty of $19,639, absent aggravating circumstances. Second and subsequent offenses by persons shall be subject to an appropriate civil penalty between $19,639 and $196,387 as determined by the agency head or his or her designee.

* * * * *

## PART 180—CONSOLIDATED HUD HEARING PROCEDURES FOR CIVIL RIGHTS MATTERS

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

**Authority:** 28 U.S.C. 1 note; 29 U.S.C. 794; 42 U.S.C. 2000d–1, 3535(d), 3601–3619, 5301–5320, and 6103.

■ 17. In § 180.671, revise paragraphs (a)(1) through (3) to read as follows:

**§ 180.671 Assessing civil penalties for Fair Housing Act cases.**

(a) * * *

(1) $20,521, if the respondent has not been adjudged in any administrative hearing or civil action permitted under the Fair Housing Act or any state or local fair housing law, or in any licensing or regulatory proceeding conducted by a federal, state, or local governmental agency, to have committed any prior discriminatory housing practice.

(2) $51,302, if the respondent has been adjudged in any administrative hearing or civil action permitted under the Fair Housing Act, or under any state or local fair housing law, or in any licensing or regulatory proceeding conducted by a federal, state, or local government agency, to have committed one other discriminatory housing practice and the adjudication was made during the 5-year period preceding the date of filing of the charge.

(3) $102,606, if the respondent has been adjudged in any administrative hearings or civil actions permitted under the Fair Housing Act, or under

any state or local fair housing law, or in any licensing or regulatory proceeding conducted by a federal, state, or local government agency, to have committed two or more discriminatory housing practices and the adjudications were made during the 7-year period preceding the date of filing of the charge.

* * * * *

## PART 3282—MANUFACTURED HOME PROCEDURAL AND ENFORCEMENT REGULATIONS

■ 18. The authority citation for part 3282 continues to read as follows:

**Authority:** 28 U.S.C. 1 note; 28 U.S.C. 2461 note; 42 U.S.C. 3535(d) and 5424.

■ 19. Revise § 3282.10 to read as follows:

**§ 3282.10 Civil and criminal penalties.**

Failure to comply with these regulations may subject the party in question to the civil and criminal penalties provided for in section 611 of the Act, 42 U.S.C. 5410. The maximum amount of penalties imposed under section 611 of the Act shall be $2,852 for each violation, up to a maximum of $3,565,045 for any related series of violations occurring within one year from the date of the first violation.

Dated: July 8, 2018.

**J. Paul Compton, Jr.,**

*General Counsel.*

[FR Doc. 2018–15116 Filed 7–13–18; 8:45 am]

**BILLING CODE 4210–67–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[EPA–R03–OAR–2017–0337; FRL–9980–68—Region 3]**

## Approval and Promulgation of Air Quality Implementation Plans; Virginia; Interstate Transport Requirements for the 2012 Fine Particulate Matter Standard

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the Commonwealth of Virginia (the Commonwealth or Virginia). This revision pertains to the infrastructure requirement for interstate transport of pollution with respect to the 2012 fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS). EPA is approving this revision in accordance with the requirements of the Clean Air Act (CAA).

**DATES:** This final rule is effective on August 15, 2018.

**ADDRESSES:** EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2017–0337. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the ''For Further Information Contact'' section for additional availability information.

**FOR FURTHER INFORMATION CONTACT:** Joseph Schulingkamp, (215) 814–2021, or by email at *schulingkamp.joseph@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

On May 9, 2018 (83 FR 21233), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. In the NPR, EPA proposed approval of Virginia's submittal to address the infrastructure requirements under section 110(a)(2)(D)(i) of the CAA for the 2012 $PM_{2.5}$ NAAQS. The formal SIP revision was submitted by Virginia through the Department of Environmental Quality (VADEQ) on May 16, 2017.

### II. Summary of SIP Revision and EPA Analysis

Virginia's May 16, 2017 SIP submittal includes a summary of annual emissions of oxides of nitrogen ($NO_X$) and sulfur dioxide ($SO_2$), both of which are precursors of $PM_{2.5}$. The emissions summary shows that emissions from Virginia sources have been steadily decreasing for sources that could potentially contribute, with respect to the 2012 $PM_{2.5}$ NAAQS, to nonattainment in, or interfere with maintenance of, any other state. The submittal also included currently available air quality monitoring data for $PM_{2.5}$, and its precursors $SO_2$ and $NO_2$, which Virginia alleged show that $PM_{2.5}$ levels continue to be below the 2012 $PM_{2.5}$ NAAQS in Virginia.

Additionally, Virginia described in its submittal several existing SIP-approved measures and other federally enforceable source-specific measures, pursuant to permitting requirements under the CAA, that apply to sources of $PM_{2.5}$ and its precursors within Virginia. Virginia concludes that the Commonwealth does not significantly contribute to, nor interfere with the maintenance of, another state for the 2012 $PM_{2.5}$ NAAQS.

A detailed summary of Virginia's submittal and EPA's review and rationale for approval of this SIP revision as meeting CAA section 110(a)(2)(D)(i)(I) for the 2012 $PM_{2.5}$ NAAQS may be found in the NPR and Technical Support Document (TSD) for this rulemaking action, which are available online at *www.regulations.gov,* Docket number EPA–R03–OAR–2017–0337.

EPA used the information in the 2016 $PM_{2.5}$ Memorandum[1] and additional information for the evaluation and came to the same conclusion as Virginia. As discussed in greater detail in the TSD, EPA identified the potential downwind nonattainment and maintenance receptors identified in the 2016 $PM_{2.5}$ Memorandum, and then evaluated them to determine if Virginia's emissions could potentially contribute to nonattainment and maintenance problems in 2021, the attainment year for moderate $PM_{2.5}$ nonattainment areas. EPA concluded Virginia was not significantly contributing to nonattainment nor interfering with maintenance with 2012 $PM_{2.5}$ NAAQS by any other state.

### III. Public Comments

Two anonymous public comments were received on the NPR. The first comment generally discussed greenhouse gases and climate change and was determined to not be relevant nor specific to this rulemaking action. Thus, no response is provided for this comment. The second comment expressed that the commenter would not like to see particulate pollution from Virginia or any state degrade Allegheny County, Pennsylvania's air. As explained in the proposed rulemaking in detail, EPA determined that Virginia's emission sources do not contribute significantly to nonattainment, nor interfere with maintenance, of the 2012 $PM_{2.5}$ NAAQS in another state. EPA also concluded

[1] ''Information on the Interstate Transport ''Good Neighbor'' Provision for the 2012 Fine Particulate Matter National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I),'' Memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards (March 17, 2016). A copy is included in the docket for this rulemaking action.

that Allegheny County, Pennsylvania was likely to attain the 2012 $PM_{2.5}$ NAAQS without the need for further emission reductions. Thus, EPA does not expect emissions from Virginia to degrade Allegheny County, Pennsylvania's air quality.

## IV. Final Action

EPA is approving the May 16, 2017 SIP revision addressing the interstate transport requirements for the 2012 $PM_{2.5}$ NAAQS to the Virginia SIP because the submittal adequately addresses section 110(a)(2)(D)(i)(I) of the CAA.

## V. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce federally authorized environmental programs in a manner that is no less stringent than their federal counterparts. . . .'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

## VI. Statutory and Executive Order Reviews

### *A. General Requirements*

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land as defined in 18 U.S.C. 1151 or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

### *B. Submission to Congress and the Comptroller General*

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement

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

*C. Petitions for 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 September 14, 2018. 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, addressing Virginia's interstate transport for the 2012 $PM_{2.5}$ NAAQS, 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, Particulate matter.

Dated: July 2, 2018.

**Cosmo Servidio,**

*Regional Administrator, Region III.*

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 VV—Virginia

■ 2. In § 52.2420, the table in paragraph (e)(1) is amended by adding a second entry for Section 110(a)(2) Infrastructure Requirements for the 2012 Particulate Matter NAAQS after the first entry to read as follows:

**§ 52.2420 Identification of plan.**

* * * * *

(e)* * *

(1)* * *

| Name of non-regulatory SIP revision | Applicable geographic area | State submittal date | EPA approval date | Additional explanation |
|---|---|---|---|---|
| * | * | * | * | * |
| Section 110(a)(2) Infrastructure Requirements for the 2012 Particulate Matter NAAQS. | Statewide ..... | 05/16/17 | 7/16/2018, [Insert **Federal Register** citation]. | Docket 2017–0337. This action addresses the infrastructure element of CAA section 110(a)(2)(D)(i)(I). |
| * | * | * | * | * |

* * * * *

[FR Doc. 2018–15049 Filed 7–13–18; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R03–OAR–2017–0637; FRL–9980–70—Region 3]**

## Approval and Promulgation of Air Quality Implementation Plans; MD; Emissions Statement Requirement for the 2008 Ozone Standard

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the State of Maryland. This SIP revision fulfills Maryland's emissions statement requirement for the 2008 ozone national ambient air quality standard (NAAQS). EPA is approving these revisions in accordance with the requirements of the Clean Air Act (CAA).

**DATES:** This final rule is effective on August 15, 2018.

**ADDRESSES:** EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2017–0637. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

**FOR FURTHER INFORMATION CONTACT:** Erin Trouba, (215) 814–2023, or by email at *trouba.erin@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

On February 20, 2018 (83 FR 7124), EPA published a notice of proposed rulemaking (NPR) for the State of Maryland. In the NPR, EPA proposed approval of Maryland's certification that Maryland's emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2008 ozone NAAQS. The formal SIP revision (#17–02) was submitted by Maryland, through the Maryland Department of the Environment (MDE), on September 25, 2017.

### II. Summary of SIP Revision and EPA Analysis

In Maryland's September 25, 2017 SIP revision submittal, Maryland states that the existing COMAR 26.11.01.05–1 ''Emissions Statements'' rule satisfies CAA section 182(a)(3)(B) for the 2008 ozone NAAQS. Under CAA section 182(a)(3)(B), states are required to have an emission statements rule for nonattainment areas for the 2008 ozone NAAQS. In addition, states in the ozone transport region are required to have an emission statement rule statewide, including for attainment areas. *See* CAA sections 182(a)(3)(B), 182(f), and 184(b)(2). EPA previously approved Maryland's emissions statement rule for the 1979 1-hour ozone standard, COMAR 26.11.01.05–1, into the

Maryland SIP. *See* 59 FR 51517 (October 12, 1994). EPA has determined that COMAR 26.11.01.05–1, which is currently in the Maryland SIP, is appropriate to address the emissions statement requirement in section 182(a)(3)(B) for the 2008 ozone NAAQS. Therefore, EPA is approving this SIP revision that certifies that COMAR 26.11.01.05–1 is adequate. Other specific requirements of the revised Maryland COMAR regulations and the rationale for EPA's proposed action are explained in the NPR and will not be restated here.

## III. Public Comments and EPA's Responses

EPA received fourteen public comments on our February 20, 2018 NPR proposing to approve Maryland's September 25, 2017 submittal. Only one comment was adverse and relevant to this action. The adverse comment is summarized and responded to in the following paragraph. All other comments received were not specific to this action, and thus are not addressed here.

*Comment:* The commenter alleges that the EPA is requesting a modification to Maryland's SIP. The commenter stated that this action will not directly affect Maryland's atmosphere, small businesses, organizations or governments. The commenter stated that EPA could choose to not change the SIP and leave the regulations as they are without effect to pollutant emissions. The commenter also expressed the need for more detailed social and cultural impacts of the plan revision and stated social and cultural effects should be monitored as the plan is implemented. Finally, the commenter stated further impacts should be evaluated once the ''new plan'' is established.

*Response:* Maryland submitted this SIP revision certifying that requirements already in the Maryland SIP are adequate to meet the statutory requirement of section 182(a)(3)(B) as it pertains to the 2008 ozone NAAQS. Section 110(k)(3) states that ''the Administrator shall approve a plan revision as a whole if it meets all of the applicable requirements of the CAA. As stated in the NPR, Maryland's submission meets requirements in CAA section 182 for emission statements. Thus, pursuant to section 110(k)(3), EPA does not have discretion to disapprove the submittal if the state-requested SIP revision meets the requirements of section 182(a)(3)(B). This action pertains to certification of the requirement for the State of Maryland to have an emissions statement rule for the 2008 8-hour ozone standard for nonattainment areas. The State has certified that the state regulation that is already in the existing SIP is adequate. EPA is approving the State certification and not imposing any new requirements. EPA disagrees with the commenter that further social and cultural ''impacts'' should be evaluated because nothing in the CAA requires monitoring of such impacts from SIP revisions.

## IV. Final Action

EPA is approving the State of Maryland's September 25, 2017 SIP revision submittal which addresses the 2008 8-hour ozone NAAQS emissions statement requirements as a revision to the Maryland SIP.

## V. Statutory and Executive Order Reviews

### *A. General Requirements*

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

### *B. Submission to Congress and the Comptroller General*

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

### *C. Petitions for 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 September 14, 2018. 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, approving Maryland's certification that it's SIP-approved emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2008 ozone NAAQS, 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping

requirements, Volatile organic compounds.

Dated: June 27, 2018.

**Cecil Rodrigues,**

*Acting Regional Administrator, Region III.*

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 V—Maryland

■ 2. In § 52.1070, the table in paragraph (e) is amended by adding the entry for Maryland's emission statement requirement certification for the 2008 ozone national ambient air quality standard at the end of the table to read as follows:

**§ 52.1070 Identification of plan.**

* * * * *

(e) * * *

EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MATERIAL

| Name of non-regulatory SIP revision | Applicable geographic area | State submittal date | EPA approval date | Additional explanation |
|---|---|---|---|---|
| * | * | * | * | * |
| Emission statement requirement certification for the 2008 ozone national ambient air quality standard. | State-wide .... | September 25, 2017 .. | 7/16/2018, [Insert **Federal Register** citation]. | Certification that Maryland's previously approved regulation at COMAR 26.11.01.05–1 meets the emission statement requirements for the 2008 ozone NAAQS. |

[FR Doc. 2018–15048 Filed 7–13–18; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 300

**[EPA–HQ–SFUND–1990–0011; FRL–9980–64—Region 5]**

## National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Beloit Corporation Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Deletion of the Research Center Property (RCP) of the Beloit Corporation Superfund Site (Site), in Rockton, Illinois from the National Priorities List (NPL). This partial deletion includes all media at the 20-acre RCP. The rest of the Site remains on the NPL and is not affected by this action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan. EPA is publishing this direct final partial deletion with the concurrence of the State of Illinois because all appropriate response actions at the RCP under CERCLA have been completed, other than maintenance, monitoring and five-year reviews. However, this partial deletion does not preclude future actions under Superfund.

**DATES:** This direct final partial deletion is effective September 14, 2018 unless EPA receives adverse comments by August 15, 2018. If adverse comments are received, will publish a timely withdrawal of the direct final partial deletion in the **Federal Register** informing the public that the partial deletion will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1990–0011, by one of the following methods: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

*Email: cano.randolph@epa.gov.*

*Mail:* Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036.

*Hand deliver:* Superfund Records Center, U.S. Environmental Protection Agency Region 5, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, (312)886–0900. Such deliveries are only accepted during the Record Center's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

*Instructions:* Direct your comments to Docket ID No. EPA–HQ–SFUND–1990–0011. The *http://www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any

disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statue. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

U.S. Environmental Protection Agency, Region 5, Superfund Records Center, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, Phone: (312) 886–0900, Hours: Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

Talcott Free Library, 101 East Main Street, Rockton, IL 61072, Phone: (815) 624–7511, Hours: Monday, Tuesday and Thursday, 9:00 a.m. to 8:00 p.m., Wednesday and Friday 9:00 a.m. to 5:30 p.m., and Saturday 9:00 a.m. to 3:00 p.m.

**FOR FURTHER INFORMATION CONTACT:**

Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036, or via email at *cano.randolph@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## Table of Contents

I. Introduction
II. NPL Deletion Criteria
III. Partial Deletion Procedures
IV. Basis for Site Partial Deletion
V. Partial Deletion Action

## I. Introduction

EPA Region 5 is publishing this direct final Notice of Partial Deletion for the Beloit Corporation (Beloit Corp.) Site (Site), from the National Priorities List (NPL). This partial deletion pertains to the Former Beloit Corp. Research Center Property portion of the Site, PIN 03–12–452–003, located at 1155 Prairie Hill Road, Rockton, Illinois. The NPL constitutes Appendix B of 40 CFR. Part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). This partial deletion of the Beloit Corp. Site is proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466 (Nov. 1, 1995). As described in § 300.425(e)(3) of the NCP, a portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses the procedures that EPA is using for this action. Section IV discusses the Former Beloit Corp. Research Center Property, PIN 03–12–452–003 of the Beloit Corp. Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to partially delete this portion of the Site from the NPL unless adverse comments are received during the public comment period.

## II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required,

ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA Section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

## III. Partial Deletion Procedures

The following procedures apply to the deletion of the Former Beloit Corp. Research Center Property, PIN 03–12–452–003 of the Beloit Corp. Site:

(1) EPA has consulted with the State of Illinois prior to developing this direct final Notice of Partial Deletion and the Notice of Intent for Partial Deletion published in the ''Proposed Rules'' section of the **Federal Register**.

(2) EPA has provided the State thirty (30) working days for review of this action and the parallel Notice of Intent for Partial Deletion prior to their publication today, and the State, through the Illinois Environmental Protection Agency (IEPA), has concurred on the partial deletion of the Site from the NPL.

(3) Concurrent with the publication of this direct final Notice of Partial Deletion, a notice of the availability of the parallel Notice of Intent for Partial Deletion is being published in two major local newspapers, the Rockton Herald and the Rockford Register Star. The newspaper notices announce the 30-day public comment period concerning the Notice of Intent for Partial Deletion of the Site from the NPL.

(4) EPA placed copies of documents supporting the partial deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified in the **ADDRESSES** Section of this rule.

(5) If adverse comments are received within the 30-day public comment period on this partial deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Partial Deletion in the **Federal Register** before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent for Partial Deletion and the comments already received.

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of

the NCP states that the deletion of a site from the NPL does not preclude eligibility for further response actions, should future conditions warrant such actions.

**IV. Basis for Partial Site Deletion**

The following information provides EPA's rationale for deleting the Former Beloit Corp. Research Center Property, PIN 03–12–452–003, of the Beloit Corp. Site from the NPL:

*Site Background and History*

The Beloit Corp. Site (CERCLIS ID ILD021440375) is located in Rockton, Winnebago County, Illinois. The Site consists of one, site-wide operable unit. The Site includes the approximately 200-acre former Beloit Corp. property and additional adjacent areas, including the Blackhawk Acres residential subdivision, and other industrial properties adjacent to the subdivision, including the former Soterion/United Recovery facility, a portion of the Taylor, Inc. property and the Safe-T-Way property. The Site is bound on the north by Prairie Hill Road, on the west by the Rock River, on the south by a line projected from the Rock River along the south edge of a Village of Rockton easement and access road to Blackhawk Boulevard, and on the east by Blackhawk Boulevard. See Figures 1 and 2 in Maps—Beloit Corp. Site and Area for Partial Deletion, Docket Document ID No. EPA–HQ–SFUND–1990–0011–0286 in the Docket.

The Beloit Corp. used approximately 20 acres of its 200-acre property for a research center (the Former Beloit Corp. Research Center Property), and 55 acres for a manufacturing plant, a wastewater treatment plant and lagoons, a gravel pit, and parking and outdoor storage areas. The Beloit Corp. used about 39 acres of open field south of its manufacturing and storage areas for foundry sand disposal and fibrous sludge spreading. About 86 heavily wooded acres of the Beloit Corp. property located west and south of the operations areas remain vacant and are within a backwater and floodplain area of the Rock River.

The Beloit Corp. property is divided into several parcels of land and has been redeveloped. The northern parcel of the Site is the location of the Former Beloit Corp. Research Center, PIN 03–12–452–003, and is the property EPA is deleting from the Site (see Property Map for 03–12–452–003 in Maps—Beloit Corp. Site and Area for Partial Deletion, Docket Document ID EPA–HQ–SFUND–1990–0011–0286 in the Docket). This property is approximately 20.757 acres and is owned by the Rock River Land Development Company (Rock River). The address for this property is 1155 Prairie Hill Road, Rockton, Illinois. The property is zoned for heavy industrial use and is occupied by Andritz Paperchine, a supplier of papermaking technology.

The remaining western and southern parcels of the former Beloit Corp. property are owned by Lubrizol Holding, Inc. (Lubrizol) and are not being deleted as part of this action. These parcels include the locations of the former Beloit Corp. manufacturing building, the former Beloit Corp. wastewater treatment plant and lagoons, the vacant fields, woods and floodplain areas, EPA's groundwater extraction and treatment system cleanup remedy, and the majority of EPA's groundwater monitoring well network (former Beloit Corp. Manufacturing Property). The PINs for these properties are 03–13–201–002, 03–12–452–002, 03–12–376–001, 03–13–126–001, 03–13–176–004. These parcels are also zoned for heavy industrial use. This part of the Site is occupied by Chemtool Inc. (Chemtool) and is used to manufacture specialized industrial lubricants. The address for the portion of the Site remaining on the NPL is 1165 Prairie Hill Road, Rockton, Illinois.

The Beloit Corp. property was farmland until Beloit Corp. purchased it in 1957. The property has been used for industrial purposes since 1957. Beloit Corp. manufactured machines at the Site that produced layered paper products from paper pulp. Beloit Corp. used solvents at its plant for parts cleaning operations. Beloit Corp. used petroleum-based, non-chlorinated solvents until the mid-1970s, and chlorinated solvents from the mid-1970s until 1983. The exact composition of the chlorinated solvents and the amounts Beloit Corp. used are unknown. Beloit Corp. used mineral spirits for metal degreasing and parts cleaning from 1983 until the facility closed in 1999.

IEPA began investigating potential contamination on the Beloit Corp. property and in the surrounding area in the 1980s. In 1986, IEPA sampled residential wells in the Blackhawk Acres subdivision adjacent to the Beloit Corp. facility. Sixteen of the 55 private drinking water wells that were sampled were contaminated.

IEPA's investigations determined that the most likely source of the groundwater contamination in the Blackhawk Acres subdivision was the Beloit Corp. EPA proposed the Beloit Corp. property and the surrounding area to the NPL as the Beloit Corp. Superfund Site on June 24, 1988 (53 FR 23988). EPA finalized listing the Beloit Corp. Site on the NPL on August 30, 1990 (55 FR 35502).

Beloit Corp. entered into a Consent Decree with IEPA in 1991 to conduct a Remedial Investigation (RI) and Feasibility Study (FS) at the Site. The RI found that the groundwater is contaminated with volatile organic compounds (VOCs) including tetrachloroethene (PCE), 1,1,1-tricloroethane (1,1,1-TCA), and trichloroethene (TCE).

In 1993, IEPA determined that three residential wells in the Blackhawk Acres subdivision contained TCE in groundwater above the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act. IEPA subsequently fitted these three residential wells contaminated above the MCL with carbon filtration systems plus IEPA fitted a fourth residential well with a carbon filtration system. The filtration systems continue to be maintained by IEPA. In 1999, IEPA connected a fifth residence with contaminated well water to the Rockton municipal water supply when the contamination was discovered in 1998.

The highest area of groundwater contamination is located under the southern area of the Erection Bay section of the Beloit Corp. manufacturing building. The primary groundwater contaminant in this area is PCE. The PCE contamination is believed to be due to the discharge of VOCs to the ground surface before Beloit Corp. constructed the Erection Bay over this area in 1989. The groundwater contamination is in the upper aquifer and generally flows from north to south. The groundwater contamination does not impact the Former Beloit Corp. Research Center Property, which is upgradient of the contaminant plume and EPA is deleting from the NPL in this action.

IEPA issued an Action Memorandum to Beloit Corp. in 1996 to implement an Interim Source Control Action (ISCA) at the Site. The Action Memorandum required immediate measures to control the high levels of VOC groundwater contamination near the Beloit Corp. manufacturing building.

Beloit Corp. conducted an Engineering Evaluation/Cost Analysis (EE/CA) to evaluate potential ISCA alternatives. The non-time critical removal action objectives developed in the EE/CA were to: Limit the potential for the migration of VOCs in groundwater at the Site through the installation of a groundwater containment system; initiate the removal of VOCs from the groundwater at the source area (the vicinity of the Erection Bay and groundwater

monitoring well W23); install and operate an appropriate treatment system for groundwater generated by the containment system to limit unacceptable discharges or emissions; and dispose of waste streams from the action.

IEPA selected a groundwater pump and treat system as the ISCA. Beloit Corp. developed a Removal Action Design Report and constructed the groundwater extraction and treatment system in 1996. The pump and treat system consists of four extraction wells and an air stripper tower adjacent to the southwest corner of the Beloit Corp. manufacturing building on PIN 03–13–201–002. This system is currently operated by IEPA. The treated groundwater is discharged to the Rock River at an outfall located on Beloit Corp.'s former wastewater treatment plant and lagoons property, PIN 03–12–452–002, under a National Pollutant Discharge Elimination System (NPDES) permit.

Beloit Corp. filed for bankruptcy in 1999. As part of the bankruptcy, the court entered an order which, among other things, transferred the ownership of Beloit Corp.'s assets and liabilities, including the Beloit Corp. property, to the Beloit Liquidating Trust (the Trust). The ownership of the Beloit Corp. property then transferred to Giuffre II, LLC (Giuffre). The United States and Giuffre signed a settlement agreement in February 2002 under section 122(h) of CERCLA (the section 122(h) Agreement). The State of Illinois was also a party to the settlement agreement. The State of Illinois signed the agreement in April 2002.

The section 122(h) Agreement settled and resolved the potential liability of Giuffre resulting from its ownership and/or operation of the Beloit Corp. property. The purpose of the section 122(h) Agreement was to facilitate the cleanup of the Site and the reuse of the property.

On March 18, 2003, Giuffre sold the Former Beloit Corp. Research Center Property portion of the Site (the part of the Site being deleted as part of this action, outside the area of groundwater contamination) to PPC Investment Group LLC (PPC). PPC leased the property to Paperchine. PPC sold the Former Beloit Corp. Research Center Property to Rock River on January 5, 2015. Rock River continues to lease the Property to Paperchine (now known as Andritz Paperchine).

Giuffre deeded the remaining areas of the former Beloit Corp. property (*i.e.,* the Former Beloit Corp. manufacturing building, former wastewater treatment plant and lagoons, parking and storage areas and vacant/floodplain areas) to Rock River on January 31, 2008. Rock River subsequently leased this property to Chemtool. Lubrizol acquired Chemtool and purchased the remaining former Beloit Corp. property on August 30, 2013. Lubrizol continues to operate at the Site as Chemtool.

This partial deletion pertains to all media at the approximately 20.757-acre Former Beloit Corp. Research Center Property portion of the Beloit Corp. Site, PIN 03–12–452–003, located at 1155 Prairie Hill Road, Rockton, Illinois (see Property Map for 03–12–452–003 in Maps—Beloit Corp. Site and Area for Partial Deletion, Docket Document ID EPA–HQ–SFUND–1990–0011–0286 in the Docket).

*Remedial Investigation and Feasibility Study (RI/FS)*

Beloit Corp. conducted the RI in four phases between 1992 and 1998. The Phase I and II investigations identified and investigated the source area(s) of the VOCs at the Site. The Phase III investigation determined the extent of the VOC groundwater contamination. The Phase IV investigation evaluated potential sources of a deeper TCE contaminant plume in the upper aquifer in wells in the southern portion of the Beloit property, the southern Blackhawk Acres subdivision and in the Village of Rockton. The Phase IV investigation also evaluated whether VOCs detected at a home in the Blackhawk Acres subdivision were migrating from an upgradient source area, and determined what effect the ISCA pump and treat system was having on groundwater in the southern portion of the Blackhawk Acres subdivision.

The RI investigated the former Beloit Corp. foundry sand disposal area, former on-Site wastewater treatment plant (WWTP) lagoons, fibrous sludge spreading area where sludge from WWTP lagoons was applied, storage yard area, Erection Bay, chip pad, former dry well, welding area, loading dock, paint room, a nearby gravel pit, the Blackhawk Acres subdivision, the Rock River and the wetlands west of the Beloit Corp. operations areas, Rockton Excavating's property, the Village of Rockton, and the Soterion property.

The RI determined that the primary groundwater contamination at the Site originates under the southern area of the Erection Bay section of the Beloit Corp. manufacturing building. This area is located on PIN 03–13–201–002 within the Former Beloit Corp. Manufacturing Property, not the Former Beloit Corp. Research Center Property. The groundwater contamination is located in the shallow zone of the upper aquifer, from the water table, which is about 20 feet below ground surface (ft-bgs), to a depth of approximately 60 ft-bgs. The groundwater contamination flows generally from north to south, off-Site and away from the Former Beloit Corp. Research Center Property.

The groundwater contamination is believed to be due to the discharge of VOCs to the ground surface in this area before Beloit Corp. constructed the Erection Bay over this location in 1989. Soil and soil gas sampling in this area during the RI and during an additional Source Area Investigation in 2007, however, could not find any significant residual levels of VOCs in any unsaturated soil at the Site, including below the floor of the Erection Bay building.

The RI found a plume of deeper groundwater contamination at the Site in the upper aquifer near the southeast corner of the Former Beloit Corp. Manufacturing Property. This groundwater contamination also flows off-Site, towards Rockton and the Rock River. This groundwater contamination is also downgradient of, and flows away from the Former Beloit Corp. Research Center Property.

The groundwater in the deeper plume is contaminated primarily with TCE and is found at a depth of approximately 70 ft-bgs. The source of the deeper, TCE Plume could not be located, but is believed to be in the vicinity of groundwater monitoring wells W26C and W18, near the southeast corner of the Former Beloit Corp. Manufacturing Property and the northwest corner of the Soterion facility. Extensive sampling of the soils and groundwater in these areas did not indicate the presence of residual TCE in the soils. The groundwater data however, provides evidence that a historical release of TCE occurred in this area, even though the source has since dissipated.

The only structure on the Former Beloit Corp. Research Center Property (the part of the Site that is being deleted) that was operated by Beloit Corp. was its research center. Beloit Corp. built the research center in 1960 and used the building to design and demonstrate its papermaking machines.

Beloit Corp. conducted a Feasibility Study (FS) to evaluate cleanup alternatives to address the groundwater contamination at the Site. The FS did not develop cleanup alternatives to address other Site media because the baseline risk assessment did not identify any unacceptable risks associated with exposure to the other media including surface and subsurface soil, dust, vapor, surface water or sediment.

*Selected Remedy*

EPA's and IEPA's remedial action objectives for the Site are to: Prevent exposure to contaminated groundwater; prevent or minimize further migration of the contaminated groundwater plumes located at and downgradient of the Beloit Corp. manufacturing building; and to remediate the contaminated groundwater to the more stringent of either the MCLs or applicable State of Illinois Groundwater Quality Standards (35 IAC Part 620), including 35 IAC Part 620.410 Class I Groundwater Quality Standards for Class I Potable Resource Groundwater, or 35 IAC Part 620.450 Alterative Groundwater Quality Standards.

The only remedial alternative EPA and IEPA considered for the Former Beloit Corp. Research Center Property was institutional controls (ICs). EPA and IEPA did not evaluate an active groundwater remedy for the Former Beloit Corp. Research Center Property because the RI determined that the groundwater in this area of the Site was not contaminated.

EPA and IEPA issued a Record of Decision (ROD) for the Site in 2004. The ROD selected a cleanup remedy for the Site which included: Continued operation and monitoring of the groundwater pump and treat ISCA system located on the Former Beloit Corp. Manufacturing Property; VOC source area treatment on the Former Beloit Corp. Manufacturing Property by in-situ chemical oxidation; monitored natural attenuation to address the off-property and off-Site groundwater contamination; and ICs.

The only remedy component applicable to the Former Beloit Corp. Research Center Property in the ROD is the ICs. The ICs would be in the form of a restrictive covenant and would prohibit the use of shallow groundwater on the Beloit Corp. property (*i.e.,* the Former Beloit Corp. Manufacturing Property and the Former Beloit Corp. Research Center Property) for potable purposes until the drinking water standards in the groundwater are attained. The ROD specifies that the current facilities at the Beloit Corp. property use groundwater from a lower groundwater aquifer that is not affected by the VOC contamination, and that this deeper groundwater can continue to be used.

IEPA conducted additional investigations in the former manufacturing plant source area of the Site in 2006 for the remedial design. IEPA's investigations indicated that the source area of the groundwater contamination is larger than previously indicated (but not on the Former Beloit Corp. Research Center Property), and that the aquifer material is not conducive to in-situ chemical treatment.

EPA and IEPA issued an Explanation of Significant Differences (ESD) in 2007 modifying the Site remedy. The ESD changed the treatment component of the remedy from in-situ chemical oxidation to installing one or more additional extraction wells south and southeast of the Erection Bay on the Former Beloit Corp. Manufacturing Property. The new extraction wells would capture additional groundwater contamination. The groundwater from the additional wells would be conveyed to the existing ISCA air-stripper for treatment and discharged to the Rock River under the NPDES permit. The ESD also included pneumatic fracturing at the additional extraction well locations to loosen up the soil to increase the effectiveness of the new wells.

The ESD did not alter the conclusion that the southern area of the Erection Bay in the manufacturing plant area of the Former Beloit Corp. Manufacturing Property is the primary source of the groundwater contamination at the Site. The ESD did not change the IC component for the Former Beloit Corp. Research Center Property or require any additional remedial action for the Former Beloit Corp. Research Center Property.

The ROD as modified by the ESD, requires: (1) The continued operation of the existing groundwater pump and treat ISCA system at the source area on the Former Beloit Corp. Manufacturing Property (not on the Former Beloit Corp. Research Center Property); (2) installing additional extraction wells in the source area on the Former Beloit Corp. Manufacturing Property (not on the Former Beloit Corp. Research Center Property); (3) groundwater monitoring; (4) operating and maintaining (O&M) the ISCA pump and treat system on the Former Beloit Manufacturing Property (not on the Former Beloit Corp. Research Center Property), and (5) implementing ICs to prohibit the withdrawal of the shallow groundwater for potable use.

*Response Actions*

IEPA completed the remedial action to expand and increase the effectiveness of the 1996 groundwater pump and treat system on the Former Beloit Manufacturing Property in 2008. IEPA expanded the groundwater pump and treat building to accommodate the increase in the volume of extracted groundwater, installed three new groundwater extraction wells, and shut down one extraction well (EW01) to adjust the zone of groundwater extraction to better target the source area.

IEPA conducted pneumatic fracturing at the three additional extraction well locations to increase the volume of water pumped out by the extraction wells in the source area. IEPA connected the new extraction wells to the groundwater treatment system and tested the system to ensure it was properly operating. EPA documented the completion of the remedial action construction activities in a September 29, 2008 PCOR (Docket Document ID EPA–HQ–SFUND–1990–0011–0260).

*Cleanup Levels*

The cleanup levels for the groundwater contaminants at the Beloit Corp. Site are federal MCLs and/or Illinois Class I standards, whichever are more stringent. The RI determined that the groundwater below the Former Beloit Corp. Research Center Property is upgradient of, and is not affected, by the groundwater contamination at the Site, and that the groundwater below the Research Center Property already meets the cleanup levels for the Site.

IEPA conducted an updated hydraulic capture zone analysis of the expanded groundwater extraction system in 2013. The updated capture zone analysis further confirms that the VOC-contaminated groundwater originating from the former Erection Bay source area is being captured and treated by the expanded ISCA pump and treat system, and is not affecting the Former Beloit Corp. Research Center Property. The results of the capture zone analysis are provided in the Task 1 Follow-Up Activities to the Five-Year Review Report, June 2014 (Docket Document ID EPA–HQ–SFUND–1990–0011–0269).

Annual VOC sampling of a deep, water supply well located on the Former Beloit Corp. Research Center Property (well WW441K) also confirms that the groundwater in the lower aquifer below the Former Beloit Corp. Research Center Property has not been affected by Site contamination. Well WW441K is located in the lower aquifer, which is separated from the upper aquifer by approximately 40 feet of silty clay. The well is screened from 175 to 185 ft-bgs and from 225 to 235 ft-bgs, and is approximately 100 feet deeper than the deepest contamination detected at the Site.

Well WW441K is used to supply water for employee toilets and sink uses, and for limited cleaning purposes. The Illinois Department of Public Health requires the well to be sampled annually for VOCs and for other contaminants as scheduled (Water

System ID IL3121418). The VOC analytical results for 2012 through 2017 for WW441K show no detected VOCs. The 2013 analyses of pesticides, herbicides, semi-volatile organic compounds and metals show no detectable organics and metals concentrations below drinking water standards in the water.

A second, deeper water supply well is located on the Former Beloit Corp. Research Center Property (WW441L). Well WW441L is an open borehole well from 330 ft-bgs to 554 ft-bgs and is maintained as a backup well for fire protection. Based on other Site information and data, well WW441L is also not expected to be impacted by Site-related contamination. Additional information about wells WW441K and WW441L is provided in the Technical Memorandum: Paperchine Investment Group LLC Water Supply Wells at Beloit Corp. NPL Site, June 2017, Docket Document ID EPA–HQ–SFUND–1990–0011–0284.

*Operation and Maintenance (O&M)*

The only O&M required for the Former Beloit Corp. Research Center Property is to maintain and monitor upgradient groundwater monitoring wells on the property as needed, and to maintain, monitor and enforce the ROD-required IC.

PPC filed a Uniform Environmental Covenant, pursuant to the Illinois Uniform Environmental Covenants Act [UECA, 765 Illinois Compiled Statutes (ILCS) 122] on the Former Beloit Corp. Research Center Property, PIN 03–12–452–003, with the Winnebago County Recorder's Office on February 7, 2013, Instrument 20131006292. A copy of the recorded Environmental Covenant (EC) is in Docket Document ID EPA–HQ–SFUND–1990–0011–0276 in the Docket.

PPC's EC: (1) Restricts or limits the use of the land to industrial land use; (2) prohibits the construction of new or non-existing wells or consumptive use of the groundwater underlying the property; (3) prohibits any activity that may interfere with or would affect the integrity or the configuration of the RA at the Site, or the operation and maintenance of any RA component; and (4) grants authorized representatives of IEPA and EPA the right to enter and have continued access to the Site at reasonable times to perform the RA. The covenant ''runs with the land'' and remains in effect until the contaminated groundwater at the Site is restored to the more stringent of either the federal MCLs or State of Illinois Class I groundwater standards for all contaminants of concern. Similar ICs will be placed on the Former Beloit Corp. Manufacturing Property. IEPA is also in the process of establishing a Groundwater Management Zone to prevent the use of contaminated groundwater in other Site areas beyond the former Beloit Corp. property.

Other O&M at the Site includes IEPA's operation of the groundwater treatment system on the Former Beloit Corp. Manufacturing Property and semi-annual groundwater monitoring at 21 groundwater monitoring locations. Eight of the groundwater monitoring locations have nested wells screened at different elevations within the aquifer to monitor the groundwater at different depths. IEPA's groundwater monitoring indicates that the contaminant plume has stabilized and that the contaminated groundwater is not moving off-Site. IEPA samples nearby residential wells every two years to ensure that the groundwater containment system continues to be protective. The concentrations of contaminants in private residential wells have been below MCLs since 2001.

*Five-Year Review*

EPA and IEPA conducted the first statutory five-year review (FYR) at the Beloit Corp. Site under Section 121(c) of CERCLA on September 27, 2013. A FYR evaluates whether the remedial action at a site remains protective of human health and the environment at sites where contaminants remain on-site at levels that do not allow for unlimited use and unrestricted exposure.

The FYR Report determined that a protectiveness determination could not be made at the Site without further information to assess the potential for vapor intrusion into nearby residences and commercial properties, and updated groundwater modeling. The issues and recommendations in the FYR Report did not apply to the Former Beloit Corp. Research Center Property, which is upgradient from the source area of the groundwater contamination at the Site and is not subject to vapor intrusion concerns.

IEPA conducted a vapor intrusion assessment and updated the Site groundwater model to address the issues in the FYR Report. The vapor intrusion assessment determined that the Site does not pose a risk to Site workers or nearby residents through the vapor intrusion pathway. The updated Site groundwater model capture zone analysis demonstrates that the groundwater contamination in the Former Beloit Corp. Manufacturing Property source area of the Site is being captured and treated by the expanded groundwater pump and treat system required by the 2007 ESD.

EPA issued a FYR Addendum documenting that the Site is currently protective of human health and the environment on January 25, 2018. The FYR Addendum also determined that in order for the Site to be protective over the long-term an EC must be implemented on the Former Beloit Corp. Manufacturing Property, a GMZ must be implemented in Site areas beyond the Former Beloit Corp. property, and an institutional controls action plan and long-term stewardship plan for monitoring and maintaining ICs need to be implemented. The next FYR is scheduled to be completed by September 27, 2018.

*Community Involvement*

EPA and IEPA satisfied public participation activities for the Site required in CERCLA Section 113(k), 42 U.S.C. 9613(k), and CERCLA Section 117, 42 U.S.C. 9617. IEPA has actively engaged the Rockton community about the Beloit Corp. Superfund Site since the 1980s. IEPA held public meetings and availability sessions about the Site throughout the RI/FS at the Talcott Free Library and the Hononegah High School. These forums allowed citizens, local officials and the media to learn about the Site, ask questions and express their concerns directly to IEPA community involvement and technical staff. IEPA announced all meetings and availability sessions to the public in local newspaper advertisements and IEPA fact sheets prior to the meetings.

IEPA developed and distributed four fact sheets about the Site throughout the RI/FS. The fact sheets provided information about the residential well sampling, the environmental investigations, Site updates, public meeting announcements, the proposed plan, new documents and reports added to the information repository, the start and completion of cleanup actions, schedule delays and the establishment of the Administrative Record.

IEPA published three weekly notices about its proposed cleanup plan for the Site in the Rockton Herald in 2004 prior to issuing the ROD. The notices included information about the 30-day public comment period and the public meeting. IEPA mailed a proposed plan fact sheet summarizing the proposed cleanup plan and the other cleanup alternatives that were considered, to citizens, the media, and local officials prior to selecting a final cleanup plan in the 2004 ROD. The fact sheet also announced and included information about the public comment period and the public meeting. IEPA extended the public comment period for the proposed plan period by 30 days in response to

a citizen request. IEPA responded to 26 questions and comments about the Site and the proposed cleanup plan in a responsiveness summary that is attached to the ROD.

IEPA published a notice announcing the 2013 FYR and inviting the public to comment and express their concerns about the Site at the start of the FYR. IEPA published these notices in the Rockton Herald and the Rockford Register Star.

EPA published notices announcing this proposed Direct Final Partial Deletion in the Rockton Herald and the Rockford Register Star prior to publishing this deletion in the **Federal Register**. Documents in the deletion docket which EPA relied on to support this partial deletion of the Site from the NPL are available to the public in the information repositories and at *http://www.regulations.gov.*

*Determination That the Criteria for Deletion Have Been Met*

The Former Beloit Corp. Research Center Property portion of the Beloit Corp. Site, PIN 03–12–452–003, meets all of the site deletion requirements specified in Office of Solid Waste and Emergency Response (OSWER) Directive 9320.22, *Close-Out Procedures for National Priorities List Sites.* All cleanup actions for this property required by the 2004 ROD and 2007 ESD (*i.e.,* the IC) have been implemented. The RI determined that the groundwater below the Former Beloit Corp. Research Center Property is upgradient of, and is not affected, by the groundwater contamination at the Site, and that the groundwater below the Former Beloit Corp. Research Center Property already meets cleanup levels. IEPA's updated capture zone analysis in 2013, and sampling at the deep, water supply well in the lower aquifer on the property required by the Illinois Department of Public Health, provide additional confirmation that the groundwater below the Former Beloit Corp. Research Center Property is not contaminated and that this portion of the Site does not pose a threat to human health or the environment. Therefore, EPA has determined that no further Superfund response is necessary to protect human health or the environment at the Former Beloit Corp. Research Center Property.

The NCP (40 CFR 300.425(e)) states that a Superfund site or a portion of a site may be deleted from the NPL when no further response action is appropriate. EPA, in consultation with the State of Illinois, has determined that all required response actions have been implemented at the Former Beloit Corp. Research Center Property portion of the Beloit Corp. Site, PIN 03–12–452–003, and that no further response action by the responsible parties is appropriate on this property.

## V. Partial Deletion Action

EPA, with concurrence of the State of Illinois through the IEPA, has determined that all appropriate response actions under CERCLA at the Former Beloit Corp. Research Center Property, PIN 03–12–452–003, other than maintenance and monitoring of groundwater monitoring wells and ICs, and five-year reviews, have been completed. Therefore, EPA is deleting the Former Beloit Corp. Research Center Property, PIN 03–12–452–003, of the Beloit Corp. Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective September 14, 2018 unless EPA receives adverse comments by August 15, 2018. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final Notice of Partial Deletion before the effective date of the partial deletion and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Partially Delete and the comments already received. There will be no additional opportunity to comment.

**List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: June 25, 2018.

**Cathy Stepp,**

*Regional Administrator, Region 5.*

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

## PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

**Authority:** 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

### Appendix B to Part 300—[Amended]

■ 2. Table 1 of appendix B to part 300 is amended by revising the listing under Illinois for ''Beloit Corp.'' to read as follows:

### Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

| State | Site name | City/county | Notes (a) |
|---|---|---|---|
| * * * * * * * | | | |
| IL | Beloit Corp. | Rockton | P |
| * * * * * * * | | | |

(a) * * *

P = Sites with partial deletion(s).

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[FR Doc. 2018–15144 Filed 7–13–18; 8:45 am]

BILLING CODE 6560–50–P

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 21**

**[Docket No. FWS–HQ–MB–2017–0091; FF09M21200–189–FXMB12320900000]**

**RIN 1018–BC12**

# Migratory Bird Permits; Removal of Depredation Orders for Double-Crested Cormorants To Protect Aquaculture Facilities and Public Resources

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

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, are issuing this final rule to comply with a court order that vacated provisions of regulations governing control of depredating double-crested cormorants at aquaculture facilities and for control of double-crested cormorants to protect public resources. Pursuant to the U.S. District Court for the District of Columbia order dated May 25, 2016, this rule removes regulatory provisions that allowed take of double-crested cormorants at aquaculture facilities and to protect public resources without the need for a permit.

**DATES:** This action is effective July 16, 2018.

**ADDRESSES:** This final rule is available on the internet at *http://www.regulations.gov* at Docket No. FWS–HQ–MB–2017–0091.

**FOR FURTHER INFORMATION CONTACT:** Ken Richkus, Acting Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, Falls Church, Virginia 22041–3803, telephone (703) 358–1780. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

**SUPPLEMENTARY INFORMATION:**

## Background

The U.S. Fish and Wildlife Service (Service) is delegated the primary responsibility of conserving migratory birds through protection, restoration, and management. This delegation is authorized by the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703 *et seq.*), which implements conventions with Great Britain (for Canada), Mexico, Japan, and Russia. We implement the provisions of the MBTA through regulations in parts 10, 13, 20, 21, and 22 of title 50 of the Code of Federal Regulations (CFR).

Regulations pertaining to migratory bird permits are at 50 CFR part 21. Subpart D of part 21 contains regulations for the control of depredating birds. Depredation and control orders authorize the take of specific species of migratory birds for specific purposes without a Federal depredation permit, as long as the control and depredation actions comply with the regulatory requirements of the order.

The two depredation orders at issue in this final rule—the Aquaculture Depredation Order (''AQDO''), at 50 CFR 21.47, and the Public Resource Depredation Order (''PRDO''), at 50 CFR 21.48 (collectively, the ''Orders'')—have been reissued every 5 years since their initial promulgation in 1998 and 2003, respectively. The AQDO was adopted by the Service in 1998 in response to complaints that the fish-eating habits of the cormorants were becoming increasingly costly to aquaculture and other industries. The AQDO authorized ''landowners, operators, and tenants actually engaged in the production of commercial freshwater aquaculture stocks (or their employees or agents)'' in certain States to take cormorants ''when found committing or about to commit depredations to aquaculture stocks'' (63 FR 10550, March 4, 1998). The authority granted by the AQDO would ''automatically expire on April 30, 2005, unless revoked or specifically extended prior to that date.''

In 1999, in response to continued complaints, the Service issued a notice of intent to develop a national cormorant plan. *See* Migratory Bird Permits; Notice of Intent To Prepare an Environmental Impact Statement and National Management Plan for the Double-Crested Cormorant (64 FR 60826, November 8, 1999). In 2003 the agency issued a final environmental impact statement (EIS), which presented six alternatives for the management of double-crested cormorants: (1) No action (continuation of existing management practices); (2) only nonlethal management techniques; (3) expansion of existing management policies; (4) a new depredation order; (5) reduction of regional cormorant populations; and (6) frameworks for a cormorant hunting season. *See* Migratory Bird Permits; Regulations for Double-Crested Cormorant Management (68 FR 58022, October 8, 2003). The EIS recommended the fourth of these alternatives: Issuance of a new depredation order. Accordingly, the Service promulgated the PRDO, which authorized State fish and wildlife agencies, Federally recognized Tribes, and State Directors of the Wildlife Services program of the U.S. Department of Agriculture Animal and Plant Health Inspection Service to ''take,'' without a permit, cormorants found committing or about to commit depredations on the public resources of fish, wildlife, plants, and their habitats. Both orders, issued in 2003, would expire on April 30, 2009.

In 2009, the two depredation orders were reissued for another 5 years. *See* Migratory Bird Permits; Revision of Expiration Dates for Double-Crested Cormorant Depredation Orders (74 FR 15394, April 6, 2009). Finally, in 2014, both orders were reissued until June 30, 2019. *See* Migratory Bird Permits; Extension of Expiration Dates for Double-Crested Cormorant Depredation Orders (79 FR 30474, May 28, 2014). The 2014 final rule was accompanied by an environmental assessment (EA).

On May 25, 2016, the U.S. District Court for the District of Columbia vacated the two depredation orders (*Pub. Emps. for Envtl. Responsibility* v. *U.S. Fish & Wildlife Serv.,* 189 F. Supp. 3d 1 (D.D.C. 2016)). The Court concluded that the Service failed to consider a reasonable range of alternatives in the 2014 EA and directed the Service to take ''a hard look'' at the effects of the depredation orders on double-crested cormorant populations and other affected resources. Finally, the Court ordered that the Service perform a new and legally adequate EA or EIS under the National Environmental Policy Act.

## Administrative Procedure

This rulemaking is necessary to comply with the May 25, 2016, court order. Therefore, under these circumstances, we have determined, pursuant to 5 U.S.C. 553(b)(3)(B), that prior notice and opportunity for public comment are impractical and unnecessary. Public opportunity for comment is simply not required when an agency amends a regulation to comply with a court order. When an agency removes regulatory provisions set aside by a court order, that action is ministerial in nature and allows for no discretion on the part of the agency.

We have further determined, pursuant to 5 U.S.C. 553(d)(3), that the agency has good cause to make this rule effective upon publication, which is to comply with the District Court's order as soon as practicable.

## List of Subjects in 50 CFR Part 21

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

**Regulation Promulgation**

To comply with the court order and mandate discussed above, we amend subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

## PART 21—MIGRATORY BIRD PERMITS

■ 1. Remove the second authority citation for part 21.

■ 2. The remaining authority citation for part 21 continues to read as follows:

**Authority:** 16 U.S.C. 703–712.

### §§ 21.47 and 21.48 [Removed and Reserved]

■ 3. Remove and reserve §§ 21.47 and 21.48.

Dated: June 15, 2018.

**Susan Combs,**

*Senior Advisor to the Secretary, Exercising the Authority of the Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2018–15103 Filed 7–13–18; 8:45 am]

BILLING CODE 4333–15–P

# Proposed Rules

Federal Register
Vol. 83, No. 136
Monday, July 16, 2018

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 25

**[Docket No.: FAA–2018–0653–; Notice No. 18–04]**

**RIN 2120–AK89**

## Yaw Maneuver Conditions—Rudder Reversals

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

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

**SUMMARY:** The FAA proposes to add a new load condition to the design standards for transport category airplanes. The new load condition would require the airplane be designed to withstand the loads caused by rapid reversals of the rudder pedals and would apply to transport category airplanes that have a powered rudder control surface or surfaces. This rule is necessary because accident and incident data show that pilots sometimes make rudder reversals during flight, even though such reversals are unnecessary and discouraged by flightcrew training programs. The current design standards do not require the airplane structure to withstand the loads that may result from such reversals. If the airplane loads exceed those for which it is designed, the airplane structure may fail, resulting in catastrophic loss of control of the airplane. This proposal aims to prevent structural failure of the rudder and vertical stabilizer that may result from these rudder reversals.

**DATES:** Send comments on or before October 15, 2018.

**ADDRESSES:** Send comments identified by docket number [Insert docket number from heading] 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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *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:** For technical questions concerning this action, contact Robert C. Jones, Propulsion & Mechanical Systems Section, AIR–672, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax (206) 231–3182; email *Robert.C.Jones@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General Requirements.'' Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for the design and performance of aircraft that the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority. It prescribes new safety standards for the design of transport category airplanes.

### I. Overview of Proposed Rule

The FAA proposes to add a new load condition to the design standards in title 14, Code of Federal Regulations (14 CFR) part 25. The new load condition, to be located in new proposed § 25.353, would require that the airplane be designed to withstand the loads caused by rapid reversals of the rudder pedals. Specifically, applicants would have to show that their proposed airplane design can withstand an initial full rudder pedal input, followed by three rudder reversals at the maximum sideslip angle, followed by return of the rudder to neutral. Due to the rarity of such multiple reversals, the proposed rule would specify the new load condition is an ultimate load condition rather than a limit load condition. Consequently, the applicant would not have to apply an additional factor of safety to the calculated load levels.[1]

The proposed rule would affect manufacturers of transport category airplanes applying for a new type certificate after the effective date of the final rule. The proposed rule may also affect applicants applying for an amended or supplemental type certificate as determined under 14 CFR 21.101 after the effective date of the final rule. Proposed § 25.353 would apply to transport category airplanes that have a powered rudder control surface or surfaces, as explained in the ''Discussion of the Proposal.''

### II. Background

#### *A. Statement of the Problem*

Accident and incident data from the events described in section II.B.1 show pilots sometimes make multiple and unnecessary rudder reversals during flight. In addition, FAA-sponsored

[1] The terms ''limit,'' ''ultimate,'' and ''factor of safety'' are specified in § 25.301, ''Loads,'' § 25.303, ''Factor of safety,'' and § 25.305, ''Strength and deformation.'' To summarize, design loads are typically expressed in terms of limit loads, which are then multiplied by a factor of safety, usually 1.5, to determine ultimate loads. In this proposal, the design loads would be expressed as ultimate loads, and no additional safety factor would be applied.

research [2] indicates that pilots use the rudder more often than previously thought and often in ways not recommended by manufacturers. Section 25.1583(a)(3)(ii) requires manufacturers to provide documentation that warns pilots against making large and rapid control reversals as they may result in structural failures at any speed, including below the design maneuvering speed ($V_A$). Despite the requirement, and though such rudder reversals are unnecessary and discouraged by flightcrew training programs, these events continue to occur (see section II.B.1, ''History—Accidents and Incidents'' below).

Section 25.351, the standard for protecting the airplane's vertical stabilizer from pilot-commanded maneuver loads, only addresses single, full rudder inputs at airspeeds up to the design diving speed ($V_D$).[3] This design standard does not protect the airplane from the loads imposed by repeated inputs in opposing directions, or rudder reversals.[4] If the loads on the vertical stabilizer exceed those for which it is designed, the vertical stabilizer may fail, resulting in the catastrophic loss of airplane control.

Incidents and accidents related to rudder reversals have occurred in the past, and the FAA believes that another such event could occur, resulting in injuries to occupants or a structural failure that jeopardizes continued safe flight and landing of the airplane.

*B. History*

1. Accidents and Incidents

Rudder reversals have caused a number of accidents and incidents. On November 12, 2001, American Airlines Flight 587 (AA587), an Airbus Model A300–600 series airplane, crashed at Belle Harbor, New York, resulting in 265 deaths and the loss of the airplane. The National Transportation Safety Board (NTSB) found that the probable cause of this accident was the in-flight separation of the vertical stabilizer as a result of the loads beyond ultimate design that were created by the first officer's unnecessary and excessive rudder pedal inputs. The NTSB also noted that contributing to these rudder pedal inputs were characteristics of the Airbus A300–600 rudder system design and elements of the American Airlines Advanced Aircraft Maneuvering Program.[5]

In two additional events—commonly known as the Interflug incident [6] and Miami Flight 903 accident (AA903) [7]—the vertical stabilizer of each airplane experienced loads above the ultimate load level due to pedal reversals commanded by the pilot after the airplane stalled.[8] While none of the passengers and crew were injured in the Interflug incident, a passenger was seriously injured and a crewmember sustained minor injuries in the AA903 accident. The AA903 airplane also sustained sheared fasteners, deformed nacelles, and engine component damage, but landed safely. A catastrophe similar to AA587 was averted in each of these events because the vertical stabilizer was stronger than required by the design standards.[9]

Other rudder reversal events have occurred more recently. On January 10, 2008, an Airbus Model 319–114 series airplane, operated as Air Canada Flight 190 (AC190), encountered a wake vortex while at cruise altitude over Washington State.[10] The pilot responded with inputs that included six rudder reversals. The flightcrew eventually stabilized the airplane and diverted to an airport capable of handling the injured passengers.

The Transportation Safety Board of Canada (TSB) investigated this event, along with NTSB accredited representatives, and classified it as an accident. Analysis by the TSB showed that the pilot's actions resulted in a load on the vertical stabilizer that exceeded its limit load by approximately 29 percent. The TSB found that the flightcrew was startled by wake turbulence at that altitude, erroneously believed that the airplane had malfunctioned, and therefore responded with erroneous actions. The pilot had received training to avoid rudder reversals.

On May 27, 2005, a Bombardier DHC–8–100 series airplane, operated by Provincial Airlines Limited for passenger service, experienced a stall and uncontrolled descent over Canada.[11] During climb-out, the indicated airspeed gradually decreased, due to the flightcrew's inadvertent selection of an incorrect autopilot mode. The airplane stalled at an unexpectedly high airspeed, likely due to the formation of ice. The flightcrew's failure to recognize the stall resulted in incorrect control inputs and the loss of 4,200 feet of altitude in approximately 40 seconds before recovery. There were no injuries and the airplane was not damaged. During this event, the pilot commanded a rudder reversal.

2. New Transport Airplane Programs

Since the AA587 accident, the FAA has responded to the risk posed by rudder reversals, in part, by requesting that applicants for new type certificates show that their designs are capable of continued safe flight and landing after experiencing repeated rudder reversals. Applicants have been able to show this capability through rudder control laws in flight control systems. Applicants have incorporated these control laws through software and, therefore, added no weight or maintenance cost to the airplanes.

In 2016, the European Aviation Safety Agency (EASA) began applying special conditions to new airplane certification programs. EASA mandated these special conditions to address the exact risk of rudder reversals explained in this NPRM. The requirements in the EASA special conditions are identical to the requirements proposed in this NPRM.

3. FAA Survey of Pilots' Rudder Use

In 2006, the FAA sponsored a survey [12] to better comprehend transport category pilots' understanding and use of the rudder. This survey included

[2] Report No. DOT/FAA/AM–10/14, ''An International Survey of Transport Airplane Pilots' Experiences and Perspectives of Lateral/Directional Control Events and Rudder Issues in Transport Airplanes (Rudder Survey),'' dated October 2010, is available in the Docket and on the internet at *http://www.faa.gov/data_research/research/med_humanfacs/oamtechreports/2010s/media/201014.pdf.*

[3] $V_D$ is the design diving speed: The maximum speed at which the airplane is certified to fly. See 14 CFR 1.2. Advisory Circular 25–7C provides additional information related to $V_D$.

[4] A rudder reversal is a continuous, pilot-commanded pedal movement starting from pedal displacement in one direction followed by pedal displacement in the opposite direction.

[5] Aircraft Accident Report NTSB/AAR–04/04, ''In-flight Separation of Vertical Stabilizer, American Airlines Flight 587, Airbus Industrie A300–605R, N14053, Belle Harbor, New York, November 12, 2001,'' dated October 26, 2004, is available in the Docket and on the internet at *https://www.ntsb.gov/investigations/AccidentReports/Reports/AAR0404.pdf.*

[6] On February 11, 1991, an Airbus Model A310 series airplane experienced in-flight loss of control over Moscow, Russia.

[7] On May 12, 1997, an Airbus Model A300–600 series airplane experienced in-flight loss of control near West Palm Beach, Florida, after the flightcrew failed to recognize that the airplane had entered a stall.

[8] The Interflug and Miami Flight 903 events are discussed in NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 103–110. See footnote 5 on p. 6.

[9] FCHWG Recommendation Report, ''Rudder Pedal Sensitivity/Rudder Reversal,'' dated November 7, 2013, is available in the Docket and on the internet at *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/TAEfch-rpsrr-3282011.pdf.* See p. 5 of the report.

[10] TSB Aviation Investigation Report A08W0007, ''Encounter with Wake Turbulence,'' is available in the Docket and on the internet at *http://tsb.gc.ca/eng/rapports-reports/aviation/2008/a08w0007/a08w0007.pdf.*

[11] TSB Aviation Investigation Report A05A0059. See footnote 10 on p. 7.

[12] Report No. DOT/FAA/AM–10/14 (see footnote 2 on p. 5), OMB Control No. 2120–0712.

transport pilots from all over the world. The FAA's analysis of the survey data found that—

- Pilots use the rudder more than previously thought and often in ways not recommended by manufacturers.
- Pilots make erroneous rudder pedal inputs, and some erroneous rudder pedal inputs include rudder reversals.
- Even after specific training, many pilots are not aware that they should not make rudder reversals, even below $V_A$. Over the last several years, training and changes to the airplane flight manual (AFM) have directed the pilot to avoid making cyclic control inputs. The rudder reversals that caused the AC190 incident in 2008, and the Provincial Airlines Limited incident in 2005, occurred despite this effort.
- The survey indicated that pilots in airplane upset situations (*e.g.,* wake vortex encounters) may revert to prior training and make sequential rudder reversals.

*C. Aviation Rulemaking Advisory Committee (ARAC) Activity*

In 2011, the FAA tasked ARAC to consider the need to add a new flight maneuver load condition to part 25, subpart C, that would ensure airplane structural capability in the presence of rudder reversals and increasing sideslip angles (yaw angles) at airspeeds up to $V_D$. The FAA also tasked ARAC to consider if other airworthiness standards would more appropriately address this concern, such as pedal characteristics that would discourage pilots from making rudder reversals.[13] ARAC delegated this task to the Transport Airplane and Engine subcommittee, which assigned it to the Flight Controls Harmonization Working Group (FCHWG).

The FCHWG was tasked to examine several options to protect the airplane from pilot-commanded rudder reversals. These options included developing new standards for—

- Loads,
- Maneuverability,
- System design,
- Control sensitivity,
- Alerting, and
- Pilot training.

The FCHWG completed its report in November 2013.[14] ARAC and the FAA accepted the report. The report's findings and recommendations guided the formation of this proposal.

While multiple rudder reversals are a very low probability event, they have occurred in service and cannot be ruled out in the future. The FCHWG found that a load condition was the optimal way to protect the airplane from the excessive loads that can result from multiple rudder reversals. The FCHWG recommended a load condition over the other options because it would be a performance-based requirement. The FCHWG noted that this would provide applicants for design approval with the flexibility to determine the best way to meet a load condition.

*D. NTSB Safety Recommendation*

Following the AA587 accident described in section II.B.1 of this NPRM, the NTSB provided safety recommendations to the FAA. The NTSB stated, ''For airplanes with variable stop rudder travel limiter systems, protection from dangerous structural loads resulting from sustained alternating large rudder pedal inputs can be achieved by reducing the sensitivity of the rudder control system (for example, by increasing the pedal forces), which would make it harder for pilots to quickly perform alternating full rudder inputs.'' In Safety Recommendation A–04–056,[15] the NTSB recommended that the FAA modify part 25 to include a certification standard that will ensure safe handling qualities in the yaw axis throughout the flight envelope, including limits for rudder pedal sensitivity.

This proposed rule would address this recommendation and, if incorporated on new airplane designs, would reduce the risk of an event similar to AA587. The proposed rule would also respond to the NTSB's concern about rudder pedal sensitivity.

*E. Other Regulatory Actions*

1. 2010 Revisions to § 25.1583

During its investigation of the AA587 accident, the NTSB found that many pilots of transport category airplanes mistakenly believed that, as long as the airplane's speed is below $V_A$, they can make any control input they desire without risking structural damage to the airplane. AA587 exposed the fact that this assumption is incorrect. As a result, the NTSB recommended that the FAA amend its regulations to clarify that operating at or below $V_A$ does not provide structural protection against multiple, full control inputs in one axis, or full control inputs in more than one axis at the same time.[16] After making its own assessment, the FAA agreed, and revised § 25.1583(a)(3) at Amendment 25–130, effective October 15, 2010.

Section 25.1583(a)(3) was revised to change the information that applicants must furnish in the AFM explaining the use of $V_A$ to pilots. The amendment clarified that, depending on the particular airplane design, flying at or below $V_A$ does not allow a pilot to make multiple large control inputs in one airplane axis or full control inputs in more than one airplane axis at a time without endangering the airplane's structure. However, the AC190 accident shows that even a properly trained pilot might make rudder reversals when startled or responding to a perceived failure.

2. Airworthiness Directives

In 2012, the FAA adopted an airworthiness directive (AD) applicable to all Airbus Model A300–600 and Model A310 series airplanes.[17] The AD was prompted by the excessive rudder pedal inputs and consequent high loads on the vertical stabilizer in the events described previously, including AA587. The AD required operators to either incorporate a design change to the rudder control system or other systems, or install a modification that alerts the pilot to stop making rudder inputs.

In 2015, the FAA adopted an AD applicable to all Airbus Model A318, A319, A320, and A321 series airplanes.[18] That AD was prompted by a determination that, in specific flight conditions, the allowable load limits on the vertical stabilizer could be reached and possibly exceeded. Exceeding allowable load could result in detachment of the vertical stabilizer. The AD also required a modification that alerts the pilot to stop making rudder inputs.

*F. Advisory Material*

The FAA has developed proposed Advisory Circular (AC) 25.353–X, ''Design Load Conditions for Rudder Control Reversal,'' to be published concurrently with this NPRM. This proposed AC would provide guidance

[13] This notice of ARAC tasking was published in the **Federal Register** on March 28, 2011 (76 FR 17183).

[14] FCHWG Recommendation Report, ''Rudder Pedal Sensitivity/Rudder Reversal,'' dated November 7, 2013, is available in the Docket and on the internet at *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/TAEfch-rpsrr-3282011.pdf.* See footnote 9 on p. 7.

[15] NTSB Safety Recommendation A–04–056 is available in the Docket and on the internet at *http://www.ntsb.gov/safety/safety-recs/RecLetters/A04_56_62.pdf.*

[16] NTSB Safety Recommendation A–04–60 is available in the Docket and on the internet at *http://www.ntsb.gov/safety/safety-recs/recletters/A04_56_62.pdf.*

[17] AD 2012–21–15 was published in the **Federal Register** on November 9, 2012 (77 FR 67526). For more information, see Docket No. FAA–2011–0518 on the internet at *http://www.regulations.gov.*

[18] AD 2015–23–13 was published in the **Federal Register** on December 29, 2015 (77 FR 67526). For more information, see Docket No. FAA–2011–0518 on the internet at *http://www.regulations.gov.*

material on acceptable means, but not the only means, of showing compliance with proposed § 25.353. The FAA will post the proposed AC on the ''Aviation Safety Draft Documents Open for Comment'' web page at *http://www.faa.gov/aircraft/draft_docs/*.[19] The FAA requests that you submit comments on the proposed AC through that web page.

## III. Discussion of the Proposal

The FAA proposes to revise 14 CFR by adding new § 25.353 to add a design load condition. It would apply to transport category airplanes that have a powered rudder control surface or surfaces, as explained later in this section. The load condition would require that the airplane be able to withstand three full reversals of the rudder pedals at the most critical points in the flight envelope. From a neutral position, the pedal input would be sudden and to one side and held; then, as the maximum sideslip angle is reached, the pedals would be suddenly displaced in the opposite direction and held until the opposite angle is reached; then again to the first side; then again to the second side; then suddenly moved back to the neutral position.

The reason for this proposal is that pilots make inadvertent and erroneous rudder pedal inputs, and the accident and incident data show that the loads caused by rudder reversals can surpass the airplane's structural limit load and sometimes its ultimate load. Compliance with the proposed rule would require a showing that the airplane's vertical stabilizer and other airplane structure are strong enough to withstand the rudder reversals.

Ten of the eleven members of the FCHWG recommended proposing some form of a new load condition to protect the airplane against rudder reversals. During discussions, five members of the FCHWG [20] recommended requiring a load condition that would protect the airplane from three, sequential, full rudder reversals. This notice puts forth those proposals.

Five members of the FCHWG [21] recommended a similar load condition, which would only protect against a single reversal of the rudder pedals. The FAA is not proposing this alternative because a new rule that only includes a single rudder reversal, with a safety factor of 1.0, would not materially increase the design load level from current design loads criteria and would not be effective in preventing accidents such as the AA587 accident.

One member, The Boeing Company (Boeing), took the position that no new rulemaking or design standards are required, and that the risk from rudder reversals should be addressed by flightcrew training. Boeing stated that rudder reversals are always inappropriate and that pilots should never make such commands. Boeing argued it is inappropriate to issue an airworthiness standard to mitigate a situation caused by actions that pilots should avoid. The FAA rejects this alternative because, while multiple rudder reversals are a very low probability event, they have been seen in service, despite training, and cannot be ruled out in the future.

As indicated previously, yaw maneuver loads are currently specified in § 25.351, ''Yaw maneuver conditions.'' The FAA used this requirement as a template to develop the proposed new rudder reversal design load condition. Therefore, the proposed load condition would be similar to the load condition required by § 25.351, except as follows:

- Section 25.351 specifies a single, full-pedal command followed by a sudden pedal release after the airplane has reached the steady-state sideslip angle. Proposed § 25.353 would specify a single, full-pedal command followed by three rudder reversals, and return to neutral.
- In the proposed rule, the rudder reversals must be performed at the maximum sideslip angle, which is referred to as the ''overswing sideslip angle.'' This term is also used in § 25.351 and would have the same meaning. The overswing sideslip angle is the maximum sideslip angle that occurs following full rudder pedal input and includes the additional sideslip that may occur beyond the steady-state sideslip angle.
- The § 25.353 load requirement would be an ultimate design load condition, instead of a limit load condition as in § 25.351. This means that applicants would apply a safety factor of 1.0, rather than 1.5. The proposed rudder reversal maneuver would cover the worst-case rudder maneuver expected to occur in service. Because service history has shown that three full rudder reversals are unusual, the FAA proposes that a safety factor of 1.0 is appropriate.
- The proposed § 25.353 condition would require only that the applicant account for the rudder reversals at speeds up to the design cruising speed ($V_C$). In contrast, § 25.351 requires applicants to account for speeds up to $V_D$. The reason for this difference is that $V_C$ represents the majority of the flight envelope, and compliance to $V_D$ is not necessary due to the infrequency of exposure to such speeds and the low probability that a rudder reversal will occur at speeds above $V_C$.
- Section 25.351 requires a pilot force of up to 300 pounds, depending on the airplane's speed. In contrast, the pilot force specified in § 25.353 would be limited to 200 pounds because it would be difficult, and therefore very unlikely, for a pilot to maintain 300 pounds of force while performing rapid alternating inputs.
- The proposed § 25.353 condition would be evaluated only with the landing gear retracted and speed brakes (and spoilers when used as speed brakes) retracted. This is because flight loads would be more severe with the gear and speed brakes retracted.

### *A. Expected Methods of Compliance*

The proposed rule is performance-based. For example, an applicant could choose to comply with the proposed standard by using control system architecture and control laws to limit the airplane response to rudder reversals, and thereby reduce structural loads on the airplane. An applicant could also choose to comply by increasing the capability of the airplane to withstand the maximum expected structural loads that could result from the proposed load condition.

### *B. Proposed Applicability*

After examining all the data and considering stakeholder opinions, the FAA has determined that the proposed rule should apply to new type certification programs of transport category airplane designs and to amended or supplemental type certificate programs as determined under § 21.101. The proposed rule would affect manufacturers of transport category airplanes. In the future, applicants who want to certify new airplanes under part 25 would have to comply with proposed § 25.353.

As noted previously, this proposed rule would apply only to airplanes that use powered rudder control surfaces. In this proposed rule, a powered rudder control surface is one in which the force required to deflect the surface against the airstream is generated or augmented by hydraulic or electric systems. An unpowered rudder control surface is

[19] The proposed AC is also available in the Docket. To ensure the FAA receives your comments on the proposed AC, please submit them via the instructions found on the ''Aviation Safety Draft Documents Open for Comment'' web page.

[20] The Air Line Pilots Association, International (ALPA), EASA, National Civil Aviation Agency—Brazil (ANAC), and Transport Canada Civil Aviation (TCCA), and FAA representatives.

[21] Airbus, Bombardier, Cessna, Dassault Aviation, and Embraer.

one for which the force required to deflect the surface against the airstream is transmitted from the pilot's rudder pedal directly through mechanical means, without any augmentation from hydraulic or electrical systems. Powered rudder control systems include fly-by-wire (FBW) and hydro-mechanical systems. Unpowered rudder control systems are also referred to as mechanical systems. Incorporation of a powered yaw damper into an otherwise unpowered rudder control system does not constitute a powered rudder control surface, for the purpose of this proposed rule. The reasons that the FAA proposes to exclude airplanes with unpowered (mechanical) rudder control surfaces are as follows, and the FAA seeks comment on these reasons:

1. The only U.S. transport category airplane models, currently in production, that use unpowered rudder control surfaces are small business jets. Small airplanes typically have a minimal delay between pilot yaw control inputs and airplane response. The pilots of these airplanes receive more immediate feedback of airplane response to their yaw control inputs and, therefore, are less likely to execute inappropriate pedal movements resulting in rudder reversals.

2. The only U.S. transport category airplane models, currently in production, that use an unpowered rudder control surface are also equipped with a yaw damper. The FAA has assessed the design of this yaw damper and determined its normal operation would be adequate to reduce yaw overshoot loads resulting from rudder reversals to acceptable levels. However, the yaw damper system on these airplanes is not required to be operational on any given flight. The yaw damper is included in these airplanes primarily to improve ride quality for passenger comfort (as opposed to providing adequate stability about the yaw axis to ensure airplane safety). Since the yaw damper may not be available on a given flight, the manufacturer of these airplanes has stated it might need to add structure or an improved yaw damper to any new type certificated airplanes to comply with the proposed rule.[22] This would significantly increase design, production, and operation costs. The FAA considers that, for these airplanes, the cost to comply with the proposed, new load condition through structural modification is not justified by the relatively low risk these airplanes face from rudder reversals. Further, the FAA considers it unlikely that many of these airplanes would fly for extended periods without an operable yaw damper that provides acceptable ride quality. Therefore, most of these airplanes have protection against yaw overshoot loads, even if they are not required to demonstrate this protection during certification.

3. The use of unpowered rudder control surfaces is diminishing in the transport category airplane fleet. The FAA expects that most, if not all, new type certificate applications to which this proposed rule would apply will employ powered rudder control surfaces.

4. The FAA has reviewed the accident and incident records and has found no events in which pilots commanded inappropriate rudder reversals on airplanes with unpowered rudder control surfaces. This alone does not mean such systems cannot be affected by pilot-commanded inappropriate rudder reversals. However, the absence of any previous incidents indicates that excluding these designs would not appreciably increase the future risk of such events above acceptable levels.

*C. Summary*

The proposed design criteria would provide a practical, relatively low-cost solution that would be achievable on future designs without the requirement to significantly strengthen the vertical stabilizer, or make significant changes to system design. In fact, some current airplanes would be able to meet the proposed criteria with no changes whatsoever. This proposal should require a minimal increment of applicant resources to show compliance. While an applicant might choose to comply with this performance-based standard by strengthening the airplane structure, the FAA believes that most applicants would use control laws to comply with this proposed rule. These control laws are a part of the flight control computer, and they adjust control surface deflections based on pilot input and other factors like airspeed. Since control laws are typically implemented through systems and software, there would be little to no incremental cost in the form of weight, equipment, maintenance, or training.

## IV. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 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 of 1979 (Pub. L. 96–39), 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, the Trade Agreements 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 proposed rule.

In conducting these analyses, FAA has determined that this proposed rule has benefits that justify its costs and is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866. The rule is also not ''significant'' as defined in DOT's Regulatory Policies and Procedures. The proposed rule will not have a significant economic impact on a substantial number of small entities, will not create unnecessary obstacles to the foreign commerce of the United States, and will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified previously.

*A. Regulatory Evaluation*

Department of Transportation 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 a statement to that effect and the basis for it to 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 proposed rule. The reasoning for this determination follows.

1. Background

The genesis of this proposed rule is the crash of American Airlines Flight 587 (AA587), near Queens, New York,

[22] A record of this conversation between the FAA and airplane manufacturer is available in the Docket.

on November 12, 2001, resulting in the death of all 260 passengers and crew aboard, and the death of five persons on the ground. The airplane was destroyed by impact forces and a post-crash fire.

The National Transportation Safety Board (NTSB) found that the probable cause of the accident was ''the in-flight separation of the vertical stabilizer [airplane fin] as a result of loads above ultimate design created by the first officer's unnecessary and excessive rudder pedal inputs.'' [23] Ultimate loads on the airplane structure are the limit loads (1.0) multiplied by a safety factor, usually 1.5 (as for the vertical stabilizer). An airplane is expected to experience a limit load once in its lifetime and is never expected to experience an ultimate load.[24] For the AA587 accident, loads exceeding ultimate loads ranged from 1.83 to 2.14 times the limit load on the vertical stabilizer,[25] as a result of four, full, alternating rudder inputs known as ''rudder reversals.''

Significant rudder reversals events are unusual in the history of commercial airplane flight, having occurred during just five notable accidents and incidents, with AA587 being the only catastrophic accident resulting from rudder reversals.[26] Ultimate loads were exceeded in two of the other notable rudder reversal accidents, the Interflug incident (Moscow, February 11, 1991) and American Airlines Flight 903 (AA903) (near West Palm Beach, Florida, May 12, 1997).[27] For the Interflug incident, with multiple rudder reversals, loads of 1.55 and 1.35 times the limit load were recorded; and for AA903 (eight rudder reversals), a load of 1.53 times the limit load was recorded.[28] A catastrophe similar to AA587 was averted in these two events only because the vertical stabilizer was stronger than required by design standards.[29] In a fourth event—Air Canada Flight 190 (AC190) (over the state of Washington, January 10, 2008)—with four rudder reversals, the limit load was exceed by 29 percent.

In transport category airplanes, rudder inputs are generally limited to aligning the airplane with the runway during crosswind landings and controlling engine-out situations, which occur predominately at low speeds. At high speeds, the pilot normally directly rolls the airplane using the ailerons.[30] If the pilot does use the rudder to control the airplane at high speeds, there will be a significant phase lag between the rudder input and the roll response because the roll response is a secondary effect of the yawing moment generated by the rudder.[31] The roll does not result from the rudder input directly. Even if the rudder is subsequently deflected in the opposite direction (rudder reversal), the airplane can continue to roll and yaw in one direction before reversing because of the phase lag. The relationship between rudder inputs and the roll and yaw response of the airplane can become confusing to pilots, particularly with the large yaw and roll rates that would result from large rudder inputs, causing the pilots to input multiple rudder reversals.

Following the AA587 accident, in November 2004 the NTSB released Safety Recommendation A–04–56 recommending that the FAA modify part 25 ''to include a certification standard that will ensure safe handling qualities in the yaw axis throughout the flight envelope. . . .'' [32] In 2011, the FAA tasked the Aviation Rulemaking Advisory Committee (ARAC) to consider the need for rulemaking to address the rudder reversal issue. ARAC delegated this task to the Transport Airplane and Engine subcommittee, which assigned it to the Flight Controls Harmonization Working Group (FCHWG). One of the recommendations of the ARAC Rudder Reversal Report, issued on November 7, 2013, was to require transport category airplanes to be able to safely withstand the loads imposed by three rudder reversals. This proposed rule adopts that recommendation. The ARAC report indicates that requiring transport category airplanes to safely operate with the vertical stabilizer loads imposed by three full-stroke rudder reversals accounts for most of the attainable safety benefits. With more than three rudder reversals, the FCHWG found little increase in vertical stabilizer loads.

2. Costs and Benefits of This Proposed Rule

Since the catastrophic AA587 accident, the FAA has responded to the risk posed by rudder reversals by requesting, through the issue paper process, that applicants for new type certificates show that their designs are capable of continued safe flight and landing after experiencing repeated rudder reversals. For airplanes with FBW systems, manufacturers have been able to show capability by means of control laws, incorporated through software changes and, therefore, adding no weight and imposing no additional maintenance cost to the airplanes. Many if not all of these designs have demonstrated tolerance to three or more rudder reversals. Aside from converting to an FBW system, alternatives available to manufacturers specializing in airplane designs with mechanical or hydro-mechanical rudders include increasing the reliability of the yaw damper and strengthening the airplane vertical stabilizer.

To estimate the cost of the proposed rule, the FAA solicited unit cost estimates from U.S. industry and incorporated these estimates into an airplane life cycle model. The FAA received one estimate for large part 25 airplanes and two estimates for small part 25 airplanes (business jets).

One of the business jet estimates was provided by a manufacturer specializing in mechanical rather than FBW rudder systems; therefore, that estimate reflects significantly higher compliance costs. This manufacturer's most cost-efficient approach to addressing the proposed requirement—although high in comparison to manufacturers who use FBW systems exclusively—is to comply with a strengthened vertical stabilizer. The cost of complying with a more reliable yaw damper was higher than strengthening the vertical stabilizer, and higher yet if complying by converting to a FBW rudder system for new models.

As a result of these high costs and other reasons set forth in the preamble, the FAA has decided that the proposed rule would not apply to airplanes with ''unpowered'' (mechanical) rudder control surfaces. An ''unpowered'' rudder control surface is one whose movement is affected through mechanical means, without any augmentation from hydraulic or electrical systems. Accordingly, the proposed rule would not apply to models with mechanical rudder control systems, but would apply only to models with FBW or hydro-mechanical

[23] NTSB Aircraft Accident Report NTSB/AAR–04/04, p. 160. See footnote 5 on p. 6.

[24] NTSB Aircraft Accident Report NTSB/AAR–04/04, p. 31, n. 53.

[25] NTSB Aircraft Accident Report NTSB/AAR–04/04, p. 104.

[26] FAA Aviation Rulemaking Advisory Committee. Flight Controls Harmonization Working Group. Rudder Pedal Sensitivity/Rudder Reversal Recommendation Report, Nov. 7, 2013. (ARAC Rudder Reversal Report). This Report identifies four notable rudder events to which we add the Interflug incident discussed in the NTSB AA587 Report.

[27] NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 106–109.

[28] NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 104.

[29] NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 38–39.

[30] An aileron is a hinged control service on the trailing edge of the wing of a fixed-wing aircraft, one aileron per wing.

[31] The yaw axis is defined to be perpendicular to the wings and to the normal line of flight. A yaw movement is a change in the direction of the aircraft to the left or right around the yaw axis.

[32] NTSB Safety Recommendation A–04–56, Nov. 10, 2004.

rudder systems. The FAA solicits comments on the exclusion of airplanes with unpowered rudder control surfaces from the proposed rule and the corresponding inclusion of FBW and hydro-mechanical models.

The FAA estimates the costs of the proposed rule using unit cost per model estimates from industry for FBW models and our estimates of the number of new large airplane and business jet certifications with FBW rudder systems in the ten years after the effective date of the proposed rule. These estimates are shown in table 1. The FAA solicits comments, with detailed cost estimates, on our estimates.

TABLE 1—COST ESTIMATED FOR PROPOSED RULE

[$ 2016]

| | Cost per model | Number of new FBW models (10 yrs) | Costs |
|---|---|---|---|
| Large Airplanes | $300,000 | 2 | $600,000 |
| Business Jets | 235,000 | 2 | 470,000 |
| Total Costs | | | 1,070,000 |

With these cost estimates, the FAA finds the proposed rule to be minimal cost, with expected net safety benefits from the reduced risk of rudder reversal accidents.

*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. As noted above, because manufacturers with FBW rudder systems have been able to show compliance by means of low-cost changes to control laws incorporated through software changes, the FAA estimates the costs of this proposed rule to be minimal. Therefore, as provided in section 605(b), the head of the FAA certifies that this proposed rule will not have 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) 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 this Act, 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 effect of this proposed rule and determined that its purpose is to protect the safety of U.S. civil aviation. Therefore, the proposed rule is in compliance with the Trade Agreements Act.

*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 proposed 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 would be no new requirement for information collection associated with this proposed rule.

*F. International Compatibility and Cooperation*

(1) 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 determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

(2) Executive Order 13609, ''Promoting International Regulatory Cooperation,'' 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.

*G. Environmental Analysis*

FAA Order 1050.1E 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 312f of Order 1050.1E and involves no extraordinary circumstances.

## V. Executive Order Determinations

*A. Executive Order 13132, Federalism*

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, ''Federalism.'' The agency has determined that this action would 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 proposed 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 would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

*C. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs*

This proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866.

## VI. Additional Information

*A. Comments Invited*

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The agency also invites 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.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The agency may change this proposal in light of the comments it receives.

Proprietary or Confidential Business Information: Commenters should not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD–ROM, mark the outside of the disk or CD–ROM, and identify electronically within the disk or CD–ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

*B. Availability of Rulemaking Documents*

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

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);
2. Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies* or
3. Accessing the Government Printing Office's web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9680. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the internet through the Federal eRulemaking Portal referenced in item (1) above.

### List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

### The Proposed Amendment

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

## PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

■ 1. The authority citation for part 25 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702 and 44704.

■ 2. Add § 25.353 to read as follows:

**§ 25.353 Rudder control reversal conditions.**

For airplanes with a powered rudder control surface or surfaces, the airplane must be designed to withstand the ultimate loads that result from the yaw maneuver conditions specified in paragraphs (a) through (e) of this section at speeds from $V_{MC}$ or the highest airspeed for which it is possible to achieve maximum rudder deflection at zero sideslip, whichever is greater, up to $V_C/M_C$. The applicant must evaluate these conditions with the landing gear retracted and speed brakes (and spoilers when used as speed brakes) retracted. In computing the loads on the airplane, the applicant may assume yawing velocity to be zero. The applicant must assume a pilot force of 200 pounds when evaluating each of these conditions:

(a) With the airplane in unaccelerated flight at zero yaw, the flight deck rudder control is displaced as specified in § 25.351(a) and (b).

(b) With the airplane yawed to the overswing sideslip angle, the flight deck rudder control is suddenly displaced in the opposite direction.

(c) With the airplane yawed to the opposite overswing sideslip angle, the flight deck rudder control is suddenly displaced in the opposite direction.

(d) With the airplane yawed to the subsequent overswing sideslip angle, the flight deck rudder control is suddenly displaced in the opposite direction.

(e) With the airplane yawed to the opposite overswing sideslip angle, the flight deck rudder control is suddenly returned to neutral.

Issued under authority provided by 49 U.S.C. 106(f) and 44701(a) in Washington, DC, on July 2, 2018.

**Dorenda D. Baker,**

*Executive Director, Aircraft Certification Service.*

[FR Doc. 2018–15154 Filed 7–13–18; 8:45 am]

**BILLING CODE 4910–13–P**

## PENSION BENEFIT GUARANTY CORPORATION

### 29 CFR Parts 4041A, 4245, and 4281

**RIN 1212–AB38**

### Terminated and Insolvent Multiemployer Plans and Duties of Plan Sponsors

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Proposed rule.

**SUMMARY:** The Pension Benefit Guaranty Corporation proposes to amend its multiemployer reporting, disclosure, and valuation regulations to reduce the number of actuarial valuations required for smaller plans terminated by mass withdrawal, add a valuation filing requirement and a withdrawal liability reporting requirement for certain terminated plans and insolvent plans, remove certain insolvency notice and update requirements, and reflect the repeal of the multiemployer plan reorganization rules.

**DATES:** Comments must be submitted on or before September 14, 2018 to be assured of consideration.

**ADDRESSES:** Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* (Follow the online instructions for submitting comments.)
- *Email: reg.comments@pbgc.gov.* Refer to RIN 1212–AB38 in the subject line.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026.

All submissions must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and the RIN for this rulemaking (RIN 1212–AB38). All comments received will be posted without change to PBGC's website, *www.pbgc.gov,* including any personal information provided. Copies of comments may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, or calling 202–326–4040 during normal business hours. (TTY users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4040.)

**FOR FURTHER INFORMATION CONTACT:** Hilary Duke (*duke.hilary@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–326–4400, extension 3839. (TTY users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4400, extension 3839.)

**SUPPLEMENTARY INFORMATION:**

### Executive Summary—Purpose of the Regulatory Action

This proposed rule would make certain reporting and disclosure of multiemployer information to PBGC and interested parties more efficient and reflect the repeal of the multiemployer plan reorganization rules. The proposal would reduce costs by allowing smaller plans terminated by mass withdrawal to perform actuarial valuations less frequently and by removing certain notice requirements for insolvent plans. This would reduce plan administrative costs and, in turn, may reduce financial assistance provided by PBGC.

PBGC's legal authority for this action is based on section 4002(b)(3) of the Employee Retirement Income Security Act of 1974 (ERISA), which authorizes PBGC to issue regulations to carry out the purposes of title IV of ERISA; section 4041A(f)(2) of ERISA, which gives PBGC authority to prescribe reporting requirements for terminated plans; section 4245(e) of ERISA, which directs PBGC to prescribe requirements for notices regarding multiemployer plan insolvency; section 4261 of ERISA, which authorizes PBGC to provide financial assistance to insolvent plans, and section 4281(d)(3) of ERISA, which directs PBGC to prescribe requirements for notices to plan participants and beneficiaries in the event of a benefit suspension by an insolvent plan.

### Executive Summary—Major Provisions of the Regulatory Action

*Plan Sponsor Duties—Annual Valuation and Withdrawal Liability*

The plan sponsor of a multiemployer plan terminated by mass withdrawal is responsible for specific duties, including an annual actuarial valuation of the plan's assets and benefits. This proposed rule would reduce administrative burden by allowing the plan sponsor to perform an actuarial valuation only every 5 years if the present value of the plan's nonforfeitable benefits is $50 million or less. The proposed rule would add a new requirement for plan sponsors of certain terminated or insolvent plans to file actuarial valuations with PBGC. Where the present value of the plan's nonforfeitable benefits is $50 million or less, a plan receiving financial assistance from PBGC would be able to file alternative valuation information.

The plan sponsor of a multiemployer plan also is responsible for determining, giving notice of, and collecting withdrawal liability. The proposal would require plan sponsors of certain terminated or insolvent plans to file with PBGC information about withdrawal liability payments and whether any employers have withdrawn but have not yet been assessed withdrawal liability.

*Insolvency Notices and Updates*

A multiemployer plan terminated by mass withdrawal that is insolvent or is expected to be insolvent for a plan year must provide certain notices to PBGC and participants and beneficiaries. Similarly, a multiemployer plan that is certified by the plan's actuary to be in critical status and that is expected to become insolvent under section 4245 of ERISA must provide certain notices to PBGC and interested parties. Notices include a notice of insolvency and a notice of insolvency benefit level. The proposed rule would eliminate outdated information included in the notices. The proposal would require a plan to provide notices of insolvency if the plan sponsor determines the plan is insolvent in the current plan year or is expected to be insolvent in the next plan year. The proposal also would eliminate the requirement to provide most annual updates to the notices of insolvency benefit level.

### Background

The Pension Benefit Guaranty Corporation (PBGC) administers two insurance programs for private-sector defined benefit pension plans under title IV of the Employee Retirement Income Security Act of 1974 (ERISA): A single-employer plan termination insurance program and a multiemployer plan insolvency insurance program. In general, a multiemployer pension plan is a collectively bargained plan involving two or more unrelated employers. This proposed rule deals with multiemployer plans.

Under section 4041A of ERISA, a mass withdrawal termination of a plan occurs when all employers withdraw or cease to be obligated to contribute to the plan. A plan terminated by mass

withdrawal continues to pay all vested benefits from existing plan assets and withdrawal liability payments from withdrawn employers. PBGC's financial assistance to the terminated plan starts only if and when the plan sponsor determines that the plan is insolvent under section 4281(d) of ERISA. PBGC also provides financial assistance to certain plans in critical status that are not terminated or are terminated by plan amendment [1] if the plan sponsor determines that the plan is insolvent under section 4245 of ERISA.

Before 2015, financially troubled multiemployer plans entered a ''reorganization'' status if their funding was below a certain level. Plans in reorganization status were subject to certain rules affecting plan funding, benefits, and reporting and disclosure. The plan sponsor of a plan in reorganization that determined the plan was insolvent or was expected to be insolvent for a plan year was required to provide PBGC and interested parties notices regarding the plan's insolvency. The Pension Protection Act of 2006 established critical and endangered statuses for underfunded plans and provided new tools to help multiemployer plans in those statuses improve plan funding but did not repeal the reorganization rules. Section 108 of the Multiemployer Pension Reform Act of 2014 (MPRA) repealed the rules on reorganization under section 4241 of ERISA effective for plan years beginning after December 31, 2014. MPRA also amended the notice requirements under section 4245(e) of ERISA and 418E(e) of the Internal Revenue Code (Code) to replace the references to a plan in reorganization with references to a plan in critical status. These amendments did not substantively change the notice requirements.

This proposed rule would reduce reporting and disclosure requirements for multiemployer plans that are terminated by mass withdrawal or in critical status and that are, or are expected to be, insolvent.[2] PBGC identified these proposed amendments as part of its ongoing retrospective review under Executive Order 13563 ''Improving Regulation and Regulatory Review.'' Executive Order 13563 provides for Federal regulations to use less burdensome means to achieve policy goals, and for agencies to give careful consideration to the benefits and costs of those regulations. Comments received from one commenter in response to PBGC's July 2017 Request for Information[3] support the proposed changes to reduce notice requirements for insolvent plans.

## Proposed Regulatory Changes

### *Annual Valuation Requirement*

PBGC's regulation on Termination of Multiemployer Plans (29 CFR part 4041A) establishes rules for the administration of multiemployer plans that have terminated by mass withdrawal, including basic duties of plan sponsors of plans terminated by mass withdrawal. Among the requirements, the plan sponsor of a plan terminated by mass withdrawal must value the plan's nonforfeitable benefits and assets as of the last day of the plan year in which the plan terminates and the last day of each plan year thereafter. The details of the annual actuarial valuation requirement are provided in subpart B of PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281).

The plan sponsor of a plan terminated by mass withdrawal uses the annual actuarial valuation to determine whether the value of nonforfeitable benefits exceeds the value of assets. If benefits exceed assets, the plan may need to reduce benefits. If no benefits are subject to reduction, the plan will continue to make periodic determinations of plan solvency. The proposed rule would revise § 4041A.25 of the multiemployer termination regulation to clarify the timing of the plan sponsor's determinations of plan solvency by combining similar provisions to eliminate repetition and by removing potentially confusing language.

The plan sponsor of a plan in critical status must also make determinations of plan solvency. If the plan sponsor determines under section 4245(d) of ERISA that the plan is expected to be insolvent for a plan year, the plan must file a notice with PBGC, including a copy of the most recent actuarial valuation for the plan. PBGC uses the annual actuarial valuation to estimate the liabilities PBGC will incur when the plan becomes insolvent and for purposes of its financial statements.

PBGC is proposing to reduce the number of plans terminated by mass withdrawal that are required to prepare an annual actuarial valuation. Section 4041A.24 of the multiemployer termination regulation provides that if the value of nonforfeitable benefits for a plan terminated by mass withdrawal is $25 million or less as determined for a plan year, the plan sponsor may use the actuarial valuation for the next two years and perform a new actuarial valuation for the third plan year. The proposed rule would increase the threshold requirement for plans and allow them to use less frequent actuarial valuations. A plan would be able to use an actuarial valuation for 5 years if the present value of the plan's nonforfeitable benefits is $50 million or less and be in compliance with the statutory requirement that there be an annual written determination of the value of the plan's nonforfeitable benefits and the plan's assets.

If the present value of a plan's nonforfeitable benefits exceeds $50 million, the plan would continue to be required to perform actuarial valuations annually.[4] Plans could move in and out of the 5-year or annual valuation cycle, as applicable, as the value of nonforfeitable benefits changes. Thus, a plan that had been using an actuarial valuation for 5 years would be required to perform actuarial valuations annually if the most recent actuarial valuation indicates that the present value of the plan's nonforfeitable benefits exceeds $50 million. Similarly, a plan that had been performing the actuarial valuation annually would be able to use the actuarial valuation for 5 years if the most recent actuarial valuation shows the present value of the plan's nonforfeitable benefits to be $50 million or less.

To estimate PBGC's multiemployer plan liabilities, PBGC also is proposing to add the annual actuarial valuation requirement for insolvent plans receiving financial assistance from PBGC (whether terminated or not terminated) and plans terminated by plan amendment that are expected to become insolvent.[5] The provision allowing smaller plans to use less frequent actuarial valuations would be available to these plans. In addition, where the present value of the plan's nonforfeitable benefits is $50 million or less, a plan receiving financial assistance from PBGC could comply with the actuarial valuation requirement by filing alternative information as

[1] Termination of a multiemployer plan by plan amendment is determined under section 4041A(a)(1) of ERISA.

[2] In 2014, PBGC amended its regulations to reduce the number of actuarial valuations required for certain smaller terminated plans and remove certain insolvency notice and update requirements. *See* 79 FR 30459 (May 28, 2014). This rulemaking is a continuation of that effort to reduce plan burden.

[3] PBGC Regulatory Planning and Review of Existing Regulations, Request for Information (82 FR 34619, July 26, 2017).

[4] No valuation is required for a plan year in which the plan is closed out in accordance with subpart D of part 4041A.

[5] Section 4041A.24(a)(2) of PBGC's termination regulation currently excludes plans receiving financial assistance from PBGC from the annual actuarial valuation requirement.

specified in valuation instructions on PBGC's website.

SUMMARY OF ACTUARIAL VALUATION FILING REQUIREMENTS

| Size of plan according to most recent actuarial valuation | Frequency of actuarial valuation: terminated plans and insolvent plans | Alternative information permitted to be filed: plans receiving financial assistance |
|---|---|---|
| Present Value of Plan's Nonforfeitable Benefits is $50 Million or Less | Every 5 Years | Yes. |
| Present Value of Plan's Nonforfeitable Benefits Exceeds $50 Million | Each Year | No. |

The proposed amendments would enable PBGC to continue to have reasonably reliable data to measure its liabilities, while reducing burden on plans that present smaller exposure. PBGC currently obtains actuarial valuations for plans receiving financial assistance by contacting plan sponsors. The proposal would require a plan sponsor to file the plan's actuarial valuation with PBGC within 180 days after the end of the plan year for which the actuarial valuation is performed. Having plans file the actuarial valuation or alternative valuation information within the proposed time period would provide for a more efficient process for plans and PBGC. The proposed rule would also make clarifications and other editorial changes to part 4041A.

*Withdrawal Liability Payments*

The plan sponsor of a multiemployer plan is required to determine and collect withdrawal liability in accordance with section 4219 of ERISA. The plan sponsor assesses withdrawal liability by issuing a notice to an employer, including the amount of the employer's liability and a schedule of payments. The plan sponsor also must file with PBGC a certification that notices have been provided to employers.[6]

PBGC uses information about withdrawal liability payments and settlements, and whether employers have withdrawn from the plan but have not yet been assessed withdrawal liability, to estimate PBGC's multiemployer liabilities for purposes of its financial statements and to provide financial assistance to plans.[7] It is particularly important for PBGC to identify all sources of available funding given the declining financial position of the multiemployer program. As of September 30, 2017, there were 72 insolvent plans that received financial assistance from PBGC and 68 terminated plans not yet receiving financial assistance.[8] The number of plans receiving and expected to receive financial assistance led PBGC to examine the way it obtains withdrawal liability information.

PBGC is proposing that plan sponsors of plans subject to the actuarial valuation requirement (plans terminated by mass withdrawal, plans terminated by plan amendment that are expected to become insolvent, and insolvent plans receiving financial assistance from PBGC (whether terminated or not terminated)), file with PBGC information about withdrawal liability, in the aggregate and by employer, that the plan has or has not yet assessed withdrawn employers. The information would be specified in the withdrawal liability instructions on PBGC's website. For each employer not yet assessed withdrawal liability, information would include the name of the employer and the reasons the employer has not yet been assessed withdrawal liability. For each employer assessed withdrawal liability, information would include the name of the employer and whether there are scheduled periodic payments or there has been a lump-sum settlement. For periodic payments, information would include the start date, end date, frequency of payment (monthly, quarterly, annually), amount of payment, and whether the employer is current on making its payments. For lump sum settlements, information would include the amount and date of payment. To satisfy the filing requirement for employers assessed withdrawal liability, a plan sponsor could choose to file documents already prepared containing the withdrawal liability information for each employer, such as withdrawal liability notices setting forth scheduled payments or withdrawal liability settlement agreements.

The proposal would require a plan sponsor to file the withdrawal liability information with PBGC within 180 days after the earlier of the end of the plan year in which the plan terminates or becomes insolvent and each plan year thereafter, unless there is no updated information to file. Having plans file the withdrawal liability information electronically and within the proposed time period would provide for an efficient process for plans and PBGC.

*Terminated and Insolvent Plan Notices*

The plan sponsor of a multiemployer plan terminated by mass withdrawal must make determinations of insolvency annually in accordance with section 4281 of ERISA and the plan sponsor of a multiemployer plan in critical status must make determinations of insolvency in accordance with section 4245(d) of ERISA. When the plan sponsor of a multiemployer plan determines that the plan's resources are not sufficient to pay the promised level of benefits stated in the plan when due during the plan year, the plan sponsor must suspend benefits above the amount that assets will cover. However, benefits may not be reduced to an amount less than the PBGC guarantee level. Plans that are not able to pay benefits at the promised level of benefits stated in the plan are required to notify PBGC and plan participants and beneficiaries.

The notice requirements for plans that have terminated by mass withdrawal are provided under subpart D of PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281). Similar notice requirements are provided for plans that are in critical status under PBGC's regulation on Notice of Insolvency (29 CFR part 4245). Under the latter, in addition to notifying PBGC and participants and beneficiaries, plans must notify other interested parties, including employers required to contribute to the plan and employee organizations that, for collective bargaining purposes, represent participants employed by such employers.

There are two types of notice that plans must provide: A ''notice of insolvency,'' stating the plan year that the plan is insolvent or is expected to be insolvent, and a ''notice of insolvency benefit level,'' stating the level of benefits that will be paid during

[6] *See* 29 CFR 4219.17.

[7] PBGC may prescribe reporting requirements for terminated plans under section 4041A(f)(2) of ERISA.

[8] *See* PBGC FY 2017 Annual Report, page 94 at *https://www.pbgc.gov/sites/default/files/pbgc-annual-report-2017.pdf.*

a plan year in which a plan is insolvent. The proposed rule would require the plan sponsor of a critical status plan or of a plan terminated by mass withdrawal to provide notices of insolvency if it determines that the plan is insolvent in the current plan year or is expected to be insolvent in the next plan year. The proposal also would make the timing of the delivery of the notice of insolvency and the notice of insolvency benefit level the same—by the later of 90 days before the beginning of the insolvency year or 30 days after the date the insolvency determination is made. In addition, the proposal would allow the plan sponsor to provide one combined notice for the same insolvency year.

PBGC's regulations currently require plan sponsors to provide the notice of insolvency benefit level annually. PBGC's experience has been that virtually all multiemployer plans that become insolvent will remain so. Thus, once a plan sponsor has provided the initial notice of insolvency benefit level, there is little need to require the plan sponsor to provide similar subsequent notices. Consequently, PBGC is proposing to eliminate most of the annual updates to the notices of insolvency benefit level. The plan sponsor would provide updated notices to PBGC and to all participants and beneficiaries only if there is a change in the amount of benefits paid that affects participants and beneficiaries generally. If a participant or beneficiary enters pay status or is reasonably expected to enter pay status during the insolvency year, or there is a change in benefit level that affects only one participant or beneficiary or a participant class, a notice would only be required to be provided to PBGC and to each affected person. For example, in the latter case, if a participant enters pay status or a participant's death results in the payment of benefits to the participant's beneficiary, only PBGC and those affected participants and beneficiaries would be provided notices.

Plan sponsors are required to electronically file notices of termination, notices of insolvency, and notices of insolvency benefit level.[9] The proposed rule would move the content requirements for these notices filed with PBGC from the regulations to instructions available on PBGC's website. PBGC generally considers it preferable to describe information to be filed only in the filing instructions, and not in the regulation prescribing the filing, to avoid having two authoritative descriptions of the same requirements and to make it easier for filers to find the information they need in one place. The proposed rule also would make changes to the contents of the notice of insolvency and notice of insolvency benefit level by eliminating outdated information and, consistent with MPRA, by removing references to reorganization in the notice of insolvency regulation. The proposed rule would also make clarifications and other editorial changes to parts 4245 and 4281.

*Application for Financial Assistance*

The plan sponsor of a multiemployer plan must apply to PBGC for financial assistance if the plan sponsor determines that the plan's resource benefit level will be below the level of benefits guaranteed by PBGC or that the plan will be unable to pay guaranteed benefits when due for any month during the year. Section 4281.47 of PBGC's duties of plan sponsor regulation requires a plan sponsor to file an initial application with PBGC at the same time that it files a notice of insolvency benefit level. When the plan sponsor determines an inability to pay guaranteed benefits for any month, the plan sponsor must file a recurring application within 15 days after the plan sponsor makes the determination. To provide PBGC adequate time to review applications for financial assistance, the proposed rule would require an initial application to be filed no later than 90 days before the first day of the month for which the plan sponsor has determined that the resource benefit level will be below the level of guaranteed benefits. The proposed rule would require a recurring application to be filed as soon as practicable after the plan sponsor determines the plan will be unable to pay guaranteed benefits when due for a month and make other editorial changes. The contents of the applications for financial assistance would be moved from the regulations to instructions on PBGC's website.

**Applicability**

The amendments to §§ 4041A.2, 4041A.12 and 4041A.25 of the multiemployer termination regulation that make changes to the definitions, the content of the notice of termination, and the determination of plan solvency would be applicable as of the effective date of the final rule.

The amendments to § 4041A.23 of the multiemployer termination regulation and to part 4245 that require plan sponsors to file with PBGC withdrawal liability information would be applicable for plan years ending after the effective date of the final rule.

The amendments to § 4041A.24 of the multiemployer termination regulation and to part 4245 that change the annual actuarial valuation requirement would be applicable to actuarial valuations prepared for plan years ending after the effective date of the final rule.

The amendments to part 4245 and part 4281 that make changes to the content and timing of the notices of insolvency and notices of insolvency benefit level and that make changes to the timing of an application for financial assistance would be applicable as of the effective date of the final rule.

**Executive Orders 12866, 13563, and 13771**

PBGC has determined that this rulemaking is not a ''significant regulatory action'' under Executive Order 12866 and Executive Order 13771. Accordingly, this proposed rule is exempt from Executive Order 13771 and OMB has not reviewed the rule under Executive Order 12866.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule is associated with retrospective review and analysis in PBGC's Plan for Regulatory Review issued in accordance with Executive Order 13563.

Although this is not a significant regulatory action under Executive Order 12866, PBGC has examined the economic implications of this proposed rule and has concluded that the amendments to the annual actuarial valuation requirements and notice of insolvency and notice of insolvency benefit level would reduce costs for multiemployer plans by approximately $438,000. The analysis is as follows.

*Annual Actuarial Valuation Requirement*

PBGC has estimated the value of this proposed rule for the annual actuarial valuation requirements for plans terminated by mass withdrawal that are not insolvent (assuming an annual

[9] Section 4000.3(b)(4) of PBGC's regulation on Filing, Issuance, Computation of Time, and Record Retention requires, with exceptions, filings to PBGC under parts 4041A, 4245, and 4281 to be made electronically in accordance with the instructions on PBGC's website, except as otherwise provided by PBGC.

actuarial valuation cost of $12,000 per plan for plans whose nonforfeitable benefits have a present value of $25 million or less and cost of $30,000 per plan for plans whose nonforfeitable benefits have a present value in the range of $25 to $50 million.[10]). As of the end of the 2017 fiscal year, there were 68 terminated plans that were not insolvent. Of that total, there were 47 plans whose nonforfeitable benefits have a present value of $25 million or less that will be able to use an actuarial valuation for 5 years instead of 3 years for annual savings of approximately $75,200 (47 × $12,000 × .1333 (1/3–1/5)) and 8 plans whose nonforfeitable benefits have a present value in the range of $25 to $50 million that will be able to use an actuarial valuation for 5 years instead of 1 year for annual savings of approximately $192,000 (8 × $30,000 × .8 (1–1/5)). PBGC estimates annual aggregate savings of approximately $267,200 to these plans.

As of the end of the 2017 fiscal year, there were 72 insolvent plans. Of that total, there were 15 insolvent plans whose nonforfeitable benefits have a present value exceeding $50 million. As PBGC currently obtains actuarial valuations from these insolvent plans and provides financial assistance for the cost of performing the actuarial valuations, PBGC believes there is no additional cost under this proposed rule for performing insolvent plan actuarial valuations.

The savings under the proposed rule are offset by the annual cost of the actuarial valuation and alternative valuation filing requirements. PBGC estimates that each year, approximately 40 plans will file actuarial valuations and approximately 10 plans will file alternative valuation information. As discussed below under the Paperwork Reduction Act analysis, PBGC estimates an annual aggregate hour burden of 20 hours at an estimated dollar equivalent of $1,500 and an annual aggregate cost burden of $8,000.

*Withdrawal Liability Filing*

Under the proposed rule, PBGC expects to receive withdrawal liability information from approximately 140 plans. As discussed below under the Paperwork Reduction Act analysis, PBGC estimates an annual hour burden of 140 hours at an estimated dollar equivalent of $10,500 and an annual cost burden of $56,000.

[10] The cost of an actuarial valuation varies greatly by plan size. Based on plan actuary experience, an actuarial valuation for a smaller plan where the present value of the plan's nonforfeitable benefits is $50 million or less may cost approximately $10,000 to $35,000.

*Annual Notice Updates*

As discussed below under the Paperwork Reduction Act analysis, PBGC estimates that the annual aggregate cost of preparing the notice of insolvency and notice of insolvency benefit level without the proposed rule, and based on recent plan experience, is approximately $627,400 ($12,000 + $615,400). This estimate is based on an estimated 11 plans required to issue the notice of insolvency and 55 plans required to issue an annual update to the notice of insolvency benefit level. Allowing plans to issue a combined notice and eliminating most of the annual updates to the notice of insolvency benefit level will reduce the cost to $380,400, saving plans approximately $247,000 ($627,400 − $380,400).

**Regulatory Flexibility Act**

The Regulatory Flexibility Act imposes certain requirements with respect to rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a rule is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the Regulatory Flexibility Act requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the proposed rule describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations and governmental jurisdictions.

*Small Entities*

For purposes of the Regulatory Flexibility Act requirements with respect to this proposed rule, PBGC considers a small entity to be a plan with fewer than 100 participants. This is substantially the same criterion PBGC uses in other regulations [11] and is consistent with certain requirements in title I of ERISA [12] and the Code,[13] as well as the definition of a small entity that the Department of Labor has used for purposes of the Regulatory Flexibility Act.[14]

Thus, PBGC believes that assessing the impact of the proposed rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business based on size standards promulgated by the Small Business Administration (13 CFR 121.201) pursuant to the Small Business Act. PBGC therefore requests comments on the appropriateness of the size standard used in evaluating the impact on small entities of the proposed amendments.

*Certification*

On the basis of its definition of small entity, PBGC certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that the amendments in this rule will not have a significant economic impact on a substantial number of small entities. Based on data for the 2017 fiscal year, PBGC estimates that only 16 small plans of the approximately 1,400 plans covered by PBGC's multiemployer program will be required to file withdrawal liability information and an actuarial valuation or alternative valuation information under the proposed rule. An estimated three small plans will be relieved of the burden to prepare and distribute an annual notice of insolvency benefit level update to participants and beneficiaries. This is not a substantial number of small plans. Accordingly, as provided in section 605 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), sections 603 and 604 do not apply.

**Paperwork Reduction Act**

PBGC is submitting the information requirements under this proposed rule to the Office of Management and Budget (OMB) under the Paperwork Reduction Act. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The collection of information in part 4041A is approved under control number 1212–0020 (expires November 30, 2018). Based on recent plan experience, PBGC estimates that the current notice of termination and other requirements in part 4041A have an annual burden of 69 hours and a cost of $50,000, increased from an estimated 17 hours and $3,850.

[11] *See, e.g.,* special rules for small plans under part 4007 (Payment of Premiums).

[12] *See, e.g.,* ERISA section 104(a)(2), which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants.

[13] *See, e.g.,* Code section 430(g)(2)(B), which permits plans with 100 or fewer participants to use valuation dates other than the first day of the plan year.

[14] *See, e.g.,* Department of Labor's final rule on Prohibited Transaction Exemption Procedures, 76 FR 66637, 66644 (Oct. 27, 2011).

PBGC estimates that the proposed changes to file withdrawal liability information electronically would have a minimal hour and cost burden as it is expected that the information would be easily accessible and that most plans would use documents already prepared containing withdrawal liability information. PBGC estimates that approximately 140 plans would file withdrawal liability information and that it would take each plan approximately 2 hours to electronically file the information. PBGC further estimates that the filings would be completed by pension fund office staff (50%) and outside attorneys (50%). The total hour burden would be approximately 140 hours of pension fund office time at an estimated dollar equivalent of $10,500 (based on an assumed hourly rate of $75 for administrative, clerical, and supervisory time). The total cost burden would be approximately $56,000 (based on 140 contracted hours assuming an average hourly rate of $400).

PBGC expects that an estimated 40 plans (28 plans with nonforfeitable benefits that exceed $50 million plus 12 plans with nonforfeitable benefits of $50 million or less) would file actuarial valuations and that it would take each plan 30 minutes to file the information electronically. PBGC expects that an estimated 10 plans receiving financial assistance from PBGC would file alternative valuation information and that it would take each plan 2 hours to file the information electronically. PBGC further estimates that the filings would be completed by pension fund office staff (50%) and outside attorneys (50%). The total estimated hour burden to file the actuarial valuations and to complete and file the alternative valuation information would be approximately 20 hours of pension fund office time at an estimated dollar equivalent of $1,500 (based on an assumed hourly rate of $75 for administrative, clerical, and supervisory time). The total cost burden would be approximately $8,000 (based on 20 contracted hours assuming an average hourly rate of $400).

PBGC estimates that without the proposed rule there would be 2,111 notices and responses and that the total annual burden of the collection of information in part 4041A would be about 69 hours and $50,000. PBGC estimates that with the proposed rule there would be 2,301 notices and responses each year and that the total annual burden of the collection of information would be an hour burden of about 229 hours for pension fund office time (69+140+20) at an estimated dollar equivalent of $17,175 and a cost burden for work by outside consultants of $114,000 ($50,000+$56,000+$8,000).

The collection of information in part 4245 is approved under control number 1212–0033 (expires November 30, 2018). PBGC estimates that only 1 plan would issue new notices of insolvency under part 4245 and that each year there would be 1,038 notices or combined notices issued to participants and beneficiaries, PBGC, and other interested parties. PBGC previously estimated that the notices were prepared and distributed by outside consultants and that the annual hour burden was 1 hour and the annual cost burden was $723. Based on recent plan experience, the time to prepare and distribute the notices can vary significantly by plan size. PBGC estimates that without the proposed rule, the annual hour burden would be 20 hours and the annual cost burden would be $12,000. The proposed regulation would reduce the burden by allowing plans to combine the notice of insolvency and the notice of insolvency benefit level and by eliminating most of the annual updates to participants and beneficiaries. PBGC estimates the proposed rule would reduce the annual hour burden to 16 hours of pension fund office time and the annual cost burden for work by outside consultants to $10,000.

The collection of information in part 4281 is approved under control number 1212–0032 (expires November 30, 2018). PBGC expects to receive the following notices under part 4281: 1 notice of benefit reduction; 10 notices of insolvency; 55 notices of insolvency benefit level; 10 initial applications for financial assistance; and 300 non-initial applications for financial assistance. PBGC's estimates previously assumed that the notices were prepared and distributed by outside consultants. PBGC estimated an annual hour burden of 60 hours and an annual cost burden of $309,020. Based on recent plan experience and information that the notices are distributed by pension fund offices, PBGC estimates an annual hour burden of 1,300 hours and an annual cost burden of $615,400. Under the proposed rule, most of the annual updates to the notice of insolvency benefit level would be eliminated unless there is a change in benefit level. PBGC estimates the proposed change would reduce the number of plans issuing notices of insolvency benefit level from 55 plans to approximately 5 plans. PBGC estimates that 13,826 notices and applications would be issued annually under part 4281. PBGC estimates that the proposed rule would reduce the annual hour burden to 240 hours of pension fund office time and the annual cost burden for work by outside consultants to $370,400.

**List of Subjects**

*29 CFR Part 4041A*

Employee benefit plans, Pension insurance, Reporting and recordkeeping requirements.

*29 CFR Part 4245*

Employee benefit plans, Pension insurance, Reporting and recordkeeping requirements.

*29 CFR Part 4281*

Employee benefit plans, Pension insurance, Reporting and recordkeeping requirements.

For the reasons given above, PBGC proposes to amend 29 CFR chapter XL and 29 CFR parts 4041A, 4245, and 4281 as follows:

## PART 4041A—TERMINATION OF MULTIEMPLOYER PLANS

■ 1. The authority citation for part 4041A is revised to read as follows:

**Authority:** 29 U.S.C. 1302(b)(3), 1341a, 1431, 1441.

■ 2. In § 4041A.2:

■ a. Add in alphabetical order a definition for ''Actuarial valuation'';

■ b. Amend the definition of ''Available resources'' by removing ''means, for a plan year, available'' and adding in its place ''means available'';

■ c. Amend the definition of ''Benefits subject to reduction'' by removing ''the PBGC's'' and adding in its place ''PBGC's'';

■ d. Amend the definition of ''Financial assistance'' by removing ''the PBGC'' and adding in its place ''PBGC'';

■ e. Amend the definition of ''Insolvency benefit level'' by removing ''the PBGC'' and adding in its place ''PBGC'';

■ f. Amend the definition of ''Insolvent'' by removing in the first sentence ''that a plan is unable'' and adding in its place ''unable'' and by removing the second sentence;

■ g. Amend the definition of ''Nonguaranteed benefits'' by removing ''the PBGC's'' and adding in its place ''PBGC's''.

The addition reads as follows:

**§ 4041A.2 Definitions.**

* * * * *

*Actuarial valuation* means a report submitted to a plan of a valuation of plan assets and liabilities that is performed in accordance with subpart B of part 4281 of this chapter.

* * * * *

**§ 4041A.11 [Amended]**

■ 3. In § 4041A.11:

■ a. Amend paragraph (a) by removing ''A Notice of Termination shall be filed with the PBGC'' and adding in its place ''A notice of termination must be filed with PBGC'';

■ b. Amend the paragraph heading in paragraph (b) by removing ''shall'' and adding in its place ''must'' and the text is amended by removing ''shall sign and file the Notice.'' and adding in its place ''must sign and file the notice.'';

■ c. Amend paragraph (c)(1) by removing ''the Notice shall be filed with the PBGC'' and adding in its place ''the notice must be filed with PBGC'';

■ d. Amend paragraph (c)(2) by removing ''the Notice shall be filed with the PBGC'' and adding in its place ''the notice must be filed with PBGC'';

■ e. Amend paragraph (d) by removing ''Filings to PBGC'' and adding in its place ''Filings with PBGC''.

■ 4. Revise section 4041A.12 to read as follows:

**§ 4041A.12 Contents of notice.**

(a) *Information to be contained in notice.* A notice of termination under § 4041A.11 required to be filed with PBGC must contain the information and certification specified in the instructions for the notice of termination on PBGC's website (*www.pbgc.gov*).

(b) *Additional information.* In addition to the information required under paragraph (a) of this section, PBGC may require the submission of any other information that PBGC determines is necessary for review of a notice of termination.

**§ 4041A.21 [Amended]**

■ 5. In § 4041A.21:

■ a. Amend the first sentence by removing ''shall'' and adding in its place ''must'';

■ b. Amend the second sentence by removing ''shall be'' and adding in its place ''is'' and by removing ''this subpart.'' and adding in its place ''this subpart C.'';

■ 6. In § 4041A.23:

■ a. Amend the section heading by removing ''Imposition and collection of withdrawal liability.'' and adding in its place ''Withdrawal liability.'';

■ b. Redesignate the text of § 4041A.23 as paragraph (a) with the paragraph heading ''*Collection of withdrawal liability.*'';

■ c. Amend paragraph (a) by removing ''shall be responsible for determining, imposing and collecting'' and adding in its place ''must determine, give notice of, and collect'' and by removing ''part 4219, subpart C,'' and adding in its place ''subpart C of part 4219'';

■ d. Add paragraph (b) to read as follows:

**§ 4041A.23 Withdrawal liability.**

* * * * *

(b) *Filing of withdrawal liability information.* For each employer that has withdrawn from the plan, the plan sponsor must file with PBGC, not later than 180 days after the end of the plan year in which the plan terminates and each plan year thereafter, the information specified in the withdrawal liability instructions on PBGC's website (*www.pbgc.gov*).

■ 7. Revise § 4041A.24 to read as follows:

**§ 4041A.24 Plan valuations and monitoring.**

(a) *Annual valuation requirement.* The plan sponsor of a plan must have actuarial valuations performed in accordance with this section and with subpart B of part 4281.

(1) *Termination year valuation.* The plan sponsor of a plan must have an actuarial valuation performed for the plan for the plan year in which the plan terminates.

(2) *High-obligation valuations.* If the present value of a plan's nonforfeitable benefits exceeds $50 million according to the most recent actuarial valuation under this paragraph (a), the plan sponsor must have an actuarial valuation performed for the plan for each plan year.

(3) *Low-obligation valuations.* If the present value of a plan's nonforfeitable benefits does not exceed $50 million according to the most recent actuarial valuation under this paragraph (a), the plan sponsor may treat that actuarial valuation as the actuarial valuation for each of the four plan years following the plan year for which the actuarial valuation was performed.

(4) *Timing and filing.* Each actuarial valuation under this paragraph (a) must be performed within 150 days after the end of the plan year for which it is performed and must be filed with PBGC within 180 days after the end of that plan year in accordance with the valuation instructions on PBGC's website (*www.pbgc.gov*).

(5) *Exception for plans closing out.* Notwithstanding paragraphs (a)(1) through (a)(4) of this section, no actuarial valuation is required for the plan year in which a plan closes out under subpart D of this part.

(b) *Plan monitoring; benefit reductions*—(1) *Applicability.* This paragraph (b) applies to a plan that is not receiving financial assistance from PBGC for the plan year following the plan year for which an actuarial valuation is performed under paragraph (a) of this section.

(2) *Funding level determination.* Upon receipt of each actuarial valuation under paragraph (a) of this section, the plan sponsor must determine whether the value of nonforfeitable benefits exceeds the value of plan assets (including withdrawal liability claims). If it does, then the plan sponsor must—

(i) Amend the plan to reduce benefits subject to reduction (if any) in accordance with the procedures in subpart C of part 4281 of this chapter to the extent necessary to ensure that the plan's assets are sufficient to discharge when due all of the plan's obligations with respect to nonforfeitable benefits or, if that result cannot be achieved, to the maximum extent possible; and

(ii) If, after implementing the provisions of paragraph (b)(2)(i) of this section, the plan's assets are insufficient to discharge when due all of the plan's obligations with respect to nonforfeitable benefits, make determinations of plan solvency in accordance with § 4041A.25.

(3) *Notices of benefit reduction.* The plan sponsor of a plan that is amended to reduce benefits under paragraph (b)(2)(i) of this section must provide participants and beneficiaries and PBGC notice of the benefit reduction in accordance with § 4281.32 of this chapter.

(c) *Alternative method of compliance*—(1) *Applicability.* Paragraph (c) of this section applies to a plan that meets both of the following requirements—

(i) The plan is receiving financial assistance from PBGC for the plan year following the plan year for which an actuarial valuation is required under paragraph (a) of this section.

(ii) The present value of the plan's nonforfeitable benefits does not exceed $50 million according to the most recent actuarial valuation under paragraph (a) of this section.

(2) *Alternative compliance requirements.* A plan sponsor is considered to comply with the actuarial valuation and filing requirements of paragraph (a) of this section if both—

(i) The plan sponsor files with PBGC the information in paragraph (c)(3) of this section within the time required for filing the actuarial valuation under paragraph (a)(4) of this section, and

(ii) If, within 90 days after the plan sponsor makes the filing described in paragraph (c)(2)(i) of this section, PBGC requests other information reasonably required to determine the plan's assets and liabilities, the plan sponsor files such other information within 60 days after PBGC's request.

(3) *Information to be provided.* The information the plan sponsor must file with PBGC under paragraph (c)(2)(i) of this section is all of the following:

(i) The most recent summary plan description of the plan or the date the document was previously filed with PBGC.

(ii) The most recent actuarial valuation of the plan or the date the document was previously filed with PBGC.

(iii) Information reasonably necessary for PBGC to prepare an actuarial valuation as specified in the valuation instructions on PBGC's website (*www.pbgc.gov*).

■ 8. In § 4041A.25:

■ a. Revise paragraphs (a) and (b);

■ b. Amend paragraph (c) by removing ''shall'' and adding in its place ''must'';

■ c. Amend paragraph (d) by removing ''If the plan sponsor determines that the plan is, or is expected to be, insolvent for a plan year, it shall'' and adding in its place ''If the plan sponsor determines that the plan is insolvent in the current plan year or is expected to be insolvent in the next plan year it must'' and by removing ''the PBGC'' and adding in its place ''PBGC''.

The revisions read as follows:

**§ 4041A.25 Periodic determinations of plan solvency.**

(a) *Annual insolvency determination.* A plan that has no benefits subject to reduction and has assets insufficient to discharge when due all of the plan's obligations with respect to nonforfeitable benefits must make periodic determinations of plan solvency in accordance with this paragraph (a). No later than six months before the beginning of the applicable plan year described in this paragraph (a), or as soon as practicable after the plan sponsor determines the applicable plan year, and no later than six months before each plan year thereafter, the plan sponsor must determine in writing whether the plan is expected to be insolvent for such plan year. The applicable plan year is—

(1) For a plan that had no benefits subject to reduction when it terminated, the plan year the plan terminated; or

(2) For a plan that eliminated benefits subject to reduction by amendment after termination, the plan year in which the amendment that eliminated all (or all remaining) benefits subject to reduction is effective.

(b) *Other determination of insolvency.* Whether or not a prior determination of plan insolvency has been made under paragraph (a) of this section (or under section 4245 of ERISA), a plan sponsor that has reason to believe, taking into account the plan's recent and anticipated financial experience, that the plan is insolvent in the current plan year or is expected to be insolvent in the next plan year must determine in writing whether the plan is or is expected to be insolvent for that plan year.

* * * * *

**SUBCHAPTER J—INSOLVENCY, REORGANIZATION, TERMINATION, AND OTHER RULES APPLICABLE TO MULTIEMPLOYER PLANS**

■ 9. Amend the heading for Subchapter J by removing ''reorganization,''.

## PART 4245—NOTICE OF INSOLVENCY

■ 10. The authority citation for part 4245 is revised to read as follows:

**Authority:** 29 U.S.C. 1302(b)(3), 1341a, 1431, 1426(e).

■ 11. Revise the heading for Part 4245 to read as follows:

## PART 4245—DUTIES OF PLAN SPONSOR OF AN INSOLVENT PLAN

■ 12. Revise § 4245.1 to read as follows:

**§ 4245.1 Purpose, scope, and filing and issuance rules.**

(a) *Purpose and scope.* This part prescribes insolvency notice requirements and financial assistance requirements pertaining to critical status plans. Plans that have terminated by mass withdrawal under section 4041A(a)(2) of ERISA are required to file and issue similar insolvency notices under part 4281 of this chapter and withdrawal liability and actuarial valuation information under part 4041A of this chapter.

(b) *Filing and issuance rules.*—(1) *Method of filing.* Filing with PBGC under this part must be made by a method permitted under the rules in subpart A of part 4000 of this chapter.

(2) *Method of issuance.* The issuance of the notice of insolvency benefit level to interested parties must be made by one of the following methods—

(i) A method permitted under the rules in subpart B of part 4000 of this chapter.

(ii) For interested parties other than participants and beneficiaries who are in pay status or reasonably expected to enter pay status during the insolvency year for which the notice is given, the plan sponsor may post the notice at participants' work sites or publish the notice in a union newsletter or in a newspaper of general circulation in the area or areas where participants reside. Notice to a participant is deemed notice to that participant's beneficiary or beneficiaries.

(3) *Filing and issuance dates.* The date that a filing is sent and the date that an issuance is provided are determined under the rules in subpart C of part 4000 of this chapter.

(4) *Where to file.* Filings with PBGC under this part must be made as described in § 4000.4 of this chapter.

(5) *Computation of time.* The time period for filing or issuance under this part must be computed under the rules in subpart D of part 4000 of this chapter.

■ 13. In § 4245.2:

■ a. Revise the definition of ''Actuarial valuation'';

■ b. Amend the definition of ''Available resources'' by removing ''means, for a plan year, available'' and adding in its place ''means available'';

■ c. Amend the definition of ''Benefits subject to reduction'' by removing ''the PBGC's'' and adding in its place ''PBGC's'';

■ d. Amend the definition of ''Financial assistance'' by removing ''the PBGC'' and adding in its place ''PBGC'';

■ e. Amend the definition of ''Insolvency benefit level'' by removing ''the PBGC'' and adding in its place ''PBGC'';

■ f. Amend the definition of ''Insolvent'' by removing in the first sentence ''that a plan is unable'' and adding in its place ''unable'' and by removing the second sentence;

■ g. Add in alphabetical order a definition for ''Interested parties'';

■ h. Remove the definition of ''Reorganization''.

The revision and addition read as follows:

**§ 4245.2 Definitions.**

* * * * *

*Actuarial valuation* means a report submitted to a plan of a valuation of plan assets and liabilities that is performed in accordance with subpart B of part 4281 of this chapter.

* * * * *

*Interested parties* means, with respect to a plan,—

(1) Employers required to contribute to the plan;

(2) Employee organizations that, for collective bargaining purposes, represent plan participants employed by such employers; and

(3) Plan participants and beneficiaries.

* * * * *

■ 14. Revise § 4245.3 to read as follows:

**§ 4245.3 Notice of insolvency.**

(a) *Requirement of notice.* The plan sponsor of a plan that determines that the plan is insolvent in the current plan year or is expected to be insolvent in the next plan year must file with PBGC a

notice of insolvency containing the information described in § 4245.4(a) and must issue to interested parties a notice of insolvency containing the information described in § 4245.4(b). Once notices of insolvency with respect to a plan have been provided as required, no notices of insolvency need be provided with respect to the plan for any subsequent plan year. A notice of insolvency may be combined with a notice of insolvency benefit level under § 4245.5 for the same plan year.

(b) *When to provide notice.* The plan sponsor must provide the notices of insolvency under paragraph (a) of this section at the time described in § 4281.43(b) of this chapter.

■ 15. Revise § 4245.4 to read as follows:

**§ 4245.4 Contents of notice of insolvency.**

(a) *Notice to PBGC.* A notice of insolvency under § 4245.3 required to be filed with PBGC must contain the information and certification specified in the notice of insolvency instructions on PBGC's website (*www.pbgc.gov*).

(b) Notices to interested parties. A notice of insolvency under § 4245.3 required to be given to interested parties must contain all of the following information—

(1) The information set forth in § 4281.44(b)(1) through (4) of this chapter.

(2) The estimated total amount of annual benefit payments under the plan (determined without regard to the insolvency) for the insolvency year.

(3) The estimated amount of the plan's available resources for the insolvency year.

■ 16. Revise § 4245.5 to read as follows:

**§ 4245.5 Notice of insolvency benefit level.**

(a) *Requirement of notice.* The plan sponsor of an insolvent plan must file with PBGC and issue to interested parties notices of insolvency benefit level containing the information described in § 4245.6 in each of the following circumstances—

(1) For the initial insolvency year, provide the notices of insolvency benefit level to PBGC and to interested parties.

(2) For any insolvency year following the initial insolvency year—

(i) If there is a change in the insolvency benefit level that affects plan payees generally, provide the notices of insolvency benefit level to PBGC and to plan payees. For purposes of this section, ''plan payee'' means a participant or beneficiary in pay status or reasonably expected to enter pay status during the insolvency year.

(ii) If there is a change in the insolvency benefit level that affects only one plan payee or a class of plan payees but not plan payees generally (treating commencement of a person's benefits for this purpose as a change in the insolvency benefit level for that person), provide the notices of insolvency benefit level to PBGC and to each affected plan payee.

(b) *Combined notices.* The plan sponsor may combine a notice of insolvency benefit level and a notice of insolvency under § 4245.3 for the same plan year.

(c) *When to provide notice.* The plan sponsor must provide the required notices under this section at the time described in § 4281.45(c) of this chapter.

■ 17. Revise § 4245.6 to read as follows:

**§ 4245.6 Contents of notice of insolvency benefit level.**

(a) *Notice to PBGC.* A notice of insolvency benefit level under § 4245.5(a) required to be filed with PBGC must contain the information and certification specified in the notice of insolvency benefit level instructions on PBGC's website (*www.pbgc.gov*).

(b) *Notices to interested parties other than participants and beneficiaries in or entering pay status.* A notice of insolvency benefit level under § 4245.5(a) required to be delivered to interested parties, other than to a participant or beneficiary who is in pay status or is reasonably expected to enter pay status during the insolvency year, must include all of the following information—

(1) The name of the plan.

(2) The plan year for which the notice is issued.

(3) The estimated amount of annual benefit payments under the plan (determined without regard to the insolvency) for the insolvency year.

(4) The estimated amount of the plan's available resources for the insolvency year.

(5) The amount of financial assistance, if any, requested from PBGC.

(c) *Notices to participants and beneficiaries in or entering pay status.* A notice of insolvency benefit level required by § 4245.5(a) to be delivered to participants and beneficiaries who are in pay status or are reasonably expected to enter pay status during the insolvency year for which the notice is given must include the information set forth in § 4281.46(b)(1) through (7) of this chapter.

■ 18. Revise § 4245.7 to read as follows:

**§ 4245.7 Successor plan.**

The plan sponsor of a successor plan created by a partition order under § 4233.14 of this chapter must issue to participants and beneficiaries any notice required under the partition order and is not required to file or issue notices under §§ 4245.3 or 4245.5.

■ 19. Revise § 4245.8 to read as follows:

**§ 4245.8 Financial assistance.**

(a) *Application for financial assistance.* If the plan sponsor of a plan determines that the plan's resource benefit level for an insolvency year is below the level of benefits guaranteed by PBGC or that the plan will be unable to pay guaranteed benefits when due for any month during the year, the plan sponsor must apply to PBGC for financial assistance pursuant to section 4261 of ERISA and in accordance with § 4281.47 of this chapter.

(b) *Actuarial valuations and withdrawal liability.* The plan sponsor of an insolvent plan or a terminated plan that is expected to become insolvent under section 4245 of ERISA must—

(1) File withdrawal liability information with PBGC in accordance with § 4041A.23 of this chapter. The filing under paragraph § 4041A.23(b) of this chapter must be not later than 180 days after the earlier of the end of the plan year in which the plan becomes insolvent or terminates and each plan year thereafter.

(2) Have performed and file with PBGC actuarial valuations in accordance with § 4041A.24 of this chapter, except that if a plan is not terminated, the termination year valuation under § 4041A.24(a)(1) of this chapter must be performed for the plan for the plan year in which the plan becomes insolvent.

## PART 4281—DUTIES OF PLAN SPONSOR FOLLOWING MASS WITHDRAWAL

■ 20. The authority citation for part 4281 is revised to read as follows:

**Authority:** 29 U.S.C. 1302(b)(3), 1341(a), 1399(c)(1)(D), 1431, and 1441.

■ 21. In § 4281.2:

■ a. Add in alphabetical order a definition for ''Actuarial valuation'';

■ b. Amend the definition of ''Available resources'' by removing ''means, for a plan year, available'' and adding in its place ''means available'';

■ c. Amend the definition of ''Benefits subject to reduction'' by removing ''the PBGC's'' and adding in its place ''PBGC's'';

■ d. Amend the definition of ''Financial assistance'' by removing ''the PBGC'' and adding in its place ''PBGC'';

■ e. Amend the definition of ''Insolvency benefit level'' by removing ''the PBGC'' and adding in its place ''PBGC'';

■ f. Amend the definition of ''Insolvent'' by removing in the first sentence ''that

a plan is unable'' and adding in its place ''unable'' and by removing the second sentence;

■ g. Amend the definition of ''Pro rata'' by removing ''shall'' and adding in its place ''must''.

The addition reads as follows:

**§ 4281.2 Definitions.**

* * * * *

*Actuarial valuation* means a report submitted to a plan of a valuation of plan assets and liabilities that is performed in accordance with subpart B of this part.

* * * * *

■ 22. Revise § 4281.3 to read as follows:

**§ 4281.3 Filing and issuance rules.**

(a) *Method of filing.* Filing with PBGC under this part must be made by a method permitted under the rules in subpart A of part 4000 of this chapter.

(b) *Method of issuance.* The notices must be issued to interested parties by the methods provided in § 4281.32(c) for notices of benefit reductions, § 4281.43(c) for notices of insolvency, and § 4281.45(d) for notices of insolvency benefit level.

(c) *Filing and issuance dates.* The date that a filing is sent and the date that an issuance is provided are determined under the rules in subpart C of part 4000 of this chapter.

(d) *Where to file.* Filings with PBGC under this part must be made as described in § 4000.4 of this chapter.

(e) *Computation of time.* The time period for filing or issuance under this part must be computed under the rules in subpart D of part 4000 of this chapter.

**§ 4281.11 [Amended]**

■ 23. In § 4281.11:

■ a. Amend paragraph (a) by removing ''annual valuation'' and adding in its place ''annual actuarial valuation'', by removing ''shall be'' and adding in its place ''are'', and by removing ''year thereafter.'' and adding in its place ''year thereafter for which an actuarial valuation is required to be performed under § 4041A.24 of this chapter.''.

■ b. Amend paragraph (b) introductory text by removing ''shall be'' and adding in its place ''is''.

**§ 4281.13 [Amended]**

■ 24. In § 4281.13:

■ a. Amend the introductory text by removing ''shall'' and adding in its place ''must'';

■ b. Amend paragraph (b) by removing ''described in § 4281.14;'' and by adding in its place ''under § 4044.53 of this chapter;''.

**§ 4281.14 [Removed and Reserved]**

■ 25. Section 4281.14 is removed and reserved.

■ 26. Revise § 4281.43 to read as follows:

**§ 4281.43 Notice of insolvency.**

(a) *Requirement of notice.* The plan sponsor of a plan that determines that the plan is insolvent in the current plan year or is expected to be insolvent in the next plan year must file with PBGC a notice of insolvency containing the information described in § 4281.44(a) and issue to plan participants and beneficiaries a notice of insolvency containing the information described in § 4281.44(b). Once notices of insolvency with respect to a plan have been provided as required, no notice of insolvency need be provided with respect to the plan for any subsequent year. A notice of insolvency may be combined with a notice of insolvency benefit level under § 4281.45 for the same plan year.

(b) *When to provide notice*—(1) Except as provided in paragraph (b)(2) of this section, the plan sponsor must file or issue the notices of insolvency under paragraph (a) of this section by the later of—

(i) 90 days before the beginning of the insolvency year, or

(ii) 30 days after the date the insolvency determination is made.

(2) *Participants and beneficiaries in pay status.* The plan sponsor may deliver the notices of insolvency under paragraph (a) of this section to participants and beneficiaries in pay status concurrently with the first benefit payment made after the date the insolvency determination is made.

(c) *Method of issuance to participants and beneficiaries.* The issuance of the notice of insolvency to participants and beneficiaries must be made by one of the following methods—

(1) A method permitted under the rules in subpart B of part 4000 of this chapter.

(2) For participants and beneficiaries other than those who are in pay status or reasonably expected to enter pay status during the insolvency year for which the notice is given, the plan sponsor may post the notice at participants' work sites or publish the notice in a union newsletter or in a newspaper of general circulation in the area or areas where participants reside. Notice to a participant is deemed notice to that participant's beneficiary or beneficiaries.

■ 27. Revise § 4281.44 to read as follows:

**§ 4281.44 Contents of notice of insolvency.**

(a) *Notice to PBGC.* A notice of insolvency required under § 4281.43(a) to be filed with PBGC must contain the information and certification specified in the notice of insolvency instructions on PBGC's website (*www.pbgc.gov*).

(b) *Notice to participants and beneficiaries.* A notice of insolvency required under § 4281.43(a) to be issued to plan participants and beneficiaries must contain all of the following information—

(1) The name of the plan.

(2) A statement of the plan year for which the plan sponsor has determined that the plan is or is expected to be insolvent.

(3) A statement that benefits above the amount that can be paid from available resources or the level guaranteed by PBGC, whichever is greater, will be suspended during the insolvency year, with a brief explanation of which benefits are guaranteed by PBGC under section 4022A of ERISA.

(4) The name, address, and telephone number of the plan administrator or other person designated by the plan sponsor to answer inquiries concerning benefits.

■ 28. Revise § 4281.45 to read as follows:

**§ 4281.45 Notice of insolvency benefit level.**

(a) *Requirement of notice.* The plan sponsor of an insolvent plan must file with PBGC a notice of insolvency benefit level containing the information described in § 4281.46(a) and issue to plan payees (which for purposes of this section means participants and beneficiaries in pay status or reasonably expected to enter pay status during the insolvency year) a notice of insolvency benefit level containing the information described in § 4281.46(b) in each of the following circumstances—

(1) Except as provided in paragraph (a)(2) of this section, for the initial insolvency year and for any insolvency year following the initial insolvency year, if there is a change in insolvency benefit level that affects plan payees generally, provide the notices of insolvency benefit level to PBGC and to plan payees.

(2) For any insolvency year following the initial insolvency year, if there is a change in the insolvency benefit level that affects only one plan payee or a class of plan payees but not plan payees generally (treating commencement of a person's benefits for this purpose as a change in the insolvency benefit level for that person), provide the notices of

insolvency benefit level to PBGC and to each affected plan payee.

(b) *Combined notices.* The plan sponsor may combine a notice of insolvency benefit level under this section and a notice of insolvency under § 4281.43 for the same plan year.

(c) *When to provide notice*—(1) Except as provided in paragraph (c)(2) of this section, the plan sponsor must provide the notices under this section by the later of—

(i) 90 days before the beginning of the insolvency year, or

(ii) 30 days after the date the insolvency determination is made.

(2) *Participants and beneficiaries in or entering pay status.* The plan sponsor may deliver the notices required under this section to participants and beneficiaries who are in pay status or reasonably expected to enter pay status during the insolvency year for which the notice is given concurrently with the first benefit payment made after the date the insolvency determination is made.

(d) *Method of issuance to participants and beneficiaries.* The issuance of the notice of insolvency benefit level to participants and beneficiaries who are in pay status or reasonably expected to enter pay status during the insolvency year for which the notice is given must be made by a method permitted under the rules in subpart B of part 4000 of this chapter.

■ 29. Revise § 4281.46 to read as follows:

**§ 4281.46 Contents of notice of insolvency benefit level.**

(a) *Notice to PBGC.* A notice of insolvency benefit level required by § 4281.45(a) to be filed with PBGC must contain the information and certification specified in the notice of insolvency benefit level instructions on PBGC's website (*www.pbgc.gov*).

(b) *Notice to participants and beneficiaries in or entering pay status.* A notice of insolvency benefit level required by § 4281.45(a) to be delivered to plan participants and beneficiaries in pay status or reasonably expected to enter pay status during the insolvency year must contain all of the following information—

(1) The name of the plan.

(2) The insolvency year for which the notice is being sent.

(3) The monthly benefit that the participant or beneficiary may expect to receive during the insolvency year.

(4) A statement that in subsequent plan years, depending on the plan's available resources, this benefit level may be increased or decreased but not below the level guaranteed by PBGC, and that the participant or beneficiary will be notified in advance of the new benefit level if it is less than the participant's full nonforfeitable benefit under the plan.

(5) The amount of the participant's or beneficiary's monthly nonforfeitable benefit under the plan.

(6) The amount of the participant's or beneficiary's monthly benefit that is guaranteed by PBGC.

(7) The name, address, and telephone number of the plan administrator or other person designated by the plan sponsor to answer inquiries concerning benefits.

■ 30. In § 4281.47:

■ a. Amend the first sentence in paragraph (a) by removing ''plan sponsor'' and adding in its place ''plan sponsor of a plan'' and by removing ''shall'' and adding in its place ''must''; the second sentence is amended by removing ''shall'' and adding in its place ''must'' and by removing ''prescribed in paragraph (b) of this section.'' and adding in its place ''under paragraph (b) of this section and contain the information under paragraph (c) of this section.''; and the third and fourth sentences are removed.

■ b. Revise paragraphs (b) and (c);

■ c. Remove paragraphs (d) and (e).

The revisions read as follows:

**§ 4281.47 Application for financial assistance.**

* * * * *

(b) *When, how, and where to apply*—(1) *Initial application.* Except as provided in the next sentence, a plan sponsor must apply for financial assistance no later than 90 days before the first day of the month for which the plan sponsor has determined the resource benefit level will be below the level of guaranteed benefits. If a plan sponsor cannot practicably apply for financial assistance no later than 90 days before such date, the application must be made as soon as practicable.

(2) *Recurring application.* A plan sponsor must apply for financial assistance as soon as practicable after the plan sponsor determines that the plan will be unable to pay guaranteed benefits when due for a month.

(3) *How and where to apply.* Application to PBGC for financial assistance must be made in accordance with the rules in subpart A of part 4000 of this chapter. See § 4000.4 of this chapter for information on where to apply.

(c) *Contents of application*—(1) *Initial application.* A plan sponsor applying for financial assistance because the plan's resource benefit level is below the level of guaranteed benefits must file an application that includes the information specified in the instructions for an application for initial financial assistance on PBGC's website (*www.pbgc.gov*).

(2) *Recurring application.* A plan sponsor applying for financial assistance because the plan is unable to pay guaranteed benefits for any month must file an application that includes the information specified in the instructions for an application for recurring financial assistance on PBGC's website (*www.pbgc.gov*).

(3) *Additional information.* PBGC may request any additional information that it needs to calculate or verify the amount of financial assistance necessary as part of the conditions of granting financial assistance pursuant to section 4261 of ERISA.

Issued in Washington, DC.

**William Reeder,**

*Director, Pension Benefit Guaranty Corporation.*

[FR Doc. 2018–15076 Filed 7–13–18; 8:45 am]

BILLING CODE 7709–02–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 300

**[EPA–HQ–SFUND–1990–0011; FRL–9980–63—Region 5]**

## National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Beloit Corporation Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule; notification of intent.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 5 is issuing a Notice of Intent to Delete the Former Beloit Corporation Research Center Property (RCP) of the Beloit Corporation Superfund Site (Site), in Rockton, Illinois, from the National Priorities List (NPL) and requests public comments on this proposed action. This partial deletion includes all media at the 20-acre RCP. The rest of the Site remains on the NPL and is not affected by this action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Illinois, through the Illinois Environmental Protection Agency, have

determined that all appropriate response actions at the RCP identified under CERCLA have been completed, other than maintenance, monitoring and five-year reviews. However, this partial deletion does not preclude future actions under CERCLA.

**DATES:** Comments must be received by August 15, 2018.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1990–0011, by mail to Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the Rules section of this **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036, email: *cano.randolph@epa.gov.*

**SUPPLEMENTARY INFORMATION:** In the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing a direct final Notice of Partial Deletion for the Former Beloit Corp. Research Center Property of the Beloit Corp. Superfund Site without prior Notification of Intent for Partial Deletion because EPA views this as a noncontroversial revision and anticipates no adverse comment. We have explained our reasons for this partial deletion in the preamble to the direct final Notice of Partial Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this partial deletion action, we will not take further action on this Notification of Intent for Partial Deletion. If we receive adverse comment(s), we will publish a timely withdrawal of the direct final partial deletion in the **Federal Register** informing the public that the partial deletion will not take effect. We will then, as appropriate, address all public comments in a subsequent final Notice of Partial Deletion based on this Notification of Intent for Partial Deletion. We will not institute a second comment period on this Notification of Intent for Partial Deletion. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Partial Deletion which is located in the Rules section of this **Federal Register**.

**List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

**Authority:** 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: June 25, 2018.

**Cathy Stepp,**

*Regional Administrator, Region 5.*

[FR Doc. 2018–15145 Filed 7–13–18; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

### 49 CFR Part 210

**[Docket No. FRA–2017–0038]**

**RIN 2130–AC69**

## Railroad Noise Emission Compliance Regulations

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

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

**SUMMARY:** FRA proposes to eliminate the requirement that certain locomotives display a badge or tag to demonstrate the railroad has certified the locomotives comply with noise emission standards. This proposed rule would reduce economic burdens on the rail industry by removing the badge or tag requirement.

**DATES:**

(1) Written comments must be received by September 14, 2018. Comments received after that date will be considered to the extent practicable.

(2) FRA anticipates being able to resolve this rulemaking without a public, oral hearing. However, if FRA receives a specific request for a public, oral hearing prior to August 15, 2018, one will be scheduled and FRA will publish a supplemental document in the **Federal Register** to inform interested parties of the date, time, and location of any such hearing.

**ADDRESSES:**

*Comments:* Comments related to Docket No. FRA–2017–0038 may be submitted by any of the following methods:

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

*Instructions:* All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to 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.

**FOR FURTHER INFORMATION CONTACT:** Michael Watson, Industrial Hygienist, Office of Railroad Safety, Federal Railroad Administration, 1200 New Jersey Avenue SE, W38–224, Washington, DC 20590 (telephone 202–493–1388), or Sam Gilbert, Trial Attorney, Office of Chief Counsel, Federal Railroad Administration, 1200 New Jersey Avenue SE, W31–228, Washington, DC 20590 (telephone 202–493–0270).

**SUPPLEMENTARY INFORMATION:**

### I. Executive Summary

On January 30, 2017, the President issued Executive Order 13771, which requires, when an agency proposes a new significant regulation, it must identify at least two existing regulations to be repealed. FRA reviewed the Railroad Noise Emission Compliance Regulations in 49 CFR part 210 [1] (''part 210'') and identified for potential elimination the requirement that railroads display a permanent badge or tag in the cabs of their locomotives certifying the locomotives comply with FRA's noise emission standards. FRA believes eliminating this requirement

[1] Unless otherwise specified, all references to CFR sections and parts in this document refer to Title 49 of the CFR.

would reduce economic burdens on the rail industry without adversely impacting compliance with part 210. Therefore, in this NPRM, FRA proposes to eliminate the badge or tag requirement.

FRA estimates there would be no cost burden associated with this proposed rule. In fact, the elimination of the requirement to install a badge in locomotives would save most railroads both the labor to install the badge, and the cost of the badge itself. Over a 20-year period, FRA estimates $1,858,859 in cost savings would accrue—a present, discounted value of $1,053,564 (7% discount).

## II. Background and Overview of the Proposal

FRA regulations in part 210 limit the noise emitted by railroad locomotives, cars, and other equipment. FRA originally developed these regulations in consultation with the Environmental Protection Agency under the Noise Control Act of 1972 (86 Stat. 1234, Pub. L. 92–574) and FRA's general enforcement and inspection authority under the railroad safety statutes. *See* 41 FR 49183, 49183–84 (Nov. 8, 1976).

Part 210 requires railroads to certify that locomotives built after December 31, 1979, comply with FRA's noise emission standards. Under section 210.27(d), railroads must attach a permanent badge or tag in the cab of the locomotive displaying the results of the certification test (including the method, date and location of the test, and the sound level reading obtained during the test).

In 2014, the Association of American Railroads (AAR) requested FRA eliminate the requirement to display the certification of compliance with noise emission standards in the locomotive, in its comments on a separate proposed rule concerning stenciling requirements for window glazing. AAR Comment, November 25, 2014, Docket No. FRA–2012–0103. AAR noted that when FRA added section 210.27(d) in 1983, few locomotives had been tested and certified to comply with FRA's noise emission standards. AAR contended that instead of testing individual locomotives for compliance with the noise emission standards, railroads currently test locomotives by model. Documentation of that testing is maintained by the railroads as a usual and customary practice, and may be consulted if FRA has a doubt about whether a locomotive has been tested for compliance with part 210.

FRA declined to eliminate the display requirement for noise certification at that time because it was beyond the scope of the window-glazing rulemaking. However, FRA said it would consider the merits of AAR's request and evaluate how to address the issue in the future. 81 FR 6775, 6778 (Feb. 9, 2016).

FRA continually reviews and revises its regulations to ensure the regulatory burden on the rail industry is not excessive, clarify the application of existing requirements and remove requirements no longer necessary, and keep pace with emerging technology, changing operational realities and safety concerns. In addition, on January 30, 2017, the President issued Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs). Executive Order 13771 requires agencies to identify at least two existing regulations to repeal when they propose a new significant regulation. Because the badge or tag requirement is unnecessary for purposes of FRA enforcement of the noise testing requirements, FRA determined repealing section 210.27(d) would reduce the burden on the rail industry without adversely impacting FRA's ability to ensure compliance with part 210. Accordingly, FRA proposes to eliminate the requirement for locomotives to display a permanent badge or tag certifying compliance with noise emission standards.

## III. Section-by-Section Analysis

FRA seeks comments on all proposals made in this NPRM.

### *Section 210.27 New Locomotive Certification*

Section 210.27 requires railroads certify their locomotives comply with FRA's noise emission standards. Paragraph (a) requires railroads certify that locomotives built after December 31, 1979, comply with the noise emission standards. Paragraph (b) provides railroads must determine certification for each locomotive model by load cell testing or passby testing. Paragraph (c) states if railroads use passby testing, they should conduct the test with the locomotive operating at maximum rated horsepower output. Under paragraph (d), railroads must attach a permanent badge or tag in the cab of the locomotive to display the results of the certification test.

FRA determined this badge or tag is no longer necessary, and the proposed rule would remove paragraph (d) in its entirety. Although railroads would no longer need to display a badge or tag in the locomotive cab, they would still need to test their locomotives and certify they comply with the noise emission standards, as required under section 210.27(a) through (c).

## IV. Regulatory Impact and Notices

### *Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures*

FRA evaluated this proposed rule consistent with existing policies and procedures, and determined it to be non-significant under both Executive Orders 12866 and 13563 as well as DOT policies and procedures (44 FR 11034 (February 26, 1979)). The proposed rule is also consistent with Executive Order 13563, which emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Finally, this proposed rule is expected to be an E.O. 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's economic analysis.

FRA proposes to eliminate the requirement that locomotives display a permanent badge or tag to demonstrate they have been certified to comply with noise emission standards. (The permanent badge or tag will hereafter be referred to as a ''badge'' in this analysis.) A badge is typically a metal plate installed inside the cab of the locomotive. Most railroads would benefit from this proposed rule because a badge is currently required in all locomotives. Any railroad purchasing new locomotives would not be required to display a badge, therefore saving it money. Also, badges would no longer need to be replaced when locomotives are overhauled.

FRA estimates there would be no cost burden associated with this proposed rule. The elimination of the requirement to install a badge in locomotives would save most railroads both the labor to install the badge, and the cost of the badge itself. Over a 20-year period, this analysis finds $1,858,859 in cost savings would accrue through the elimination of this requirement. The present, discounted value of these cost savings is $1,053,564 (7% discount). FRA has prepared and placed in the docket a regulatory analysis addressing the economic impact of this proposed rule. FRA requests comments on all aspects of the regulatory evaluation and its conclusions.

### *Regulatory Flexibility Act and Executive Order 13272*

The Regulatory Flexibility Act (RFA) (94 Stat. 1164, Pub. L. 96–354), as amended, and codified as amended at 5 U.S.C. 601–612, and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking), require agency review of proposed and final rules to assess their impact on ''small

entities'' for purposes of the RFA. An agency must prepare a regulatory flexibility analysis unless it determines and certifies a rule is not expected to have a significant economic impact on a substantial number of small entities. FRA expects this proposed rule would not have a significant economic impact on a substantial number of small entities.

Federal agencies may adopt their own size standards for small entities, in consultation with the Small Business Administration and in conjunction with public comment. FRA published a final statement of agency policy that formally establishes ''small entities'' or ''small businesses'' as being railroads, contractors, and hazardous materials shippers with the revenue of a Class III railroad as set forth in 49 CFR 1201.1–1, which is $20 million or less in inflation-adjusted annual revenues, and commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less. *See* 68 FR 24891 (May 9, 2003), codified at 49 CFR part 209, Appendix C. FRA is using this definition for this rulemaking.

FRA estimates there are 704 Class III railroads, most of which would be affected by this proposed rule. Most Class III railroads do not purchase new locomotives; rather, they purchase used locomotives from Class I and Class II railroads. Therefore, any badges required would have already been installed by the larger railroad. If a small railroad did indeed purchase a new locomotive, however, they would save money because the badge would no longer be required. Small railroads would at all events benefit since they would not need to replace badges as they age or when locomotives are overhauled. Therefore, any impact on small railroads by this proposed regulation would likely be small and entirely beneficial.

FRA invites comments from all interested parties concerning the potential economic impact on small entities resulting from this proposed rule. FRA will consider the comments and data it receives in determining the small entity impact for the final rule.

*Paperwork Reduction Act*

The information collection requirements in this proposed rule are being submitted for approval to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The sections that contain the current information collection requirements and the estimated time to fulfill each requirement are as follows:

| CFR section | Respondent universe | Total annual responses | Average time per response | Total annual burden hours |
|---|---|---|---|---|
| 210.27(a)—New Locomotive Certification—Request to Manufacturer for Certification. | 4 Manufacturers | 4 requests | 30 minutes | 2 hours. |
| 210.27(d)—New Locomotive Certification—Identification of Certified Locomotive by Badge Plate (Proposed Rescission of Provision). | *4 Manufacturers* | *790 badges* | *30 minutes* | *minus 395 hours (Previously Approved Burden by OMB).* |
| 210.31—Recorded Measurements of Locomotive Noise Emission Test. | 4 Manufacturers | 745 forms/records | 3 hours | 2,235 hours. |

All estimates include the time for reviewing instructions, searching existing data sources, gathering or maintaining the needed data, and reviewing the information.

Pursuant to 44 U.S.C. 3506(c)(2)(B), FRA solicits comments concerning: Whether these information collection requirements are necessary for the proper performance of the functions of FRA, including whether the information has practical utility; the accuracy of FRA's estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized.

For information or a copy of the paperwork package submitted to OMB, contact Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Federal Railroad Administration, at 202–493–6292, or Ms. Kimberly Toone, Information Collection Clearance Officer, Office of Railroad Administration, Federal Railroad Administration, at 202–493–6139.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to Mr. Robert Brogan or Ms. Kimberly Toone, Federal Railroad Administration, 1200 New Jersey Avenue SE, 3rd Floor, Washington, DC 20590. Comments may also be submitted via email to Mr. Brogan at *Robert.Brogan@dot.gov,* or to Ms. Toone at *Kim.Toone@dot.gov.*

OMB is required to make a decision concerning the collection of information requirements contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

FRA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of the final rule. The current OMB control number for this information collection is OMB No. 2130–0527.

*Federalism Implications*

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132 (Federalism), agencies may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local

governments, or the agency consults with State and local government officials early in the process of developing the regulation.

This proposed rule has been analyzed consistent with the principles and criteria in Executive Order 13132. This proposed rule would not have a substantial effect on the States or their political subdivisions; it would not impose any substantial direct compliance costs; and it would not affect the relationships between the Federal government and the States or their political subdivisions, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

However, this proposed rule could have preemptive effect under certain provisions of the Federal railroad safety statutes, specifically the former Federal Railroad Safety Act of 1970 (former FRSA), repealed and re-codified at 49 U.S.C. 20106, and the former Locomotive Boiler Inspection Act (LIA) at 45 U.S.C. 22–34, repealed and re-codified at 49 U.S.C. 20701–03. The former FRSA provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the ''local safety or security hazard'' exception to section 20106. Moreover, the U.S. Supreme Court has held the former LIA preempts the field concerning locomotive safety. *See Napier* v. *Atl. Coast Line R.R.,* 272 U.S. 605 (1926) and *Kurns* v. *R.R. Friction Prods. Corp.,* 565 U.S. 625 (2012). Therefore, if this proposed rule were adopted, it is possible States would be preempted from requiring that locomotives display a permanent badge or tag certifying the locomotive complies with FRA's noise emission standards.

*Environmental Impact*

FRA has evaluated this proposed regulation consistent with its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures), 64 FR 28545 (May 26, 1999), as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined this proposed regulation is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. 64 FR 28547–48.

Under section 4(c) and (e) of FRA's Procedures, the agency has further concluded no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. Consequently, FRA finds this proposed regulation is not a major Federal action significantly affecting the quality of the human environment.

*Unfunded Mandates Reform Act of 1995*

Under Section 201 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531, each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act, 2 U.S.C. 1532, further requires that before promulgating any general notice of proposed rulemaking that is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement detailing the effect on State, local, and tribal governments and the private sector. The proposed rule would not result in the expenditure, in the aggregate, of $100,000,000 or more in any one year (adjusted annually for inflation), and thus preparation of such a statement is not required.

*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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

**List of Subjects in 49 CFR Part 210**

Noise control.

**The Proposed Rule**

For the reasons discussed in the preamble, FRA proposes to amend part 210 of chapter II, subtitle B of title 49, Code of Federal Regulations, as follows:

■ 1. The authority citation for part 210 is revised to read as follows:

**Authority:** Sec. 17, Pub. L. 92–574, 86 Stat. 1234 (42 U.S.C. 4916); 49 CFR 1.89.

**§ 210.27 [Amended]**

■ 2. Amend § 210.27 by removing paragraph (d).

Issued in Washington, DC.

**Ronald Louis Batory,**

*Administrator.*

[FR Doc. 2018–14961 Filed 7–13–18; 8:45 am]

BILLING CODE 4910–06–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Parts 648, 660, and 679

**RIN 0648–XG338**

### Request for Information on National Reform of Regional Observer Program Insurance Requirements

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

**ACTION:** Notification; Request for Information (RFI).

**SUMMARY:** NMFS requests information from the public to support a national initiative to reform and streamline observer program insurance requirements. The goals of this reform effort are to: ease the regulatory burden and reduce costs for private companies that provide observer staffing to NMFS observer programs through more efficient, nationally applicable insurance requirements; eliminate outdated and/or inappropriate regulatory requirements; reduce observer deployment risks for vessel owners and shore side processors; and identify insurance that could improve observer safety and facilitate full compensation for observer occupational injuries. To proceed with this effort, NMFS seeks technical information on the types of insurance and minimum coverage amounts (in dollars) that

would minimize observer deployment risks to the extent practicable considering costs and other factors. Additionally, NMFS seeks public comment on Federal Employees Compensation Act (FECA) claims and benefits processing for observer occupational injuries and whether observer companies should carry private insurance to supplement FECA benefits for observers.

**DATES:** Interested persons are invited to submit comments on or before September 14, 2018.

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

- *Email: NMFS-HQ-ST.Insurance-Reform@NOAA.GOV.* Please include the subject heading of ''Comments on Regional Observer Program RFI''. Attachments to electronic comments will be accepted in Microsoft Word or Excel, or Adobe PDF formats only.
- *Mail:* Dennis Hansford, 1315 East West Highway, Room 12506, Silver Spring, MD 20910.

*Instructions:* Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, or names of individuals, should not be included. Submissions will not be edited to remove any identifying or contact information. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language will not be considered.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Dennis Hansford, 301–427–8136 or *dennis.hansford@noaa.gov.*

**SUPPLEMENTARY INFORMATION:**

## Overview

The Magnuson-Stevens Fishery Conservation and Management Act (MSA), 16 U.S.C. 1801 *et seq.,* establishes a national program for conservation and management of fishery resources within the United States Exclusive Economic Zone (EEZ). *See* id. 1801(a)(6), 1811(a). NMFS, acting under authority delegated from the Secretary of Commerce, is responsible for managing fisheries under the MSA, in conjunction with eight regional fishery management councils (Councils) established under the Act. *See* id. 1852(a). Each Council has authority to develop fishery management plans (FMPs) for fisheries in a specific geographical area and to deem proposed regulations that are necessary for plan implementation. *See* id. 1852(a), (c).

Collection of information on fishing and fish processing, such as type and quantity of fishing gear used, catch in numbers of fish or weight thereof, fishing locations, and biological information, are critical to effective fishery management. *See* id. 1853(a)(5). To obtain this information, the MSA authorizes, among other things, that an FMP may ''[r]equire that one or more observers be carried on board a vessel of the United States engaged in fishing for species that are subject to the plan, for the purpose of collecting data necessary for the conservation and management of the fishery . . .''. *See* id. 1853(b)(8).

In 2016, 53 fisheries subject to management under an FMP or international authority were monitored by observer programs. To carry out required observer coverage, NMFS administers 14 observer programs that operate in the agency's five regions. These programs train and deploy observers, establish information collection protocols, debrief observers following deployment to provide quality control on information that observers collect, and oversee private companies that provide program support. At present, all NMFS observer programs staff their at-sea and shore side observer deployments through private companies, commonly referred to as observer providers. Observer providers service NMFS regional observer programs under two distinct models: (1) Direct service, where the NMFS observer program contracts with an observer provider; and (2) industry-funded, where the observer provider contracts with industry to fulfill observer coverage requirements. Further information about NMFS' regional observer programs is available at *https://www.fisheries.noaa.gov/topic/fishery-observers.*

While observers most frequently are deployed under the MSA to collect information on fishing vessels, observers also are deployed on motherships, and shore side processing facilities. Additionally, NMFS' regional observer programs deploy at-sea monitors, who collect only vessel catch information under ''catch share programs,'' which allocate a portion of a fishery total allowable catch to permit holders or sectors. For purposes of this RFI, the term ''observer'' refers to a person deployed in any of these roles.

## Observer Deployment Risks

The Bureau of Labor Statistics, Census of Fatal Occupational Injuries ranks commercial fishing as one of the most dangerous occupations. Because most observers are deployed to fishing vessels, observer risk of occupational injury is on par with that of commercial fishermen. Observer programs also entail risks for observer employers—private companies—and the fishing vessels and shore side processors that are subject to observer coverage. The risks for the three parties include:—

1. Observers—risk of occupational injury.
2. Vessel owners and shore side processors—observer claims for compensation for incidents arising out of deployment, *e.g.,* occupational injury.
3. Private companies—observer claims for compensation for incidents arising out of deployment, *e.g.,* occupational injury, and vessel/shore side processor owner claims for damages resulting from observer negligence.

Insurance and statutory compensation programs are the traditional mechanisms to address the risks that private companies entail. However, the nuances of maritime law combined with the unique nature of the fishery observer occupation have complicated efforts to address observer risks, whether through insurance or statutory program. Since 1994, Councils and NMFS have taken various efforts to resolve insurance issues for observer programs. These efforts have resulted in regulatory—or contract based—insurance requirements that differ across regions. At present, the types of insurance policies that observer providers are required to have, either by regulation or by contract, include the following:

- Maritime liability to cover ''seamen's claims'' under the Merchant Marine Act (Jones Act) and General Maritime Law
- U.S. Longshore and Harbor Worker's Compensation Act
- State Worker's Compensation
- Contractual General Liability
- Marine General Liability
- Commercial General Liability
- Marine Employers Liability

Regulatory based observer provider insurance requirements are codified at 50 CFR 679.52(b)(11)(vi) (North Pacific Groundfish Observer Program), 50 CFR 660.17(e)(vii) (West Coast Groundfish Observer Program), and 50 CFR 648.11(h)(3) (Northeast Observer Program).

In addition, Congress addressed compensation for observer occupational risks through the 1996 Sustainable

Fisheries Act (SFA). Public Law 104–297 (Oct. 11, 1996). Through that statute, Congress amended the MSA to deem observers to be federal employees for purposes of FECA while deployed on a vessel under the Act or the Marine Mammal Protection Act. 16 U.S.C. 1881b(c). The extension of FECA coverage to observers deployed at-sea filled a gap in coverage for observer occupational injuries that occur at-sea, but this extension is not applicable to shore side observers.

**NMFS Reevaluation of Observer Program Insurance Requirements**

Beginning in 2014, NMFS initiated a reevaluation of regional observer program insurance requirements. This effort included an Observer Provider Insurance Workshop in 2016 during which observer providers, insurance experts, and observers joined NMFS and representatives from other federal agencies to discuss the efficiency of observer provider insurance requirements and compensation for observer occupational injuries. Subsequent to the Insurance Workshop, NMFS published an Observer Provider Insurance Workshop Technical Report (Tech Report), available at *http://spo.nmfs.noaa.gov/tech-memos,* which summarized the Workshop's proceedings and identified actions that NMFS could take to reform observer program insurance requirements and facilitate compensation for observer occupational injuries. As detailed in the Tech Report, some of the insurance policies that observer providers are required to have are inapplicable to observers or have limited applicability depending on whether the claim concerns an injury sustained at-sea or on shore. Furthermore, prior to the publication of the Tech Report, it was noted that other forms of insurance generally not required, such as a Marine General Liability policy, may better address certain observer company risks.

In addition, NMFS has learned that, while FECA does provide coverage for observer at-sea injuries, the compensation formula under that Act does not provide for overtime pay. Because observers typically work 12–16 hour shifts to correspond with fishing vessel crew shifts, they often do not receive full wage compensation for occupational injury claims under FECA.

To address these issues, the Tech Report recommended that NMFS explore replacing regional insurance requirements with nationally applicable minimum insurance requirements. The goal of that action would be to streamline and improve the efficiency of regional observer provider insurance requirements, thereby resulting in reduced regulatory burden, cost savings, and a suite of insurance that better addresses observer deployment risks. Considering the highly technical nature of maritime insurance and insurance markets in general, the Tech Report recommended that NMFS first gather more information on the types of insurance and minimum dollar coverage amounts for the risks that observer deployments present. NMFS issues this RFI to gather that information through the questions below.

In addition, NMFS seeks public comment on the related issue of FECA compensation for observer occupational injuries and whether some form of private insurance could supplement FECA benefits. National inconsistencies with observer compensation for occupational injuries were noted not only in the Tech Report, but also in the Observer Program Safety Review (OPSR) Final Report, available at *https://www.fisheries.noaa.gov/resource/document/observer-safety-program-review-report.* The OPSR recommended that NMFS initiate action to improve the insurance scheme for compensation of observer occupational injuries. Through this notification, NMFS seeks information to respond to that recommendation and ways that insurance can improve observer safety.

**Request for Information**

To reform and streamline observer provider insurance requirements, and facilitate observer compensation for at-sea occupational injuries under FECA, NMFS seeks public comment on the issues raised in this RFI and, in particular, on the following questions. See **ADDRESSES** for information on how to submit comments.

1. What insurance policies and coverage amounts (in dollars) are appropriate to address observer deployment risks for: (a) Observers, (b) observer providers, and (c) owners of vessel and shore side processors and other observing platforms?

2. If observer providers have different insurance requirements to cover the different contexts in which observers are deployed—at-sea and shore side, what would be the most feasible and efficient insurance package and associated dollar amounts for covering all of the various contexts?

3. As an alternative to national minimum insurance requirements, would it be feasible, and more efficient, for observer providers to self-organize and self-insure?

4. If an insurance policy for a Jones Act or General Maritime Law claim is required, acknowledging that courts in some jurisdictions have held that those claims are inapplicable to observers, might it be beneficial to continue the requirement?

5. What gaps, if any, are there in FECA coverage for observer occupational injuries? For observers, what, if any, problems have you experienced with regard to claims and benefits for occupational injuries, whether under FECA, state worker's compensation, or private insurance?

6. If there are gaps in FECA coverage, is there a type of private insurance that could supplement FECA compensation for observer occupational injuries?

7. What types of insurance could advance NMFS' efforts to improve the safety of observer programs and reduce the occurrence of observer occupational injuries?

8. To maximize efficiency of observer insurance requirements, should NMFS address the requirements regionally, through regional regulatory or contractual insurance requirements, or through nationally applicable minimum insurance standards? If a, what regional or national policies and dollar amounts of coverage would be appropriate?

Dated: July 10, 2018.

**Edward C. Cyr,**

*Director, Office of Science and Technology, National Marine Fisheries Service.*

[FR Doc. 2018–15057 Filed 7–13–18; 8:45 am]

BILLING CODE 3510–22–P

# Notices

Federal Register
Vol. 83, No. 136
Monday, July 16, 2018

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 COMMERCE

### Census Bureau

### Proposed Information Collection; Comment Request; Annual Capital Expenditures Survey

**AGENCY:** U.S. Census Bureau, Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** To ensure consideration, written comments must be submitted on or before September 14, 2018.

**ADDRESSES:** Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *PRAcomments@doc.gov*).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Valerie Mastalski, U.S. Census Bureau, Room HQ–8K073, Washington, DC 20233; (301) 763–3317 (or via the internet at *Valerie.Cherry.Mastalski@census.gov*).

**SUPPLEMENTARY INFORMATION:**

#### I. Abstract

The U.S. Census Bureau plans to conduct the 2018 through 2020 Annual Capital Expenditures Survey (ACES). This survey collects data on fixed assets and depreciation, sales and receipts, capitalized computer software, and capital expenditures for new and used structures and equipment. The ACES is the sole source of detailed comprehensive statistics on actual business spending for private non-farm companies, organizations, and associations operating in the United States. Both employer and nonemployer companies are included in the survey.

The Bureau of Economic Analysis is the primary Federal user of ACES data. BEA relies on ACES data to refine and evaluate annual estimates of investment in structures and equipment in the national income and product accounts, compile annual input-output tables, and compute gross domestic product by industry. The Federal Reserve Board uses these data to improve estimates of investment indicators for monetary policy. The Bureau of Labor Statistics uses these data to improve estimates of capital stocks for productivity analysis. The Centers for Medicare and Medicaid Services use these data for developing estimates of investment in private health care structures and equipment as a part of the National Health Expenditure Accounts. Industry analysts use these data for market analysis, economic forecasting, identifying business opportunities, product development, and business planning.

Planned changes from the previous ACES are the elimination of detailed capital expenditures by type of structure and type of equipment. These data are collected in years ending in -2 and -7, concurrently with the Economic Census. They are not in scope of this notice, which covers ACES data collection for 2018 through 2020.

The Census Bureau does plan to add questions on the dollar value of new and used robotics expenditures beginning with the 2018 survey. These questions will gauge prevalence of robotics use by detail North American Industry Classification System (NAICS) industries.

#### II. Method of Collection

The initial mailing will include a letter instructing respondents to report online. The Census Bureau eliminated the use of paper forms with the 2016 ACES. The electronic reporting system provides a cost-effective and user-friendly method to collect data from companies. The Census Bureau will supply companies with a unique authentication code for the electronic reporting tool. Respondents will have the option of printing out a worksheet that lists all of the questions. Respondents will be able to print the worksheet to use as a guide to respond or can print the worksheet after completing the questionnaire as a record of their response. The online reporting instrument is tailored to the company's diversity of operations and number of industries with payroll. Employer companies will complete the ACE–1 electronic reporting instrument and nonemployers will complete the ACE–2 electronic reporting instrument.

Companies will be asked to respond to the survey within 30 days of the initial mailing. The Census Bureau will use reminder letters and/or telephone calls to encourage participation of companies that have not responded within 30 days.

#### III. Data

*OMB Control Number:* 0607–0782.

*Form Number:* ACE–1 and ACE–2.

*Type of Review:* Regular submission.

*Affected Public:* Private, non-farm businesses or other for-profit organizations; non-profit institutions.

*Estimated Number of Respondents:* Approximately 70,127 (50,127 employer companies, and 20,000 nonemployer businesses).

*Estimated Time per Response:* The average for all respondents is 2.27 hours. For employer companies completing form ACE–1, the range is 2 to 17 hours, averaging 2.78 hours. For companies completing form ACE–2, the range is less than 1 hour to 2 hours, averaging 1 hour.

*Estimated Total Annual Burden Hours:* 159,134 hours.

*Estimated Total Annual Cost:* $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

*Respondents' Obligation:* Mandatory.

*Legal Authority:* Title 13 United States Code, Sections 131 and 182.

#### IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the

proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018–15070 Filed 7–13–18; 8:45 am]

**BILLING CODE 3510–07–P**

## DEPARTMENT OF COMMERCE

### Public Hearing on Section 232 National Security Investigation of Imports of Automobiles, Including Cars, SUVs, Vans and Light Trucks, and Automotive Parts; Change of Date for the Public Hearing

**AGENCY:** U.S. Department of Commerce.

**ACTION:** Change of date for public hearing.

**SUMMARY:** The Department of Commerce is cancelling one of the days of the two-day public hearing associated with the notice of request for public comments and public hearing that appeared in the **Federal Register** on May 30, 2018. In the notice, the Department encouraged interested public participants to participate in a hearing for the investigation assist the Department in determining whether imports of automobiles, including cars, SUVs, vans and light trucks, and automotive parts threaten to impair the national security and in recommending remedies if such a threat is found to exist. The hearing was originally scheduled for July 19 and 20. Only 45 requests to testify were received. Because these requests can all be accommodated on a single day, the second day of the hearing originally scheduled for July 20 is cancelled. The hearing will be held on July 19 only. The hearing will begin at 8:30 a.m. and will end at 5:30 p.m. The location of the hearing remains unchanged.

**DATES:** The public hearing will be held on July 19, 2018, beginning at 8:30 a.m. local time and concluding at 5:30 p.m. local time.

**ADDRESSES:** The public hearing will be held at 1401 Constitution Avenue NW, Washington DC, 20230.

**FOR FURTHER INFORMATION CONTACT:** Sahra Park-Su, U.S. Department of Commerce (202) 482–2811. For more information about the section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232*.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 30, 2018, the Secretary of Commerce (''Secretary'') invited interested parties to submit written comments, data, analyses, or other information pertinent to the Department of Commerce's investigation under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862), to determine the effects on the national security of imports of automobiles, including cars, SUVs, vans and light trucks, and automotive parts (83 FR 24735). In the notice, the Secretary also announced that the Department will be holding a public hearing on the investigation on July 19 and 20, 2018. Only 45 requests to testify were received. Because these requests can all be accommodated on a single day, the second day of the hearing originally scheduled for July 20, 2018 is cancelled.

The hearing will be held on July 19 only and will take place from 8:30 a.m.-5:30 p.m. The location of the hearing remains unchanged at the Department of Commerce, 1401 Constitution Avenue NW, Washington DC, 20230.

**Procedures for Attending the Hearing**

The hearing is open to the general public and seating is on a first-come-first served basis. We anticipate a high volume of interest and encourage all members of public wishing to attend, to arrive early and be prepared to go through a security screening. You must present a valid form of identification such as a driver's license, passport, or state issued ID.

The main entrance of the Department of Commerce is on 14th Street NW. between Pennsylvania Avenue and Constitution Avenue, across from the Ronald Reagan Building. Upon entering the building, please go through security and check in at the guard's desk. DOC staff will meet and escort visitors to the auditorium.

*Non-U.S. Citizens Please Note:* All foreign national visitors who do not have permanent resident status and who wish to attend the hearing must contact *Autos232@doc.gov* by 12 p.m., July 16. You will then be asked to provide additional information. Please also bring a copy of your passport on the day of the hearing to serve as identification. Failure to provide the requested information prior to arrival will result, at a minimum, in significant delays in entering the facility.

Dated: July 11, 2018.

**Earl Comstock,**

*Director, Office of Policy and Strategic Planning, U.S. Department of Commerce.*

[FR Doc. 2018–15193 Filed 7–12–18; 11:15 am]

**BILLING CODE 3510–17–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[S–71–2018]**

### Approval of Subzone Status; VF Outdoor, LLC; Ontario, Santa Fe Springs and Corona, California

On May 9, 2018, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Port of Long Beach, grantee of FTZ 50, requesting subzone status subject to the existing activation limit of FTZ 50, on behalf of VF Outdoor, LLC, in Ontario, Santa Fe Springs and Corona, California.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (83 FR 22441, May 15, 2018). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 50R was approved on July 10, 2018, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 50's 2,000-acre activation limit.

Dated: July 10, 2018.

**Elizabeth Whiteman,**

*Acting Executive Secretary.*

[FR Doc. 2018–15113 Filed 7–13–18; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–929]**

### Small Diameter Graphite Electrodes From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2016–2017

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) determines that Fushun Jinly Petrochemical Carbon Co., Ltd. (Fushun Jinly) did not make sales of

small diameter graphite electrodes from the People's Republic of China (China) at less than normal value during the period of review (POR) February 1, 2016, through January 31, 2017.

**DATES:** Applicable July 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dennis McClure or John Anwesen, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5973, or (202) 482–0131, respectively.

**SUPPLEMENTARY INFORMATION:**

## Background

Commerce published the *Preliminary Results* [1] on March 12, 2018. For a discussion of events subsequent to the *Preliminary Results,* see Commerce's Issues and Decision Memorandum.[2]

Commerce has exercised its discretion to toll all deadlines affected by the closure of the Federal Government from January 20 through 22, 2018. The revised deadline for the final determination of this review is now July 10, 2018.[3]

## Scope of the Order

The merchandise covered by the order includes all small diameter graphite electrodes with a nominal or actual diameter of 400 millimeters (16 inches) or less and graphite pin joining systems for small diameter graphite electrodes. Small diameter graphite electrodes and graphite pin joining systems for small diameter graphite electrodes that are subject to the order are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 8545.11.0010, 3801.10, and 8545.11.0020. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive. A full description of the scope of the order is contained in the Issues and Decision Memorandum.

## Analysis of Comments Received

In the Issues and Decision Memorandum, we address all issues raised in interested parties' case and rebuttal briefs. In the Appendix to this notice, we provide a list of the issues raised by parties. The Issues and Decision Memorandum is a public document and is on file in the Central Records Unit (CRU), Room B8024 of the main Department of Commerce building, as well as electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the CRU. In addition, parties can directly access a complete version of the Issues and Decision Memorandum on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

## Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties regarding our *Preliminary Results,* we did not make any revisions to the margin calculations for Fushun Jinly.

## Final Determination of No Shipments

In the *Preliminary Results,* we preliminarily determined that Fangda Group [4] and Xuzhou Jianglong Carbon Products Co., Ltd. (Xuzhou Jianglong) had no shipments of the subject merchandise during the POR.[5] We received no information to contradict this determination. Therefore, we continue to determine that Fangda Group and Xuzhou Jianglong had no shipments of subject merchandise during the POR, and will issue appropriate liquidation instructions that are consistent with our ''automatic assessment'' clarification, for these final results.[6]

## Final Results of the Review

Commerce determines that the following weighted-average dumping margin exists for Fushun Jinly for the POR from February 1, 2016, through January 31, 2017:

| Exporter | Weighted-average dumping margin (percent) |
|---|---|
| Fushun Jinly Petrochemical Carbon Co., Ltd [7] ..... | 0.00 |

Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,[8] we did not conduct a review of the China-wide entity. Thus, the weighted-average dumping margin for the China-wide entity (*i.e.,* 159.64 percent) [9] is not subject to change as a result of this review.

## Assessment Rates

Commerce determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). We intend to issue

[1] *See Small Diameter Graphite Electrodes from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017,* 83 FR 10658 (March 12, 2018) (*Preliminary Results*), and accompanying Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Administrative Review of the Antidumping Duty Order on Small Diameter Graphite Electrodes from the People's Republic of China; 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum for The Record from Christian Marsh, Deputy Assistant Secretary for Enforcement and Compliance, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Shutdown of the Federal Government'' (Tolling Memorandum), dated January 23, 2018. All deadlines in this segment of the proceeding have been extended by 3 days.

[4] The Fangda Group consists of Beijing Fangda Carbon Tech Co., Ltd., Chengdu Rongguang Carbon Co., Ltd., Fangda Carbon New Material Co., Ltd., Fushun Carbon Co., Ltd., and Hefei Carbon Co., Ltd. In a prior administrative review Commerce determined, pursuant to sections 771(33)(F) and (G) of the Tariff Act of 1930, as amended (the Act), that these companies were affiliated. Additionally, Commerce determined, pursuant to 19 CFR 351.401(f) that it was appropriate to treat these companies as a single entity. *See Small Diameter Graphite Electrodes from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Affirmative Preliminary Determination of Critical Circumstances, in Part,* 73 FR 49408, 49411–12 (August 21, 2008), unchanged in *Final Determination of Sales at Less Than Fair Value and Affirmative Determination of Critical Circumstances: Small Diameter Graphite Electrodes from the People's Republic of China,* 74 FR 2049 (January 14, 2009). Because there is no evidence on the record of this review that would require us to reevaluate this determination, we are continuing to treat these companies as part of the Fangda Group.

[5] *See Preliminary Results* at 10658–59.

[6] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 4, 2011) (*Assessment Practice Refinement*).

[7] Also known as Fushun Jinli Petrochemical Carbon Co., Ltd. *See* Petitioner's February 28, 2017 Request for Initiation of Antidumping Administrative Review at Attachment 1, p.11; *see also Small Diameter Graphite Electrodes from the People's Republic of China: Preliminary Results of the First Administrative Review of the Antidumping Duty Order; Partial Rescission of Administrative Review; and Intent to Rescind Administrative Review, in Part,* 76 FR 12324 (March 7, 2011) at n.7.

[8] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

[9] *See, Small Diameter Graphite Electrodes from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2015–2016,* 82 FR 10876, 10877 (February 16, 2017).

assessment instructions to CBP 15 days after the publication date of these final results of review. For entries of subject merchandise during the POR produced by Fushun Jinly, we will instruct the CBP to liquidate the appropriate entries without regard to antidumping duties because Fushun Jinly's weighted-average dumping margin in these final results is zero.[10]

Consistent with Commerce's assessment practice in non-market economy cases, for sales that were not reported in the U.S. sales data submitted by companies individually examined during this review, we will instruct CBP to liquidate entries associated with those sales at the rate for the China-wide entity. Furthermore, where we found that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's cash deposit rate) will be liquidated at the rate for the China-wide entity.[11]

**Cash Deposit Requirements**

The following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) No cash deposit will be required for subject merchandise exported by Fushun Jinly; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin for the China-wide entity (*i.e.,* 159.64 percent); and (4) for all non-Chinese exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

**Disclosure**

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

**Notification to Importers Regarding the Reimbursement of Duties**

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

**Notification Regarding Administrative Protective Order**

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: July 10, 2018.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

**Appendix**

**Issues and Decision Memorandum**

Summary
Background
Scope of the Order
Changes Since the *Preliminary Results*
Discussion of the Issues
  Comment 1: U.S. Sales Process and Whether to Apply Total Adverse Facts Available (AFA)
  Comment 2: Reliability of Factors of Production (FOP) and Sales Databases and Whether to Apply Total AFA
Recommendation

[FR Doc. 2018–15114 Filed 7–13–18; 8:45 am]

BILLING CODE 3510–DS–P

[10] *See* 19 CFR 351.106(c)(2).

[11] For a full discussion of this practice, *see Assessment Practice Refinement,* 76 FR at 65694.

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–533–840]**

### Certain Frozen Warmwater Shrimp From India: Final Results of Antidumping Duty Administrative Review; 2016–2017

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) determines that 230 companies made sales of certain frozen warmwater shrimp (shrimp) from India at less than normal value during the period of review (POR) February 1, 2016, through January 31, 2017.

**DATES:** Applicable July 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** Manuel Rey or Brittany Bauer, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5518 or (202) 482–3860, respectively.

**SUPPLEMENTARY INFORMATION:**

**Background**

This review covers 231 producers and/or exporters. The producers/exporters which Commerce selected for individual examination are Devi [1] and the Liberty Group.[2] The producers/exporters which were not selected for individual examination are listed in the ''Final Results of the Review'' section of this notice.

On March 12, 2018, Commerce published the *Preliminary Results.*[3] On April 11, 2018, we received a case brief from Devi and the Liberty Group (collectively, the respondents). On April 16, 2018, we received a rebuttal brief from the petitioner.[4]

[1] Devi consists of Devi Fisheries Limited, Satya Seafoods Private Limited, Usha Seafoods, and Devi Aquatech Private Limited.

[2] The Liberty Group consists of: Devi Marine Food Exports Private Ltd.; Kader Exports Private Limited; Kader Investment and Trading Company Private Limited; Liberty Frozen Foods Pvt. Ltd.; Liberty Oil Mills Ltd.; Premier Marine Products Private Limited; and Universal Cold Storage Private Limited.

[3] *See Certain Frozen Warmwater Shrimp from India: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 10665 (March 12, 2018) (*Preliminary Results*).

[4] The petitioner is the Ad Hoc Shrimp Trade Action Committee.

## Scope of the Order

The merchandise subject to the order is certain frozen warmwater shrimp.[5] The product is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) item numbers: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30, and 1605.29.10.10. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive.

## Analysis of Comments Received

All issues raised in the case briefs by parties are listed in the Appendix to this notice and addressed in the IDM. Parties can find a complete discussion of these issues and the corresponding recommendations in this public memorandum, which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*; the IDM is also available to all parties in the Central Records Unit, Room B8024, of the main Department of Commerce building. In addition, a complete version of the IDM can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed IDM and the electronic version of the IDM are identical in content.

## Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain changes to the margin calculations performed for Devi.[6]

## Final Results of the Review

We are assigning the following dumping margins to the firms listed below for the period of February 1, 2016, through January 31, 2017:

| Exporter/producer | Weighted-average dumping margin (percent) |
|---|---|
| Devi Fisheries Limited/Satya Seafoods Private Limited/Usha Seafoods/Devi Aquatech Private Limited | 1.35 |
| Devi Marine Food Exports Private Ltd./Kader Exports Private Limited/Kader Investment and Trading Company Private Limited/Liberty Frozen Foods Pvt. Ltd./Liberty Oil Mills Ltd./Premier Marine Products Private Limited/Universal Cold Storage Private Limited | 0.00 |

Review-Specific Average Rate Applicable to the Following Companies: [7]

| Exporter/producer | Weighted-average dumping margin (percent) |
|---|---|
| Abad Fisheries | 1.35 |
| Akshay Food Impex Private Limited | 1.35 |
| Alashore Marine Exports (P) Ltd | 1.35 |
| Alpha Marine | 1.35 |
| Allana Frozen Foods Pvt. Ltd | 1.35 |
| Allanasons Ltd | 1.35 |
| AMI Enterprises | 1.35 |
| Amulya Seafoods | 1.35 |
| Amarsagar Seafoods Private Limited | 1.35 |
| Ananda Aqua Applications/Ananda Aqua Exports (P) Limited/Ananda Foods | 1.35 |
| Ananda Enterprises (India) Private Limited | 1.35 |
| Angelique Intl | 1.35 |
| Anjaneya Seafoods | 1.35 |
| Apex Frozen Foods Private Limited | 1.35 |
| Aquatica Frozen Foods Global Pvt. Ltd | 1.35 |
| Arya Sea Foods Private Limited | 1.35 |
| Asvini Exports | 1.35 |
| Avanti Feeds Limited/Avanti Frozen Foods Private Limited | 1.35 |
| Asvini Fisheries Ltd/Asvini Fisheries Private Limited | 1.35 |
| Ayshwarya Seafood Private Limited | 1.35 |
| B-One Business House Pvt. Ltd | 1.35 |
| B R Traders | 1.35 |
| Baby Marine Exports | 1.35 |
| Baby Marine International | 1.35 |
| Baby Marine Sarass | 1.35 |
| Baby Marine Ventures | 1.35 |
| Balasore Marine Exports Private Limited | 1.35 |
| Bay Seafoods | 1.35 |
| Bhatsons Aquatic Products | 1.35 |
| Bhavani Seafoods | 1.35 |

[5] For a complete description of the Scope of the Order, *see* the Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2015–2016 Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from India,'' (dated concurrently with these results) (IDM), which is hereby adopted by this notice.

[6] *See* IDM at 4.

[7] This rate is based on the rates for the respondents that were selected for individual review, excluding rates that are zero, *de minimis* or based entirely on facts available. *See* section 735(c)(5)(A) of the Tariff Act of 1930, as amended (the Act).

| Exporter/producer | Weighted-average dumping margin (percent) |
|---|---|
| Bijaya Marine Products | 1.35 |
| Blue Fin Frozen Foods Pvt. Ltd | 1.35 |
| Blue Water Foods & Exports P. Ltd | 1.35 |
| Bluepark Seafoods Private Ltd | 1.35 |
| BMR Exports | 1.35 |
| BMR Industries Private Limited | 1.35 |
| Britto Exports | 1.35 |
| C P Aquaculture (India) Ltd | 1.35 |
| Calcutta Seafoods Pvt. Ltd | 1.35 |
| Canaan Marine Products | 1.35 |
| Capithan Exporting Co | 1.35 |
| Cargomar Private Limited | 1.35 |
| Castlerock Fisheries Ltd | 1.35 |
| Chakri Fisheries Private Limited | 1.35 |
| Chemmeens (Regd) | 1.35 |
| Cherukattu Industries (Marine Div.) | 1.35 |
| Choice Trading Corporation Private Limited | 1.35 |
| Coastal Aqua | 1.35 |
| Coastal Corporation Ltd | 1.35 |
| Cochin Frozen Food Exports Pvt. Ltd | 1.35 |
| Coreline Exports | 1.35 |
| Corlim Marine Exports Pvt. Ltd | 1.35 |
| Crystal Sea Foods Private Limited | 1.35 |
| D2 D Logistics Private Limited | 1.35 |
| Damco India Private Limited | 1.35 |
| Delsea Exports Pvt. Ltd | 1.35 |
| Devi Sea Foods Limited [8] | 1.35 |
| Diamond Seafoods Exports/Edhayam Frozen Foods Pvt. Ltd./Kadalkanny Frozen Foods/Theva & Company | 1.35 |
| Esmario Export Enterprises | 1.35 |
| Exporter Coreline Exports | 1.35 |
| Falcon Marine Exports Limited/K.R. Enterprises | 1.35 |
| Febin Marine Foods | 1.35 |
| Five Star Marine Exports Private Limited | 1.35 |
| Forstar Frozen Foods Pvt. Ltd | 1.35 |
| Frontline Exports Pvt. Ltd | 1.35 |
| G A Randerian Ltd | 1.35 |
| Gadre Marine Exports | 1.35 |
| Galaxy Maritech Exports P. Ltd | 1.35 |
| Geo Aquatic Products (P) Ltd | 1.35 |
| Geo Seafoods | 1.35 |
| Goodwill Enterprises | 1.35 |
| Grandtrust Overseas (P) Ltd | 1.35 |
| Growel Processors Private Limited | 1.35 |
| GVR Exports Pvt. Ltd | 1.35 |
| Haripriya Marine Export Pvt. Ltd | 1.35 |
| Harmony Spices Pvt. Ltd | 1.35 |
| HIC ABF Special Foods Pvt. Ltd | 1.35 |
| Hiravata Ice & Cold Storage | 1.35 |
| Hiravati Exports Pvt. Ltd | 1.35 |
| Hiravati International Pvt. Ltd. (located at APM—Mafco Yard, Sector—18, Vashi, Navi, Mumbai—400 705, India) | 1.35 |
| Hiravati International Pvt. Ltd. (located at Jawar Naka, Porbandar, Gujarat, 360 575, India) | 1.35 |
| HN Indigos Private Limited | 1.35 |
| Hyson Logistics and Marine Exports Private Limited | 1.35 |
| IFB Agro Industries Ltd | 1.35 |
| Indian Aquatic Products | 1.35 |
| Indo Aquatics | 1.35 |
| Indo Fisheries | 1.35 |
| Indo French Shellfish Company Private Limited | 1.35 |
| Innovative Foods Limited | 1.35 |
| International Freezefish Exports | 1.35 |
| Interseas | 1.35 |
| ITC Limited, International Business | 1.35 |
| ITC Ltd | 1.35 |
| Jagadeesh Marine Exports | 1.35 |
| Jayalakshmi Sea Foods Pvt. Ltd | 1.35 |
| Jinny Marine Traders | 1.35 |
| Jiya Packagings | 1.35 |
| K V Marine Exports | 1.35 |
| Kalyan Aqua & Marine Exp. India Pvt. Ltd | 1.35 |
| Kalyanee Marine | 1.35 |
| Kanch Ghar | 1.35 |
| Karunya Marine Exports Private Limited | 1.35 |

| Exporter/producer | Weighted-average dumping margin (percent) |
|---|---|
| Kay Kay Exports | 1.35 |
| Kings Marine Products | 1.35 |
| KNC Agro Limited | 1.35 |
| Koluthara Exports Ltd | 1.35 |
| Landauer Ltd | 1.35 |
| Libran Cold Storages (P) Ltd | 1.35 |
| Magnum Estates Limited | 1.35 |
| Magnum Export | 1.35 |
| Magnum Sea Foods Limited | 1.35 |
| Malabar Arabian Fisheries | 1.35 |
| Malnad Exports Pvt. Ltd | 1.35 |
| Mangala Marine Exim India Pvt. Ltd | 1.35 |
| Mangala Sea Foods | 1.35 |
| Mangala Sea Products | 1.35 |
| Marine Harvest India | 1.35 |
| Meenaxi Fisheries Pvt. Ltd | 1.35 |
| Milesh Marine Exports Private Limited | 1.35 |
| Monsun Foods Pvt. Ltd | 1.35 |
| MTR Foods | 1.35 |
| Munnangi Sea Foods Pvt. Ltd | 1.35 |
| N.C. John & Sons (P) Ltd | 1.35 |
| Naga Hanuman Fish Packers | 1.35 |
| Naik Frozen Foods Private Limited | 1.35 |
| Naik Seafoods Ltd | 1.35 |
| Naik Oceanic Exports Pvt. Ltd/Rafiq Naik Exports Pvt. Ltd | 1.35 |
| Neeli Aqua Private Limited | 1.35 |
| Nekkanti Sea Foods Limited | 1.35 |
| Nezami Rekha Sea Foods Private Limited | 1.35 |
| NGR Aqua International | 1.35 |
| Nila Sea Foods Pvt. Ltd | 1.35 |
| Nine Up Frozen Foods | 1.35 |
| Nutrient Marine Foods Ltd | 1.35 |
| Oceanic Edibles International Limited | 1.35 |
| Paragon Sea Foods Pvt. Ltd | 1.35 |
| Paramount Seafoods | 1.35 |
| Parayil Food Products Pvt. Ltd | 1.35 |
| Pasupati Aquatics Private Limited | 1.35 |
| Penver Products Pvt. Ltd | 1.35 |
| Pesca Marine Products Pvt. Ltd | 1.35 |
| Pijikay International Exports P Ltd | 1.35 |
| Pisces Seafood International | 1.35 |
| Pravesh Seafood Private Limited | 1.35 |
| Premier Exports International | 1.35 |
| Premier Marine Foods | 1.35 |
| Premier Seafoods Exim (P) Ltd | 1.35 |
| R V R Marine Products Limited | 1.35 |
| Raa Systems Pvt. Ltd | 1.35 |
| Raju Exports | 1.35 |
| Ram's Assorted Cold Storage Ltd | 1.35 |
| Raunaq Ice & Cold Storage | 1.35 |
| Raysons Aquatics Pvt. Ltd | 1.35 |
| Razban Seafoods Ltd | 1.35 |
| RBT Exports | 1.35 |
| RDR Exports | 1.35 |
| RF Exports | 1.35 |
| Riviera Exports Pvt. Ltd | 1.35 |
| Rohi Marine Private Ltd | 1.35 |
| Royal Marine Impex Private Limited | 1.35 |
| Royale Marine Impex Pvt. Ltd | 1.35 |
| RSA Marines | 1.35 |
| S & S Seafoods | 1.35 |
| S Chanchala Combines | 1.35 |
| S. A. Exports | 1.35 |
| Safa Enterprises | 1.35 |
| Sagar Foods | 1.35 |
| Sagar Grandhi Exports Pvt. Ltd | 1.35 |
| Sagar Samrat Seafoods | 1.35 |
| Sagarvihar Fisheries Pvt. Ltd | 1.35 |
| Sai Marine Exports Pvt. Ltd | 1.35 |
| Sai Sea Foods | 1.35 |
| Salvam Exports (P) Ltd | 1.35 |
| Sanchita Marine Products Private Limited | 1.35 |

| Exporter/producer | Weighted-average dumping margin (percent) |
|---|---|
| Sandhya Aqua Exports | 1.35 |
| Sandhya Aqua Exports Pvt. Ltd | 1.35 |
| Sandhya Marines Limited | 1.35 |
| Santhi Fisheries & Exports Ltd | 1.35 |
| Sarveshwari Exports | 1.35 |
| Sea Foods Private Limited | 1.35 |
| Seagold Overseas Pvt. Ltd | 1.35 |
| Selvam Exports Private Limited | 1.35 |
| Sharat Industries Ltd | 1.35 |
| Sharma Industries | 1.35 |
| Shimpo Exports Pvt. Ltd | 1.35 |
| Shimpo Seafoods Private Limited | 1.35 |
| Shiva Frozen Food Exports Pvt. Ltd | 1.35 |
| Shree Datt Aquaculture Farms Pvt. Ltd | 1.35 |
| Shroff Processed Food & Cold Storage P Ltd | 1.35 |
| Silver Seafood | 1.35 |
| Sita Marine Exports | 1.35 |
| Southern Tropical Foods Pvt. Ltd | 1.35 |
| Sowmya Agri Marine Exports | 1.35 |
| Sprint Exports Pvt. Ltd | 1.35 |
| Sri Sakkthi Cold Storage | 1.35 |
| Sri Venkata Padmavathi Marine Foods Pvt. Ltd | 1.35 |
| Srikanth International | 1.35 |
| Star Agro Marine Exports Private Limited | 1.35 |
| Star Organic Foods Incorporated | 1.35 |
| Star Organic Foods Private Limited | 1.35 |
| Sterling Foods | 1.35 |
| Sun-Bio Technology Ltd | 1.35 |
| Sunrise Aqua Food Exports | 1.35 |
| Supran Exim Private Limited | 1.35 |
| Suryamitra Exim (P) Ltd | 1.35 |
| Suvarna Rekha Exports Private Limited | 1.35 |
| Suvarna Rekha Marines P Ltd | 1.35 |
| TBR Exports Pvt. Ltd | 1.35 |
| Teekay Marine P. Ltd | 1.35 |
| The Waterbase Limited | 1.35 |
| Triveni Fisheries P Ltd | 1.35 |
| U & Company Marine Exports | 1.35 |
| Ulka Sea Foods Private Limited | 1.35 |
| Uniroyal Marine Exports Ltd | 1.35 |
| Unitriveni Overseas | 1.35 |
| V V Marine Products | 1.35 |
| V.S. Exim Pvt. Ltd | 1.35 |
| Vasai Frozen Food Co | 1.35 |
| Vasista Marine | 1.35 |
| Veejay Impex | 1.35 |
| Veerabhadra Exports Private Limited | 1.35 |
| Veronica Marine Exports Private Limited | 1.35 |
| Victoria Marine & Agro Exports Ltd | 1.35 |
| Vinner Marine | 1.35 |
| Vitality Aquaculture Pvt., Ltd | 1.35 |
| Wellcome Fisheries Limited | 1.35 |
| West Coast Fine Foods (India) Private Limited | 1.35 |
| West Coast Frozen Foods Private Limited | 1.35 |
| Z A Sea Foods Pvt. Ltd | 1.35 |

**Assessment Rates**

Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries.

Because the weighted-average dumping margin for the Liberty Group is zero, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Pursuant to 19 CFR 351.212(b)(1), because Devi reported the entered value for all its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the sales for which entered value was reported. To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer-specific *ad valorem* ratios based on the entered value.

[8] Shrimp produced and exported by Devi Sea Foods was excluded from the antidumping duty order effective February 1, 2009. *See Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part,* 75 FR 41813, 41814 (July 19, 2010). Accordingly, we are conducting this administrative review with respect to Devi Sea Foods only for shrimp produced in India where Devi Sea Foods acted as either the manufacturer or exporter (but not both).

For the companies which were not selected for individual examination, we used as the assessment rate the cash deposit rate assigned to these exporters, in accordance with our practice.[9]

Commerce's ''automatic assessment'' practice will apply to entries of subject merchandise during the POR produced by Devi or the Liberty Group for which these companies did not know that the merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[10]

Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

## Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for the reviewed companies will be the rates shown above, except if the rate is less than 0.50 percent (*de minimis* within the meaning of 19 CFR 351.106(c)(1)), the cash deposit will be zero; (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 previous review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all-other manufacturers or exporters will continue to be 10.17 percent, the all-others rate established in the LTFV investigation.[11] These deposit requirements, when imposed, shall remain in effect until further notice.

## Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

## Administrative Protective Order

In accordance with 19 CFR 351.305(a)(3), this notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213(h).

Dated: July 10, 2018.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix

**List of Topics Discussed in the IDM**

I. Summary
II. Background
III. Scope of the Order
IV. Margin Calculations
V. Discussion of the Issues
1. Ministerial Errors for Devi
VI. Recommendation

[FR Doc. 2018–15115 Filed 7–13–18; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See, e.g., Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review; 2015–2016,* 82 FR 43517 (September 18, 2017) and *Certain Frozen Warmwater Shrimp from India: Notice of Correction to the Final Results of the 2015–2016 Antidumping Duty Administrative Review,* 82 FR 43740 (September 19, 2017).

[10] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[11] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp from India,* 70 FR 5147, 5148 (February 1, 2005).

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–580–837]**

# Certain Cut-to-Length Carbon-Quality Steel Plate From the Republic of Korea: Final Results of Countervailing Duty Administrative Review and Rescission of Countervailing Duty Administrative Review, in Part

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) determines that Hyundai Steel Co. (Hyundai Steel), a producer/exporter of certain cut-to-length carbon-quality steel plate (CTL plate) from the Republic of Korea (Korea), received countervailable subsidies during the period of review (POR), January 1, 2016, through December 31, 2016, and that Dongkuk Steel Mill Co., Ltd. (DSM), a producer/exporter of CTL plate did not. We are also rescinding the review for 12 companies.

**DATES:** Applicable July 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** John Conniff at 202–482–1009 (for Hyundai Steel), or Jolanta Lawska at 202–482–8362 (for DSM), AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

## Background

Commerce published the preliminary results of this administrative review of CTL plate from Korea on March 12, 2018.[1] We invited interested parties to comment on the *Preliminary Results.* On April 11, 2018, we received a timely filed case brief from Nucor Corporation (the petitioner), and on April 16, 2018, Hyundai Steel submitted a timely filed rebuttal brief. Based on an analysis of the comments received, we made no changes to the subsidy rates determined for the respondents in the *Preliminary Results.*[2] The final subsidy rates are listed in the ''Final Results of Administrative Review'' section, below.

## Scope of the Order

The products covered by the order are certain hot-rolled carbon-quality steel:

[1] *See Certain Cut-to-Length Carbon-Quality Steel Plate from the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review; and Rescission of Review, in Part; Calendar Year 2016;* 83 FR 10661 (March 12, 2018) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See Preliminary Results,* 83 FR at 10662.

(1) Universal mill plates (*i.e.,* flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, and of a nominal or actual thickness of not less than 4 mm, which are cut-to-length (not in coils) and without patterns in relief), of iron or non-alloy-quality steel; and (2) flat-rolled products, hot-rolled, of a nominal or actual thickness of 4.75 mm or more and of a width which exceeds 150 mm and measures at least twice the thickness, and which are cut-to-length (not in coils).

The merchandise subject to the order is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings: 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7225.40.3050, 7225.40.7000, 7225.50.6000, 7225.99.0090, 7226.91.5000, 7226.91.7000, 7226.91.8000, 7226.99.0000.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the order is dispositive.

## Analysis of Comments Received

All issues raised in interested parties' case briefs are addressed in the Issues and Decision Memorandum.[3] The issues are identified in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and is available to all parties in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

## Changes Since the Preliminary Results

Based on the comments received from the petitioner and Hyundai Steel, we made no changes to the net subsidy rates calculated for the mandatory respondents. For a discussion of these issues, see the Issues and Decision Memorandum.

## Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[4] For a description of the methodology underlying all of Commerce's conclusions, see the Issues and Decision Memorandum.

## Rescission of the 2016 Administrative Review, in Part

Commerce initiated a review of 14 companies in this administrative review.[5] The petitioner timely withdrew its request for an administrative review of Bookuk Steel, Daewoo International Corp., Hyundai Glovis Co., Ltd., Hyundai Mipo Dockyard Co., Ltd., Hyuosung Corporation, Samsung C&T Corporation, Samsung C&T Engineering & Construction Group, Samsung C&T Trading Investment Group, Samsung Heavy Industries, SK Networks, Steel N People Co Ltd., and Sung Jin Steel Co., Ltd.[6] Therefore, in accordance with 19 CFR 351.213(d)(l), we are rescinding this administrative review with respect to these companies.

## Final Results of Administrative Review

In accordance with section 777A(e)(1) of the Act and 19 CFR 351.221(b)(5), we determine the total estimated net countervailable subsidy rates for the period January 1, 2016, through December 31, 2016 to be:

| Company | Subsidy rate ad valorem (percent) |
|---|---|
| Dongkuk Steel Mill Co., Ltd .. | * 0.21 |
| Hyundai Steel Co ..... | 0.54 |

* *De minimis.*

## Assessment and Cash Deposit Requirements

In accordance with 19 CFR 351.212(b)(2), Commerce intends to issue appropriate instructions to U.S. Customs and Border Protection (CBP) 15 days after publication of the final results of this review. For Hyundai Steel, Commerce will instruct CBP to liquidate shipments of subject merchandise produced and/or exported by the company, entered or withdrawn from warehouse, for consumption from January 1, 2016, through December 31, 2016, at the percent rate of the entered value. Because we have calculated a *de minimis* countervailable subsidy rate for DSM in the final results of this review, we will instruct CBP to liquidate the appropriate entries without regard to countervailing duties in accordance with 19 CFR 351.212.

Commerce intends also to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above, with the exception of DSM, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

## Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

[3] *See* Memorandum for the Record from James Maeder, Senior Director performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance: ''Issues and Decision Memorandum for the Final Results of Countervailing Duty Administrative Review and Partial Rescission: Cut-to-Length Carbon-Quality Steel Plate from the Republic of Korea,'' dated concurrently with this determination and hereby adopted by this notice (Issues and Decision Memorandum).

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 17188, April 10, 2017.

[6] *See* Letter from Petitioner, Certain Cut-To-Length Carbon-Quality Steel Plate from South Korea: Withdrawal of Request for Administrative Review in Part,'' dated July 10, 2017.

Dated: July 10, 2018.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Scope of the Order
III. Period of Review
IV. Subsidies Valuation Information
V. Analysis of Programs
VI. Analysis of Comments
Comment 1: Whether Hyundai Steel and Hyundai Green Power Are Cross-Owned Affiliates
Comment 2: Whether the Government of Korea Purchased Electricity From Hyundai Green Power for More Than Adequate Remuneration During the POR
VII. Recommendation

[FR Doc. 2018–15137 Filed 7–13–18; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

**[Docket Number: 180404350–8350–01]**

### Current and Future Workforce Needs to Support a Strong Domestic Semiconductor Industry

**AGENCY:** National Institute of Standards and Technology, Department of Commerce.

**ACTION:** Notice; Request for Information (RFI).

**SUMMARY:** The National Institute of Standards and Technology (NIST) on behalf of the Department of Commerce and the National Security Council is seeking information on the scope and sufficiency of efforts to educate, train, and attract the workforce necessary to meet the demands of the current and future semiconductor industry, in support of the President's National Security Strategy.

**DATES:** Comments must be received by 5:00 p.m. Eastern time on August 15, 2018. Written comments in response to this RFI should be submitted in accordance with the instructions in the **ADDRESSES** and **SUPPLEMENTARY INFORMATION** sections below. Submissions received after that date may not be considered.

**ADDRESSES:** To respond to this RFI, please submit written comments by email to *semiwkfc@nist.gov* in any of the following formats: ASCII; Word; RTF; or PDF. Please include your name, organization's name (if any), and cite ''Semiconductor Workforce RFI'' in the subject line of all correspondence. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All personal identifying information (*e.g.,* name, address) submitted voluntarily by the sender will be publicly accessible. *Do not submit confidential business information, or otherwise sensitive or protected information.* Attachments to electronic comments will be accepted in Microsoft Word or Excel, or Adobe PDF formats only.

Comments containing references, studies, research, and other empirical data that are not widely published should include electronic copies of the referenced materials. Please do not submit additional materials.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

**FOR FURTHER INFORMATION CONTACT:** For questions about this FRN contact: Jason Boehm or David Seiler, U.S. Department of Commerce, National Institute of Standards and Technology, at 301–975–8678 or 301–975–2074.

Please direct media inquiries to Jennifer Huergo in the NIST Public Affairs Office at *jennifer.huergo@nist.gov,* (301) 975–6343.

**SUPPLEMENTARY INFORMATION:** President Trump's National Security Strategy,[1] released in December of 2017, specifically highlights the importance of emerging technologies to economic growth and security, including advances in data science, encryption, autonomous technologies, new materials, advanced computing technologies, and artificial intelligence—all of which are powered by and dependent upon continued advances in semiconductor technology. Maintaining the technological edge of the United States in this critical industry area requires a robust domestic workforce. As part of the National Security Strategy, the United States will seek to maintain and develop the necessary workforce through a multifaceted approach including enhanced support for K–12, undergraduate, and graduate STEM education (with a particular focus on semiconductor technology), targeted technical training, internship and apprenticeship programs, and cooperative education programs.

Responses to this RFI will inform recommendations to the National Security Council on steps the Administration can take to strengthen the technical workforce that supports the semiconductor and related industries. The report will assess the scope and sufficiency of efforts to educate and train the future American semiconductor workforce from primary through higher education, and provide recommendations and a plan on how the government will continue to support the growth and sustainment of this workforce to meet the needs of both the private and public sectors.

In this RFI, NIST seeks specific information from stakeholders of the semiconductor industry such as materials providers, equipment suppliers, manufacturers, designers, trade associations, educational institutions, government entities, and other interested parties about the workforce needs of the semiconductor industry, and potential efforts to strengthen the current and future workforce. In this request, the term ''semiconductor'' broadly refers to semiconductor materials, devices, sensors, integrated circuits, computing architectures, software tools, design, lithography, fabrication, testing, packaging, embedded software and firmware developers, and related technologies that, through a combination of materials processing, manufacturing, and application, form the foundation and basis for the semiconductor, memory, technology manufacturing, computing, and information technology industry sectors.

NIST seeks information that will assist U.S. Government efforts in developing recommendations for supporting the growth and sustainment of the Nation's semiconductor workforce to meet the current and future needs of the public and private sectors. Our goal is to gather input that will be utilized to refine and target relevant federal resources and programs to attract, educate, and train the necessary advanced technical workforce necessary to ensure that the U.S. maintains a robust semiconductor industrial base, including the fundamental research needed to continue to innovate in semiconductor technologies, that is necessary to drive future advances in transformational technologies including

[1] *https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905-2.pdf.*

artificial intelligence (AI), advanced and quantum computing, and autonomous systems.

**Request for Information**

Respondents are encouraged—but not required—to respond to any or all of the following questions, and may address related topics. Please identify the questions or topic areas each of your comments addresses. The following questions cover the major areas about which NIST seeks comment. These questions are directed towards domestic semiconductor manufacturers, associated supporting industries, educational institutions, and their stakeholders. Responses may include estimates. Please indicate where the response is an estimate.

Respondents may organize their submissions in response to this RFI in any manner, and all responses that comply with the requirements listed in the **DATES** and **ADDRESSES** sections of this notice will be considered.

Comments containing references, studies, research, and other empirical data that are not widely published should include electronic copies of the referenced materials. *Do not include in comments or otherwise submit proprietary or confidential information.* Comments that contain profanity, vulgarity, threats, or inappropriate language or content will not be considered.

**Basic Information**

Briefly describe your company or organization in terms of:

a. What is the name of your company or organization?

b. How is your company or organization involved with the semiconductor industry (*e.g.,* industry association, university, company involved in semiconductor design, fabrication, package test and assembly, or other)?

**Workforce Challenges and Needs**

1. When hiring technical staff, for what types of positions do you encounter the most difficultly in finding qualified employees?

a. Have you been able to identify any causes for these recruitment difficulties (lack of appropriate educational programs, lack of collaboration between industry and educational institutions, competition within your industry, competition for talent from outside your industry, etc.)

2. Are there specific educational levels that are needed for your current workforce?

a. Are there some educational levels where it is harder to find qualified staff?

b. Have you been able to identify any causes for these difficulties in finding qualified staff (high competition for a specific talent pool, lack of experienced individuals, educational programs not directly aligned with your needs, etc.)

3. Are there certain factors relating to workforce needs that your company or organization prioritizes when locating a new facility, for example a strong base of existing talent, a robust local educational ecosystem, etc.?

4. How do you see the work force needs of your company or organization changing over the next 5 years, 10 years, 15 years?

a. Do you think that certain levels of education will be more important?

b. Are there fields of training that you think will be more important?

5. As the industry continues to evolve and develop and integrate new technologies (*e.g.,* new computing paradigms, new material systems, broader use of AI) are there skillsets that you see as becoming more important?

a. Do you have an opinion on the types of training needed to develop these skillsets for the future?

b. From your experience are there types of partnerships with federal agencies and/or educational institutions that would be helpful to prepare this workforce for the future?

6. Are there certain obstacles that you see as the biggest impediment to meeting your workforce needs? For example, a lack of aligned educational programs (including internship and apprenticeship opportunities), a lack of collaboration with such educational programs, a lack of students in science and engineering, a lack of interest in your industry, a lack of facilities with appropriate equipment to train workers (*e.g.,* community colleges without access to fabrication equipment/facilities), or other issues? Please describe.

**Potential Workforce Solutions**

7. Are there specific approaches your company or organization utilizes to address your workforce needs? For example, tailored partnerships and curricula with regional universities and community colleges, internship or apprenticeship programs, training or retraining of displaced workers, or other approaches?

8. Are there certain approaches or actions that would most effectively stimulate the supply of qualified workers for the semiconductor industry in the near term (*e.g.,* targeted scholarships including internships/apprenticeships, loan repayment incentives, procurement of specialized equipment for schools and universities, immigration and visa reform, etc.)?

9. What approaches do you think would most effectively stimulate the supply of qualified workers for the semiconductor industry over the long term (*e.g.,* professional development opportunities for K–12 teachers and K–12 student programs such as camps, competitions and projects in the semiconductor space)?

10. Although apprenticeship has, in the past, been available mostly to those in the traditional trades, efforts are now underway to expand apprenticeship into new fields, including advanced manufacturing, IT, healthcare, energy supply and distribution, banking and finance and engineering (in partnership with four-year institutions). Have you considered engaging in apprenticeship training to prepare your workforce? Why or why not?

11. Are there examples of partnerships with local educational institutions (*e.g.,* a work-study program) that you use to support your operations?

12. Are there types of support (grants, economic development incentives or other benefits) from federal, state and local government agencies that have helped enable your workforce? Of these types of support what makes them most effective?

**Authority:** 15 U.S.C. 278s.

**Kevin A. Kimball,**

*Chief of Staff.*

[FR Doc. 2018–15077 Filed 7–13–18; 8:45 am]

BILLING CODE 3510–13–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XG304**

### Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of Puerto Rico and the U.S. Virgin Islands; Exempted Fishing Permit

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

**ACTION:** Notice of receipt of an application for an exempted fishing permit; request for comments.

**SUMMARY:** NMFS announces the receipt of an application for an exempted fishing permit (EFP) from the NMFS Panama City, FL laboratory. If granted, the EFP would authorize NMFS or NMFS contracted commercial fishers aboard their commercial fishing vessels

to collect certain deep-water snapper species in waters of the U.S. exclusive economic zone (EEZ) in the Caribbean off Puerto Rico. The EFP would exempt this activity from complying with certain seasonal closures in the U.S. Caribbean EEZ. The purpose of the EFP is to gather information that could be used to define essential fish habitat (EFH) of deep-water snappers off the coast of Puerto Rico and to determine life history information for queen and blackfin snappers.

**DATES:** Comments must be received no later than August 15, 2018.

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

• *Email: Sarah.Stephenson@noaa.gov.* Include in the subject line of the email comment the following document identifier: ''PR NOAA NMFS_EFP 2018''.

• *Mail:* Sarah Stephenson, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

The EFP application and related documents are available for review upon written request to any of the above addresses.

**FOR FURTHER INFORMATION CONTACT:** Sarah Stephenson, 727–824–5305; email: *Sarah.Stephenson@noaa.gov.*

**SUPPLEMENTARY INFORMATION:** The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The applicant requests authorization to collect deep-water reef fish species in the U.S. Caribbean EEZ off the west, north, and south coasts of Puerto Rico. The applicant is seeking to gather information that could be used to define essential fish habitat for deep-water snapper species off the coast of Puerto Rico, and to obtain additional life history information about queen and blackfin snapper. Specimens would be collected by NMFS researchers and/or contractors and contracted commercial fishermen aboard three commercial fishing vessels. These activities may be conducted without NMFS staff aboard the contracted vessels. Each vessel's home port is located in Puerto Rico. This permit would exempt project participants from certain seasonal and area closure regulations at 50 CFR 622.435, as identified and described below. The EFP would be effective from the date of issuance through August 1, 2020.

Activities would consist of harvesting reef fish during a total of 450 fishing trips in the 2-year project period, of which 225 would be within the U.S. Caribbean EEZ off Puerto Rico. The remaining trips would be conducted in Puerto Rico territorial waters. Sampling sites would be randomly selected from locations with a high probability of containing habitat that could be considered essential for deep-water snappers as determined by bathymetric maps recently produced by NOAA's Marine Spatial Ecology Division. The target depth range for this project is 100 to 500 m, with sampling sites selected in each 50 m depth range throughout the overall depth range.

Sampling would be conducted by hook-and-line drift fishing in deep-water habitats, with underwater cameras attached to the fishing line. On each fishing trip, three to seven sites would be fished per day based on distance between the sampling sites and weather, with an average of five sites per day at sea and an average of 15 days at sea per vessel. At each site, one vertical fishing line would be deployed from the commercial fishing vessel with a surface float and bottom weight for a 30 minute soak time. Twelve #9 hooks would be attached to the bottom 2 m of the line and manual snapper reels would be used to retrieve the line. A GoPro camera encased in a light-weight pressure-tested housing and a light would be attached to a small, neutrally buoyant fitting on the vertical line. This camera array would be attached to the fishing line at two separate points, approximately 3 m above the bottom weight.

Project activities would be conducted from September 1, 2018, through August 1, 2020. The majority of sampling would occur each year in September and October. Sampling would occur at approximately 75 sites at each of the following locations in the EEZ off Puerto Rico:

• *Western region:* From Isabela to Puerto Real, including Isla de Desecheo Marine Reserve, within 12 miles of any point of land in Puerto Rico, from depths of 100–500 m.

• *Northeast region:* From San Juan to Fajardo, extending out to Isla de Culebra, within 12 miles of any point of land in Puerto Rico, from depths of 100–500 m.

• *Southeast region:* From Patillas to Buena Vista, extending out to Isla de Vieques, within 12 miles of any point of land in Puerto Rico, from depths of 100–500 m.

The applicant will target queen and blackfin snappers, but anticipates encountering other species. All queen and blackfin snappers caught during the EFP would be retained, and the gonads and otoliths would be extracted for subsequent analysis by NMFS, Puerto Rico's Department of Natural and Environmental Resources, and the University of South Carolina. Length measurements would be recorded for all targeted and incidental species except for species for which harvest is prohibited under Federal law (*i.e.,* goliath and Nassau groupers, and midnight, rainbow, and blue parrotfishes). These species would be returned immediately to the water with a minimum of harm. In order to minimize the negative biological effects of bringing these deep-water species to the surface, the commercial fishermen would have venting tools onboard their vessels to properly vent fish being released to facilitate their return to depth.

Based on catch and effort information from the commercial sector in Puerto Rico, the applicant anticipates harvesting up to 100 specimens of both queen and blackfin snappers in each of the three sampling regions, each year. Under the EFP, the applicant would be allowed to fish for and possess blackfin snapper during the October 1 through December 31 seasonal closure in place for vermilion, black, silk, or blackfin snappers (50 CFR 622.435(a)(1)(iii)). In addition, under the EFP, the applicant would be allowed to fish for and possess queen and blackfin snappers in or from the Bajo de Sico closed area, which is located in the project's western area off Puerto Rico, during the October 1 to March 31 closure period (50 CFR 622.435(a)(2)(iv)). Based on the sampling plan, the applicant anticipates making a maximum of 10 fishing trips over the 2 year period of the EFP to the Bajo de Sico closed area during the months of October through March.

Based on catch and effort information from the commercial sector in Puerto Rico, the applicant also anticipates catching up to 100 fish of the following species from each of the three sampling regions each year, as incidental catch: Black, silk, vermilion, and wenchman snappers (Snapper Unit 1); coney, graysby, red hind, and rock hind groupers (Grouper Unit 3); black, red, tiger, and yellowfin groupers (Grouper Unit 4), and misty and yellowedge groupers (Grouper Unit 5). It is possible that the applicant may also incidentally catch cardinal snapper, which is in Snapper Unit 2 with queen snapper, as they are targeting queen snapper and these species are frequently caught together.

Some of these incidental species (namely, red, black, tiger, yellowfin, yellowedge, and red hind groupers and vermilion, black, and silk snappers) are also subject to seasonal closures (50 CFR

622.435(a)(1)(i) & (ii) & (iii)). The applicant does not intend to retain any of these species caught during the respective seasonal closures. However, the EFP would allow the applicant to possess these species during those closure periods for sufficient time to collect and record length measurements, consistent with the goals of the EFP. If these species were caught outside of a closed season, the contracted commercial fishers would be able retain them, consistent with applicable law. These species also may be encountered in the Bajo de Sico closed area (50 CFR 622.435(a)(2)(iv)), and the EFP would allow the applicant to possess the species during the seasonal area closure for sufficient time to collect and record length measurements. No species caught as incidental catch during the seasonal or area closures would be retained during the EFP.

NMFS finds this application warrants further consideration based on a preliminary review. Possible conditions the agency may impose on this permit, if it is granted, include but are not limited to, a prohibition on conducting sampling activities within marine protected areas, marine sanctuaries, or special management zones, without additional authorization, and requiring compliance with best practices in the event of interactions with any protected species. NMFS may also require annual reports summarizing the amount of reef fish species harvested during the seasonal and area closures, as well as during the period of effectiveness of any issued EFP. Additionally, NMFS would require any sea turtles taken incidentally during the course of the activities to be handled with due care to prevent injury to live specimens, observed for activity, and returned to the water.

A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, consultations with the affected state(s), the Council, and the U.S. Coast Guard, and a determination that it is consistent with all applicable laws.

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

Dated: July 10, 2018.

**Margo B. Schulze-Haugen,**

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

[FR Doc. 2018–15074 Filed 7–13–18; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XG299**

### Nominations to the Marine Mammal Scientific Review Groups

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

**ACTION:** Notice; request for nominations.

**SUMMARY:** As required by of the Marine Mammal Protection Act (MMPA), the Secretary of Commerce established three independent regional scientific review groups (SRGs) to provide advice on a range of marine mammal science and management issues. NMFS conducted a membership review of the Alaska, Atlantic, and Pacific SRGs, and is soliciting nominations for new members to fill vacancies and gaps in expertise.

**DATES:** Nominations must be received by August 15, 2018.

**ADDRESSES:** Nominations can be emailed to *Shannon.Bettridge@noaa.gov,* or mailed to: Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226, Attn: SRGs.

**FOR FURTHER INFORMATION CONTACT:** Shannon Bettridge, Office of Protected Resources, 301–427–8402, *Shannon.Bettridge@noaa.gov.* Information about the SRGs, including the SRG Terms of Reference, is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/scientific-review-groups.*

**SUPPLEMENTARY INFORMATION:** Section 117(d) of the MMPA (16 U.S.C. 1386(d)) directs the Secretary of Commerce to establish three independent regional SRGs to advise the Secretary (authority delegated to NMFS). The Alaska SRG advises on marine mammals that occur in waters off Alaska that are under the jurisdiction of the United States. The Pacific SRG advises on marine mammals that occur in waters off the U.S. West Coast, Hawaiian Islands, and the U.S. Territories in the Central and Western Pacific that are under the jurisdiction of the United States. The Atlantic SRG advises on marine mammals that occur in waters off the Atlantic coast, Gulf of Mexico, and U.S. Territories in the Caribbean that are under the jurisdiction of the United States.

SRGs members are highly qualified individuals with expertise in marine mammal biology and ecology, population dynamics and modeling, commercial fishing technology and practices, and stocks taken under section 101(b) of the MMPA. The SRGs provide expert reviews of draft marine mammal stock assessment reports and other information related to the matters identified in section 117(d)(1) of the MMPA, including:

A. Population estimates and the population status and trends of marine mammal stocks;

B. Uncertainties and research needed regarding stock separation, abundance, or trends, and factors affecting the distribution, size, or productivity of the stock;

C. Uncertainties and research needed regarding the species, number, ages, gender, and reproductive status of marine mammals;

D. Research needed to identify modifications in fishing gear and practices likely to reduce the incidental mortality and serious injury of marine mammals in commercial fishing operations;

E. The actual, expected, or potential impacts of habitat destruction, including marine pollution and natural environmental change, on specific marine mammal species or stocks, and for strategic stocks, appropriate conservation or management measures to alleviate any such impacts; and

F. Any other issue which the Secretary or the groups consider appropriate.

SRG members collectively serve as independent advisors to NMFS and the U.S. Fish and Wildlife Service and provide their expert review and recommendations through participation in the SRG. Members attend annual meetings and undertake activities as independent persons providing expertise in their subject areas. Members are not appointed as representatives of professional organizations or particular stakeholder groups, including government entities, and are not permitted to represent or advocate for those organizations, groups, or entities during SRG meetings, discussions, and deliberations.

SRG membership is voluntary; and, except for reimbursable travel and related expenses, service is without pay. The term of service for SRG members is three years, and members may serve up to three consecutive terms if reappointed.

NMFS annually reviews the expertise available on the SRG and identifies gaps in the expertise that is needed to provide advice pursuant to section 117(d) of the MMPA. In conducting the reviews, NMFS attempts to achieve, to

the maximum extent practicable, a balanced representation of viewpoints among the individuals on each SRG.

**Expertise Solicited**

For the Atlantic SRG (including waters off the Atlantic coast, Gulf of Mexico, and U.S. Territories in the Caribbean), NMFS seeks individuals with expertise in one or more of the following priority areas (not in order of priority): Acoustics methodology and anthropogenic effects of sound on cetaceans; line-transect methodology, mark-recapture methods and survey design, and quantitative ecology; Gulf of Mexico/southeast U.S. bottlenose dolphin population dynamics; and manatees. Additional areas of expertise areas include marine mammal bycatch reduction, Caribbean marine mammal species, and genetics.

For the Pacific SRG (including waters off the Pacific coast, Hawaiian Islands and the U.S. Territories in the Central and Western Pacific), NMFS seeks individuals with expertise in one or more of the following areas (not in order of priority): Marine mammal stock definition and assessment under the MMPA and ESA; abundance estimation, especially distance sampling and mark-recapture methods and survey design; West Coast and Alaska fishing gear/techniques; West Coast pinnipeds, including assessment, life history, ecology, and human-pinniped interactions; large whales, particularly with regard to entanglement issues; ocean health and veterinary expertise, especially relative to disease and habitat change; fisheries oceanography and ecology, particularly decadal and long-term understanding; quantitative ecology, population dynamics, modeling, and statistics, especially as related to abundance and bycatch estimation, Bayesian methods, applications of new technologies, and methods for data-limited circumstances; State, Tribal, or regional/local fishery and/or marine mammal entanglement issues in the Pacific Islands and West Coast states; sea otters; science-management interface, such as management approaches with imperfect data; and interdisciplinary skills combining different fields of research.

For the Alaska SRG, NMFS seeks individuals with expertise in one or more of the following areas, in order of priority: The Alaska commercial fishing industry and commercial fishery methods/gear, particularly fisheries with marine mammal bycatch interactions; population dynamics, modeling, and statistics; and abundance estimation, especially distance sampling and mark-recapture methods and survey design; and knowledge of the MMPA and processing of marine mammal stock assessments.

**Submitting a Nomination**

Nominations for new members should be sent to Dr. Shannon Bettridge in the NMFS Office of Protected Resources (see **ADDRESSES**) and must be received by August 15, 2018. Nominations should be accompanied by the individual's curriculum vitae and detailed information regarding how the recommended person meets the minimum selection criteria for SRG members (see below). Nominations should also include the nominee's name, address, telephone number, and email address. Self-nominations are acceptable.

**Selection Criteria**

Although the MMPA does not explicitly prohibit Federal employees from serving as SRG members, NMFS interprets MMPA section 117(d)'s reference to the SRGs as ''independent'' bodies that are exempt from Federal Advisory Committee Act requirements to mean that SRGs are intended to augment existing Federal expertise and are not composed of Federal employees or contractors. Therefore, NMFS will not consider any nominee who is currently a Federal employee or a full-time contractor supporting a Federal agency.

When reviewing nominations, NMFS, in consultation with the U.S. Fish and Wildlife Service, will consider the following six criteria:

(1) Ability to make time available for the purposes of the SRG;

(2) Knowledge of the species (or closely related species) of marine mammals in the SRG's region;

(3) Scientific or technical achievement in a relevant discipline, particularly the areas of expertise identified above, to be considered an expert peer reviewer for the topic;

(4) Demonstrated experience working effectively on teams;

(5) Expertise relevant to current and expected needs of the SRG, in particular, expertise required to provide adequate review and knowledgeable feedback on current or developing stock assessment issues, techniques, etc. In practice, this means that each member should have expertise in more than one topic as the species and scientific issues discussed in SRG meetings are diverse; and

(6) No conflict of interest with respect to their duties as a member of the SRG.

*Next Steps*

Following review, nominees who are identified by NMFS as potential new members must be vetted and cleared in accordance with Department of Commerce policy. NMFS will contact these individuals and ask them to provide written confirmation that they are not registered Federal lobbyists or registered foreign agents, and to complete a confidential financial disclosure form, which will be reviewed by the Ethics Law and Programs Division within the U.S. Department of Commerce's Office of General Counsel. All nominees will be notified of a selection decision in advance of the 2019 SRG meetings.

Dated: July 10, 2018.

**Donna S. Wieting,**

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

[FR Doc. 2018–15064 Filed 7–13–18; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID: DOD–2018–OS–0023]**

### Submission for OMB Review; Comment Request

**AGENCY:** Office of the Under Secretary of Defense for Acquisition and Sustainment, DoD.

**ACTION:** 30-Day information collection notice.

**SUMMARY:** The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

**DATES:** Consideration will be given to all comments received by August 15, 2018.

**ADDRESSES:** Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

**FOR FURTHER INFORMATION CONTACT:** Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

**SUPPLEMENTARY INFORMATION:**

*Title; Associated Form; and OMB Number:* Base Realignment and Closure (BRAC) Military Base Reuse Status; DD Form 2740; OMB Control Number 0790–0003.

*Type of Request:* Reinstatement.

*Number of Respondents:* 100.
*Responses per Respondent:* 1.
*Annual Responses:* 100.
*Average Burden per Response:* 1 hour.
*Annual Burden Hours:* 100.
*Needs and Uses:* Through the Office of Economic Adjustment (OEA), Department of Defense (DoD) funds are provided to communities for economic adjustment planning in response to closures and realignments of military installations. A measure of program evaluation is the monitoring of civilian job creation, and the type of redevelopment at former military installations. The respondents to the annual survey will generally be a single point of contact at the local level that is responsible for overseeing the base redevelopment effort. If this data is not collected, OEA will have no accurate, timely information regarding the civilian reuse of former military bases. As the administrator of the Defense Economic Adjustment Program, OEA has a responsibility to encourage private sector use of lands and buildings to generate jobs as military activity diminishes, and to serve as a clearinghouse for reuse data.
*Affected Public:* Business or other for-profit; State, local, or tribal government.
*Frequency:* Annually.
*Respondent's Obligation:* Voluntary.
*OMB Desk Officer:* Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

*Instructions:* All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

*DOD Clearance Officer:* Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: July 11, 2018.

**Aaron T. Siegel,**

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

[FR Doc. 2018–15132 Filed 7–13–18; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### National Security Education Board; Notice of Federal Advisory Committee Meeting

**AGENCY:** Under Secretary of Defense for Personnel and Readiness, Department of Defense.

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the National Security Education Board will take place.

**DATES:** Open to the public Thursday, September 6, 2018 from 10:00 a.m. to 4:30 p.m.

**ADDRESSES:** Washington Hilton, 1919 Connecticut Avenue NW, Washington, DC 20009.

**FOR FURTHER INFORMATION CONTACT:** Michael Nugent, (571) 256–0702 (Voice), (703) 692–2615 (Facsimile), *michael.a.nugent22.civ@mail.mil* (Email). Mailing address is National Security Education Program, 4800 Mark Center Drive, Suite 08F09–02, Alexandria, VA 22350–7000. Website: *https://www.nsep.gov/content/national-security-education-board.* The most up-to-date changes to the meeting agenda can be found on the website.

**SUPPLEMENTARY INFORMATION:** This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

*Purpose of the Meeting:* The purpose of the meeting is to review and make recommendations to the Secretary of Defense concerning requirements established by the David L. Boren National Security Education Act, Title VII of Public Law 102–183, as amended.

*Agenda:* 10:00 a.m.—Welcome and Chair Opening Remarks. 10:30 a.m.—National Security Education Program (NSEP) Programmatic Updates. 11:00 a.m.—Boren Awards: New Pathways to Building the Pipeline. 11:45 a.m.—National Language Service Corps. 12:30 p.m.—Working Lunch with Boren Scholars and Fellows. 2:00 p.m.—Language Training Centers RAND Report. 3:00 p.m.—Federal Needs and Requirements. 4:00 p.m.—Board Discussion. 4:30 p.m.—Public Comment/Adjourn.

*Meeting Accessibility:* Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis.

*Written Statements:* This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150. Pursuant to 102–3.140 and sections 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Department of Defense National Security Education Board about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of the planned meeting. All written statements shall be submitted to the Designated Federal Official for the National Security Education Board, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Designated Federal Official can be obtained from the GSA's FACA Database—*http://facadatabase.gov/.* Statements being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Official at the address listed at least five calendar days prior to the meeting that is the subject of this notice. Written statements received after this date may not be provided to or considered by the National Security Education Board until its next meeting.

Dated: July 11, 2018.

**Aaron T. Siegel,**

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

[FR Doc. 2018–15136 Filed 7–13–18; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2018–ICCD–0074]**

### Agency Information Collection Activities; Comment Request; Magnet Schools Assistance Program—Government Performance and Results Act (GPRA) Table Form

**AGENCY:** Office of Innovation and Improvement (OII), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before September 14, 2018.

**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–2018–ICCD–0074. 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 207–13, Washington, DC 20202–4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Justis Tuia, 202–453–6654.

**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:* Magnet Schools Assistance Program—Government Performance and Results Act (GPRA) Table Form.

*OMB Control Number:* 1855–0025.

*Type of Review:* A revision of an existing information collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses:* 162.

*Total Estimated Number of Annual Burden Hours:* 81.

*Abstract:* The collection of this information is part of the government-wide effort to improve the performance and accountability of all federal programs, under the Government Performance and Results Act (GPRA) passed in 1993, the Uniform Guidance, and EDGAR. Under GPRA, a process for using performance indicators to set program performance goals and to measure and report program results was established. To implement GPRA, ED developed GPRA measures at every program level to quantify and report program progress required by the Elementary and Secondary Education Act of 1965, as amended. Under the Uniform Guidance and EDGAR, recipients of federal awards are required to submit performance and financial expenditure information. The GPRA program level measures and budget information for the Magnet Schools Assistance Program (MSAP) are reported in the Annual Performance Report (APR). The APR is required under 2 CFR 200.328 and 34 CFR 75.118 and 75.590. The annual report provides data on the status of the funded project that corresponds to the scope and objectives established in the approved application and any amendments. To ensure that accurate and reliable data are reported to Congress on program implementation and performance outcomes, the MSAP APR collects the raw data from grantees in a consistent format to calculate these data in the aggregate.

Dated: July 11, 2018.

**Tomakie Washington,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018–15150 Filed 7–13–18; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER18–1839–001.
*Applicants:* ExxonMobil Baton Rouge Complex.
*Description:* Compliance filing: Compliance to 8202015 to be effective 6/26/2018.
*Filed Date:* 7/10/18.
*Accession Number:* 20180710–5000.
*Comments Due:* 5 p.m. ET 7/31/18.

*Docket Numbers:* ER18–1981–000.
*Applicants:* Pratt Wind, LLC.
*Description:* Baseline eTariff Filing: Pratt Wind, LLC Application for Market-Based Rates to be effective 9/1/2018.
*Filed Date:* 7/9/18.
*Accession Number:* 20180709–5105.
*Comments Due:* 5 p.m. ET 7/30/18.

*Docket Numbers:* ER18–1982–000.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* § 205(d) Rate Filing: 2018–07–09_MISO 2nd Quarter Tariff Clean-Up Filing to be effective 1/1/2012.
*Filed Date:* 7/9/18.
*Accession Number:* 20180709–5111.
*Comments Due:* 5 p.m. ET 7/30/18.

*Docket Numbers:* ER18–1983–000.
*Applicants:* Silver Run Electric, LLC, PJM Interconnection, L.L.C.
*Description:* § 205(d) Rate Filing: Silver Run and NTD submit revisions to OATT to reflect Notice of Succession to be effective 6/27/2018.
*Filed Date:* 7/9/18.
*Accession Number:* 20180709–5115.
*Comments Due:* 5 p.m. ET 7/30/18.

*Docket Numbers:* ER18–1984–000.
*Applicants:* Big Level Wind LLC.
*Description:* Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 9/8/2018.
*Filed Date:* 7/9/18.
*Accession Number:* 20180709–5127.
*Comments Due:* 5 p.m. ET 7/30/18.

*Docket Numbers:* ER18–1986–000.
*Applicants:* Duke Energy Florida, LLC.
*Description:* Notice of Cancellation of Standard Large Generator Interconnection Ageement (SA No. 129) of Duke Energy Florida, LLC.
*Filed Date:* 7/9/18.
*Accession Number:* 20180709–5136.
*Comments Due:* 5 p.m. ET 7/30/18.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES18–46–000.
*Applicants:* Silver Run Electric, LLC.
*Description:* Application for Authorization Under Section 204 of the Federal Power Act to Issue Securities of Silver Run Electric, LLC.
*Filed Date:* 7/9/18.
*Accession Number:* 20180709–5153.
*Comments Due:* 5 p.m. ET 7/30/18.

The filings are accessible in the Commission's eLibrary system by

clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15117 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2100–187]**

### California Department of Water Resources; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Request for temporary change in recreational trail designation.

b. *Project No.:* 2100–187.

c. *Date Filed:* July 5, 2018.

d. *Applicant:* California Department of Water Resources.

e. *Name of Project:* Feather River Project.

f. *Location:* Feather River in Butte County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Gwen Knittweis, California Department of Water Resources, 1416 Ninth Street, P.O. Box 942836, Sacramento, CA 94236, (916) 557–4554.

i. *FERC Contact:* Hillary Berlin, (202) 502–8915, *hillary.berlin@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is August 3, 2018. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/doc-sfiling/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2100–187.

k. *Description of Request:* The licensee requests Commission approval to temporarily re-designate portions of the Brad Freeman, Bidwell Canyon, Dad Beebe, and Loafer Loop recreational trails to multi-use until the reopening of the Spillway Recreation Facilities in 2019. The proposed re-designation would allow equestrian use on portions of specific trails currently designated for bicycle/hiker use only, and bicyclist use of portions of specific trails currently designated for equestrian/hiker use only. Any comments relating to project relicensing are not within the scope of this public notice and subsequent analysis.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Motions to Intervene, or Protests:* Anyone may submit comments, a motion to intervene, or a protest in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, motions to intervene, or protests must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title COMMENTS, PROTEST, or MOTION TO INTERVENE, as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding in accordance with 18 CFR 385.2010.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15122 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER18–1981–000]**

### Pratt Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Pratt Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to

intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 30, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15120 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER18–1984–000]**

### Big Level Wind LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Big Level Wind LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 30, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15121 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. CP17–495–000; CP17–494–000]**

### Jordan Cove Energy Project, L.P., Pacific Connector Gas Pipeline, L.P.; Notice of Meeting

The environmental staff of the Federal Energy Regulatory Commission (Commission) along with representatives of the U.S. Forest Service, Bureau of Land Management, and the U.S. Army Corps of Engineers will meet with representatives of the Yurok Tribe to discuss the proposed Jordan Cove LNG and Pacific Connector Pipeline Projects. The meeting will be held at the location and time listed below:

Yurok Tribe—Klamath Administrative Office, 190 Klamath Boulevard, Klamath, CA 95548, Phone: (707) 482–1350, Wednesday, July 18, 2018, 10:00 a.m. PDT

Members of the public and intervenors in the referenced proceeding may attend and observe this meeting; however, participation will be limited to tribal representatives and agency personnel. If tribal representatives decide to disclose information about a specific location which could create a risk or harm to an archeological site or Native American cultural resource, the public will be excused for that portion of the meeting. A summary of the meeting will be entered into the Commission's administrative record.

If you plan to attend this meeting, please contact Mr. John Peconom, Environmental Project Manager at (202) 502–6352 or *John.Peconom@ferc.gov.*

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15125 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

**Filings Instituting Proceedings**

*Docket Numbers:* RP18–963–000.

*Applicants:* Eastern Shore Natural Gas Company.

*Description:* § 4(d) Rate Filing: Tariff Revisions to GT&C 6.14 Procedures for Allocating Available Firm Capacity to be effective 8/6/2018.

*Filed Date:* 7/6/18.

*Accession Number:* 20180706–5156.

*Comments Due:* 5 p.m. ET 7/18/18.

*Docket Numbers:* RP18–964–000.

*Applicants:* EQT Production Company, EQT Energy, LLC.

*Description:* Joint Petition of EQT Production Co., *et al.,* for Limited Waiver of Capacity Release Regulations and Tariff Provisions.

*Filed Date:* 7/9/18.

*Accession Number:* 20180709–5133.

*Comments Due:* 5 p.m. ET 7/23/18.

*Docket Numbers:* RP18–940–002.

*Applicants:* Empire Pipeline, Inc.

*Description:* Tariff Amendment: Errata No. 2 Empire Rate Case—June 2018 to be effective 8/1/2018.

*Filed Date:* 7/10/18.

*Accession Number:* 20180710–5028.

*Comments Due:* 5 p.m. ET 7/16/18.

*Docket Numbers:* RP18–965–000.

*Applicants:* Gulf Crossing Pipeline Company LLC.

*Description:* § 4(d) Rate Filing: Amendment to Neg Rate Agmt (BP37–28) to be effective 7/11/2018.

*Filed Date:* 7/10/18.

*Comments Due:* 5 p.m. ET 7/23/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15124 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #2

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG18–106–000.
*Applicants:* Big Sky North, LLC.
*Description:* EWG self-certification for Big Sky North, LLC.
*Filed Date:* 7/10/18.
*Accession Number:* 20180710–5115.
*Comments Due:* 5 p.m. ET 7/31/18.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER18–1987–000.
*Applicants:* Southwest Power Pool, Inc.
*Description:* § 205(d) Rate Filing: 3054R1 Upstream Wind Energy LLC GIA to be effective 6/12/2018.
*Filed Date:* 7/10/18.
*Accession Number:* 20180710–5054.
*Comments Due:* 5 p.m. ET 7/31/18.

*Docket Numbers:* ER18–1988–000.
*Applicants:* PacifiCorp.
*Description:* § 205(d) Rate Filing: Obsidian Renewables E&P Agmt to be effective 6/21/2018.
*Filed Date:* 7/10/18.
*Accession Number:* 20180710–5055.
*Comments Due:* 5 p.m. ET 7/31/18.

*Docket Numbers:* ER18–1989–000.
*Applicants:* Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.
*Description:* § 205(d) Rate Filing: MAIT submits two ECSAs, Service Agreement Nos. 4926 and 4927 to be effective 9/9/2018.
*Filed Date:* 7/10/18.
*Accession Number:* 20180710–5076.
*Comments Due:* 5 p.m. ET 7/31/18.

*Docket Numbers:* ER18–1990–000.
*Applicants:* Stonepeak Kestrel Energy Marketing LLC.
*Description:* Baseline eTariff Filing: Baseline new to be effective 7/11/2018.
*Filed Date:* 7/10/18.
*Accession Number:* 20180710–5085.
*Comments Due:* 5 p.m. ET 7/31/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15118 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RM98–1–000]**

### Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202)502–8659.

| Docket No. | File date | Presenter or requester |
|---|---|---|
| Prohibited: | | |
| 1. CP15–554–000 | 6–29–2018 | Stan Knick. |
| 2. CP15–554–000 | 7–3–2018 | Alain San Giorgio. |
| Exempt: | | |
| 1. ER18–1314–000 | 6–21–2018 | U.S. Senator Robert P. Casey, Jr. |
| 2. CP16–121–000 | 6–28–2018 | U.S. Congress.[1] |
| 3. CP14–96–000 | 7–3–2018 | The New York State Agencies.[2] |
| 4. P–2299–000, P–14581–000 | 7–5–2018 | FERC Staff.[3] |
| 5. P–2428–007, P–10254–026, P–10253–032 | 7–10–2018 | FERC Staff.[4] |

[1] Senators Jack Reed and Sheldon Whitehouse. Congressmen James R. Langevin and David Cicilline.
[2] The New York State Department of Homeland Security and Emergency Services, Department of Public Service, Department of Health, and Department of Environmental Conservation.
[3] Telephone memorandum dated July 5, 2018 reporting call with John Devine with HDR Engineering.
[4] Clarification request memo dated July 10, 2018 reporting communication with applicants Kevin Webb and Beth Harris with Enel Green.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15123 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. CP17–495–000; CP17–494–000]**

### Jordan Cove Energy Project, L.P.; Pacific Connector Gas Pipeline, L.P.; Notice of Meeting

The environmental staff of the Federal Energy Regulatory Commission (Commission) along with representatives of the U.S. Forest Service, Bureau of Land Management, and the U.S. Army Corps of Engineers will meet with representatives of the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians to discuss the proposed Jordan Cove LNG and Pacific Connector Pipeline Projects. The meeting will be held at the location and time listed below:

North Bend Public Library—Big Meeting Room, 1800 Sherman Avenue, North Bend, OR 97459, Phone: (541) 756–0400, Tuesday, July 17, 2018, 1:00 p.m. PDT

Members of the public and intervenors in the referenced proceeding may attend and observe this meeting; however, participation will be limited to tribal representatives and agency personnel. If tribal representatives decide to disclose information about a specific location which could create a risk or harm to an archeological site or Native American cultural resource, the public will be excused for that portion of the meeting. A summary of the meeting will be entered into the Commission's administrative record.

If you plan to attend this meeting, please contact Mr. John Peconom, Environmental Project Manager at (202) 502–6352 or *John.Peconom@ferc.gov.*

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15126 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. CP17–495–000; CP17–494–000]**

### Notice of Meeting; Jordan Cove Energy Project, LP; Pacific Connector Gas Pipeline, LP

The environmental staff of the Federal Energy Regulatory Commission (Commission) along with representatives of the U.S. Forest Service, Bureau of Land Management, and the U.S. Army Corps of Engineers will meet with representatives of the Karuk Tribe to discuss the proposed Jordan Cove LNG and Pacific Connector Pipeline Projects. The meeting will be held at the location and time listed below:

Karuk Tribe—Headway Building, 64236 Second Avenue, Happy Camp, CA 96039, Phone: (530) 493–5322, Wednesday, July 18, 2018, 3:30 p.m. PDT

Members of the public and intervenors in the referenced proceeding may attend and observe this meeting; however, participation will be limited to tribal representatives and agency personnel. If tribal representatives decide to disclose information about a specific location which could create a risk or harm to an archeological site or Native American cultural resource, the public will be excused for that portion of the meeting. A summary of the meeting will be entered into the Commission's administrative record.

If you plan to attend this meeting, please contact Mr. John Peconom, Environmental Project Manager at (202) 502–6352 or *John.Peconom@ferc.gov.*

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15127 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER18–1977–000]**

### Brantley Farm Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Brantley Farm Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 30, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15119 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP18–511–000]**

### Dakota Natural Gas, LLC; Notice of Application

Take notice that on June 28, 2018, Dakota Natural Gas, LLC (DNG), P.O. Box 68, Le Sueur, Minnesota 56058, filed in Docket No. CP18–511–000 an application pursuant to section 7(f) of the Natural Gas Act (NGA) requesting a service area determination so that it may expand or enlarge its facilities with or without further Commission authorization. DNG is a recently formed local distribution company (LDC) which aims to serve customers primarily in Drayton, North Dakota. In order to serve customers in Drayton, DNG would need to construct approximately 17.3 miles of new pipeline facilities, of which 9.3 miles would be located in Minnesota, running west from an interconnect with Viking Gas Transmission Company at a Town Border Station northwest of Donaldson, Minnesota to the Minnesota-North Dakota Border, with an additional 1.5-mile segment running from the Minnesota-North Dakota border to a regulator station north of Drayton. The remaining 6.5 miles of pipeline would run south from the regulator station to the city of Drayton. DNG also requests that the Commission determine that DNG qualifies as an LDC for the purposes of transportation under section 311 of the Natural Gas Policy Act of 1978 and that it be granted waiver of all reporting and accounting requirements, as well as other rules and regulations that are normally applicable to natural gas companies subject to the Commission's jurisdiction, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Jason T. Gray, Gray, Duncan, Weinberg, Genzer, & Pembroke, P.C., 1615 M Street NW, Suite 800, Washington, DC 20036, by telephone at (202) 467–6370, by fax at (202) 467–6379, or by email at *jtg@dwgp.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as

possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE, Washington, DC 20426.

*Comment Date:* 5:00 p.m. Eastern Time on July 31, 2018.

Dated: July 10, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–15128 Filed 7–13–18; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[9977–46–OEI]**

## Cross-Media Electronic Reporting: Authorized Program Revision Approval, Commonwealth of Massachusetts

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

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's approval of the Commonwealth of Massachusetts' request to revise/modify certain of its EPA-authorized programs to allow electronic reporting.

**DATES:** EPA approves the authorized program revision for the Commonwealth of Massachusetts' National Primary Drinking Water Regulations Implementation as of August 15, 2018, if no timely request for a public hearing is received and accepted by the Agency. EPA approves the other authorized program revisions/modifications as of July 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** Devon Martin, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–2603, *martin.devon@epa.gov.*

**SUPPLEMENTARY INFORMATION:** On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On September 8, 2017, the Massachusetts Department of Environmental Protection (MassDEP) submitted an application titled ''EEA ePLACE Platform'' for revisions/modifications to its EPA-approved programs under title 40 CFR to allow new electronic reporting. EPA reviewed MassDEP's request to revise/modify its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Massachusetts's request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR parts 50–52, 61–63, 65, 70, 141, 144, 146, 240–259, 260–270, 272–279, and 280, is being published in the **Federal Register**:

Part 52—Approval and Promulgation of Implementation Plans;

Part 61—National Emission Standards for Hazardous Air Pollutants, Subpart M, Asbestos;

Part 62—Approval and Promulgation of State Plans for Designated Facilities and Pollutants;

Part 63—National Emission Standards for Hazardous Air Pollutants for Source Categories;

Part 70—State Operating Permit Programs;

Part 142—National Primary Drinking Water Regulations Implementation;

Part 145—State Underground Injection Control Programs;

Part 239—Requirements for State Permit Program Determination of Adequacy;

Part 271—Requirements for Authorization of State Hazardous: Waste Program; and

Part 281—Technical Standards and Corrective Action Requirements for Owners and Operators of Underground Storage Tanks.

Specifically, EPA has approved the state's authorized program revisions for electronic submissions that include a handwritten signature on a separate paper submission report instead of an electronic signature.

MassDEP was notified of EPA's determination to approve its application with respect to the authorized programs listed above.

Also, in this notice, EPA is informing interested persons that they may request a public hearing on EPA's action to approve the Commonwealth of Massachusetts' request to revise its National Primary Drinking Water Regulations implementation program under 40 CFR part 142, in accordance with 40 CFR 3.1000(f), to allow for electronic reporting. Requests for a hearing must be submitted to EPA within 30 days of publication of today's **Federal Register** notice. Such requests should include the following information: (1) The name, address and telephone number of the individual,

organization or other entity requesting a hearing; (2) A brief statement of the requesting person's interest in EPA's determination, a brief explanation as to why EPA should hold a hearing, and any other information that the requesting person wants EPA to consider when determining whether to grant the request; (3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

In the event a hearing is requested and granted, EPA will provide notice of the hearing in the **Federal Register** not less than 15 days prior to the scheduled hearing date. Frivolous or insubstantial requests for hearing may be denied by EPA. Following such a public hearing, EPA will review the record of the hearing and issue an order either affirming today's determination or rescinding such determination. If no timely request for a hearing is received and granted, EPA's approval of the Commonwealth of Massachusetts' request to revise its part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting will become effective 30 days after today's notice is published, pursuant to CROMERR section 3.1000(f)(4).

**Matthew Leopard,**

*Director, Office of Information Management.*

[FR Doc. 2018–15135 Filed 7–13–18; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OEI–2011–0096; FRL—9980–55–OEI]**

### Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Cross-Media Electronic Reporting Rule (Renewal)

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Cross-Media Electronic Reporting Rule (EPA ICR No. 2002.07, OMB Control No. 2025–0003), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through July 31, 2018. Public comments were previously requested via the **Federal Register** on January 19, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

**DATES:** Additional comments may be submitted on or before August 15, 2018.

**ADDRESSES:** Submit your comments, referencing Docket ID Number EPA–HQ–OEI–2011–0096, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *oei.docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**FOR FURTHER INFORMATION CONTACT:** Devon Martin, Office of Environmental Information (2823T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–566–2603; email address: *martin.devon@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

*Abstract:* This ICR addresses the electronic reporting components of the Cross-Media Electronic Reporting Rule (CROMERR), which is designed to: (i) Allow EPA to comply with the Government Paperwork Elimination Act of 1998; (ii) provide a uniform, technology-neutral framework for electronic reporting across all EPA programs; (iii) allow EPA programs to offer electronic reporting as they become ready for CROMERR; and (iv) provide states with a streamlined process—together with a uniform set of standards—for approval of their electronic reporting provisions for all their EPA-authorized programs. Responses to the collection of information are voluntary. In order to accommodate CBI, the information collected must be in accordance with the confidentiality regulations set forth in 40 CFR part 2, subpart B. Additionally, EPA will ensure that the information collection procedures comply with the Privacy Act of 1974 and the OMB Circular 108.

*Form numbers:* None.

*Respondents/affected entities:* Entities that report electronically to EPA and state or local government authorized programs; and state and local government authorized programs implementing electronic reporting.

*Respondent's obligation to respond:* Voluntary, required to obtain or retain a benefit (Cross-Media Electronic Reporting Rule (CROMERR) established to ensure compliance with the Government Paperwork Elimination Act (GPEA)).

*Estimated number of respondents:* 175,047 (total).

*Frequency of response:* On occasion.

*Total estimated burden:* 83,837 hours (per year). Burden is defined at 5 CFR 1320.03(b).

*Total estimated cost:* $4,055,829 (per year), including $569,916 in annualized capital or operation & maintenance costs.

*Changes in the estimates:* There is an increase of 34,233 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase occurred primarily because of the launch of substantial new e-reporting systems by EPA, such as lead-based paint abatement notifications, and the anticipated launch of the e-Manifest system. Additionally, based on consultations with industry and state, tribal, and local agencies, EPA increased some of the previous burden estimates to reflect a more realistic average.

**Courtney Kerwin,**

*Director, Regulatory Support Division.*

[FR Doc. 2018–15134 Filed 7–13–18; 8:45 am]

**BILLING CODE 6560–50–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 August 8, 2018.

*A. Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Hometown Bancorp, Ltd., Fond du Lac, Wisconsin;* to acquire 100 percent of the voting shares of United Community Bank, Poynette, Wisconsin.

*B. Federal Reserve Bank of St. Louis* (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Cross County Bancshares, Wynne, Arkansas;* to acquire up to 35 percent of the voting shares of Central Bank, Little Rock, Arkansas.

2. *First Capital, Inc., Corydon, Indiana;* to acquire 5.15 percent of the voting shares of First Bancorp of Indiana, Inc., Evansville, Indiana; and thereby indirectly acquire First Federal Savings Bank, Evansville, Indiana.

Board of Governors of the Federal Reserve System, July 11, 2018.

**Ann Misback,**

*Secretary of the Board.*

[FR Doc. 2018–15108 Filed 7–13–18; 8:45 am]

**BILLING CODE P**

## FEDERAL RESERVE SYSTEM

**[Docket No. OP–1614]**

## FEDERAL DEPOSIT INSURANCE CORPORATION

## Resolution Planning Guidance for Eight Large, Complex U.S. Banking Organizations

**AGENCY:** Board of Governors of the Federal Reserve System (Board) and Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Proposed guidance; request for comments.

**SUMMARY:** The Board and the FDIC (together, the ''Agencies'') are inviting comments on proposed guidance for the 2019 and subsequent resolution plan submissions by the eight largest, complex U.S. banking organizations (''Covered Companies'' or ''firms''). The proposed guidance is meant to assist these firms in developing their resolution plans, which are required to be submitted pursuant to Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act. The proposed guidance, which is largely based on prior guidance issued to these Covered Companies, describes the Agencies' expectations regarding a number of key vulnerabilities in plans for an orderly resolution under the U.S. Bankruptcy Code (i.e., capital; liquidity; governance mechanisms; operational; legal entity rationalization and separability; and derivatives and trading activities). The proposed guidance also updates certain aspects of prior guidance based on the Agencies' review of these firms' recent resolution plan submissions. The Agencies invite public comment on all aspects of the proposed guidance.

**DATES:** Comments should be received September 14, 2018.

**ADDRESSES:** Interested parties are encouraged to submit written comments jointly to both Agencies. Comments should be directed to: *Board:* You may submit comments, identified by Docket No. OP–1614, by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfms* submitted, unless modified for technical reasons or to remove personal information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 3515, 1801 K Street NW (between 18th and 19th Street NW), between 9:00 a.m. and 5:00 p.m. on weekdays.

*FDIC:* You may submit comments by any of the following methods:

- *Agency Website: https://www.fdic.gov/regulations/laws/federal.* Follow the instructions for submitting comments on the Agency Website.
- *Email: comments@fdic.gov.* Include ''Proposed 165(d) Guidance for the Domestic Firms'' on the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.
- *Public Inspection:* All comments received, including any personal information provided, will be posted generally without change to *https://www.fdic.gov/regulations/laws/federal.*

**FOR FURTHER INFORMATION CONTACT:**

*Board:* Michael Hsu, Associate Director, (202) 452–4330, Division of Supervision and Regulation, Jay Schwarz, Senior Counsel, (202) 452–2970, Will Giles, Senior Counsel, (202) 452–3351, or Steve Bowne, Senior Attorney, (202) 452–3900, Legal Division. Users of Telecommunications Device for the Deaf (TDD) may call (202) 263–4869.

*FDIC:* Mike J. Morgan, Corporate Expert, *mimorgan@fdic.gov,* CFI Oversight Branch, Division of Risk Management Supervision; Alexandra Steinberg Barrage, Associate Director, Resolution Strategy and Policy, Office of Complex Financial Institutions, *abarrage@fdic.gov;* David N. Wall, Assistant General Counsel, *dwall@fdic.gov;* Pauline E. Calande, Senior Counsel, *pcalande@fdic.gov;* or Celia Van Gorder, Supervisory Counsel, *cvangorder@fdic.gov,* Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5365(d)) and the jointly issued implementing regulation, 12 CFR part 243 and 12 CFR part 381 (''the Rule''), requires certain financial companies to report periodically to the Board and the FDIC their plans for rapid and orderly resolution under the U.S. Bankruptcy Code in the event of material financial distress or failure.

Among other requirements, the Rule requires each financial company's resolution plan to include a strategic analysis of the plan's components, a description of the range of specific actions the company proposes to take in resolution, and a description of the company's organizational structure, material entities and interconnections and interdependencies. The Rule also requires that resolution plans include a confidential section that contains confidential supervisory and proprietary information submitted to the Board and the FDIC (together, the ''Agencies''), and a section that the Agencies make available to the public. Public sections of resolution plans can be found on the Agencies' websites.[1]

### *Objectives of the Resolution Planning Process*

The goal of the Dodd-Frank Act resolution planning process is to help ensure that a firm's failure would not have serious adverse effects on financial stability in the United States. Specifically, the resolution planning process requires firms to demonstrate that they have adequately assessed the challenges that their structure and business activities pose to resolution and that they have taken action to address those issues. Management should also consider resolvability as part of day-to-day decision making, particularly those related to structure, business activities, capital and liquidity allocation, and governance. In addition, firms are expected to maintain a meaningful set of options for selling operations and business lines to generate resources and to allow for restructuring under stress, including through the sale or wind down of discrete businesses that could further minimize the direct impact of distress or failure on the broader financial system. While these measures cannot guarantee that a firm's resolution would be simple or smoothly executed, these preparations can help ensure that the firm could be resolved under bankruptcy without government support or imperiling the broader financial system.

The Rule describes an iterative process aimed at strengthening the resolution planning capabilities of each financial institution. With respect to the eight largest, complex U.S. banking organizations (''Covered Companies'' or ''firms''),[2] the Agencies have previously provided guidance and other feedback.[3] In general, the feedback was intended to assist firms in their development of future resolution plan submissions and to provide additional clarity with respect to the expectations against which the Agencies will evaluate the resolution plan submissions. The Agencies are now proposing to update aspects of prior guidance based on the Agencies' review of the firms' recent resolution plan submissions.[4] The Agencies reviewed the 2017 Plans and issued a letter to each firm indicating that it had taken important steps to enhance its resolvability and facilitate its orderly resolution in bankruptcy.[5] As a result of those reviews and following the Agencies' joint decisions in December 2017, the Agencies identified four areas where more work may need to be done to improve the resolvability of the firms.[6] As described below, the Agencies are proposing updates to two areas of the guidance regarding payment, clearing, and settlement services and derivatives and trading activities. The Agencies intend to provide additional information on the two other areas: Intra-group liquidity and internal loss absorbing capacity. The Agencies invite public comment on all aspects of the proposed guidance.

## II. Overview of the Proposed Guidance

The proposed guidance is organized into six substantive areas, consistent with the guidance the Agencies provided to Covered Companies in April 2016 to assist in the development of their 2017 resolution plans, *Guidance for 2017 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Resolution Plans in July 2015* (''2016 Guidance'').[7] These areas are:

1. Capital
2. Liquidity
3. Governance mechanisms
4. Operational
5. Legal entity rationalization and separability
6. Derivatives and trading activities

Each area is important to firms in resolution as each plays a part in helping to ensure that the firm can be resolved in an orderly manner. The guidance would describe the Agencies' expectations for each of these areas.

The proposed guidance is largely consistent with the 2016 Guidance, which the Covered Companies used to develop their 2017 resolution plan submissions. Accordingly, the firms have already incorporated significant aspects of the proposed guidance into their resolution planning. The proposal would update the derivatives and trading activities (DER), and payment, clearing, and settlement activities (PCS) areas of the 2016 Guidance based on the Agencies' review of the Covered Companies' 2017 plans. It would also make minor clarifications to certain areas of the 2016 Guidance. In general, the proposed revisions to the guidance are intended to streamline the firms' submissions and to provide additional clarity. The proposed guidance is not meant to limit firms' consideration of additional vulnerabilities or obstacles that might arise based on a firm's particular structure, operations, or resolution strategy and that should be factored into the firm's submission.

*Capital:* The ability to provide sufficient capital to material entities without disruption from creditors is

[1] See the public sections of resolution plans submitted to the Agencies at *www.federalreserve.gov/bankinforeg/resolutionplans.htm* and *www.fdic.gov/regulations/reform/resplans/.*

[2] Bank of America Corporation, The Bank of New York Mellon Corporation, Citigroup Inc., the Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation and Wells Fargo & Company.

[3] This includes *Guidance for 2013 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Initial Resolution Plans in 2012;* detailed guidance and firm-specific feedback in August 2014 and February 2015 for the development of firms' 2015 resolution plan submissions; and *Guidance for 2017 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Resolution Plans in July 2015,* including the frequently asked questions that were published in response to the Guidance for the 2017 Plan Submissions (taken together, ''prior guidance'').

[4] Each firm's resolution strategy is designed to have the parent company recapitalize and provide liquidity resources to its material entity subsidiaries prior to entering bankruptcy proceedings. This strategy calls for material entities to be provided with sufficient capital and liquidity resources to allow them to avoid multiple competing insolvencies and maintain continuity of operations throughout resolution.

[5] *See* Letters dated December 19, 2017, from the Board and FDIC to Bank of America Corporation, The Bank of New York Mellon Corporation, Citigroup Inc., the Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation and Wells Fargo & Company, *available at https://www.federalreserve.gov/supervisionreg/resolution-plans.htm.*

[6] *Id.*

[7] *Available at: https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20160413a1.pdf and at https://www.fdic.gov/news/news/press/2016/pr16031b.pdf.*

important in order to ensure that material entities can continue to provide critical services and maintain critical operations as the firm is resolved. The proposal describes expectations concerning the appropriate positioning of capital and other loss-absorbing instruments (e.g., debt that the parent may forgive or convert to equity) among the material entities within the firm (resolution capital adequacy and positioning or RCAP). The proposal also describes expectations regarding a methodology for periodically estimating the amount of capital that may be needed to support each material entity after the bankruptcy filing (resolution capital execution need or RCEN).

*Liquidity:* A firm's ability to reliably estimate and meet its liquidity needs prior to, and in, resolution is important to the execution of a Covered Company's resolution strategy in that it enables the firm to respond quickly to demands from stakeholders and counterparties, including regulatory authorities in other jurisdictions and financial market utilities. Maintaining sufficient and appropriately-positioned liquidity also allows the subsidiaries to continue to operate while the firm is being resolved in accordance with the firm's preferred resolution strategy.[8]

*Governance Mechanisms:* An adequate governance structure with triggers capable of identifying the onset of financial stress events is important to ensure that there is sufficient time to allow firms to prepare for resolution, and to ensure the timely execution of their preferred resolution strategies. The governance mechanism section proposes expectations that firms have playbooks that detail the board and senior management actions necessary to execute the firm's preferred strategy. In addition, the proposal describes expectations that firms have triggers that are linked to specific actions outlined in these playbooks to ensure the timely escalation of information to senior management and the board, to address the successful recapitalization of subsidiaries prior to the parent's bankruptcy to the extent called for by the firm's preferred resolution strategy, and to address how the firm would ensure the timely execution of a bankruptcy filing. The proposal also describes the expectations that firms identify and analyze potential legal challenges to the provision of capital and liquidity to subsidiaries that would precede the parent's bankruptcy filing, and any defenses and mitigants to such challenges. In addition, the proposal describes expectations that firms incorporate any developments from this analysis in their governance playbooks.

*Legal entity rationalization and separability:* It is important that firms maintain a structure that facilitates orderly resolution. To achieve this, the proposal states that a firm should develop criteria supporting the preferred resolution strategy and integrate them into day-to-day decision making processes. The criteria would be expected to consider the best alignment of legal entities and business lines and facilitate resolvability as a firm's activities, technology, business models, or geographic footprint change over time. In addition, the proposed guidance provides that the firm should identify discrete and actionable operations that could be sold or transferred in resolution to provide meaningful optionality for the resolution strategy under a range of potential failure scenarios.

*Operational:* The development and maintenance of operational capabilities is important to support and enable execution of a firm's preferred resolution strategy, including providing for the continuation of critical operations and preventing or mitigating adverse impacts on U.S. financial stability. The proposed operational capabilities include:

Possessing fully developed capabilities related to managing, identifying, and valuing the collateral that is received from, and posted to, external parties and its affiliates;

Having management information systems that readily produce key data on financial resources and positions on a legal entity basis, and that ensure data integrity and reliability;

Developing a clear set of actions to be taken to maintain payment, clearing and settlement activities and to maintain access to financial market utilities, as further discussed below; and

Maintaining an actionable plan to ensure the continuity of all of the shared and outsourced services that their critical operations rely on.

In addition, the proposed guidance provides that a firm should analyze and address legal issues that may arise in connection with emergency motions the firm anticipates filing at the outset of its bankruptcy case seeking relief needed to pursue its preferred resolution strategy, including legal precedent and evidentiary support the firm expects to provide in support of such motions, key regulatory actions, and contingency arrangements.

*Derivatives and trading activities:* It is important that a firm's derivatives and trading activities can be stabilized and de-risked during resolution without causing significant market disruption. As such, firms should have capabilities to identify and mitigate the risks associated with their derivatives and trading activities and with the implementation of their preferred strategies, as further discussed below.

*Question 1: Do the topics in the proposed guidance discussed above represent the key vulnerabilities of the Covered Companies in resolution? If not, what key vulnerabilities are not captured?*

## III. Proposed Changes to Prior Guidance

In addition to making some clarifications, this proposal differs from prior guidance in that it reflects enhancements informed by the Agencies' review of the Covered Companies 2017 plans in the areas of DER and PCS.

The following description summarizes the changes relative to the topics outlined in the 2016 Guidance to which the Agencies are seeking comment and, where relevant, provides additional detail:

### *Operational: Payment, Clearing, and Settlement Activities*

The provision of PCS by firms, financial market utilities (FMUs), and agent banks is an essential component of the U.S. financial system, and maintaining the continuity of PCS services is important for the orderly resolution of firms. Prior guidance from the Agencies indicated that a firm's resolution plan submissions should describe arrangements to facilitate continued access to PCS services through the firm's resolution.

Based upon recent resolution plan submissions and the Agencies' engagement with the firms, the Agencies believe that the firms have developed capabilities to identify and consider the risks associated with continuity of access to PCS services in resolution. All of the firms described methodologies to identify key FMUs and agent banks based on quantitative and qualitative criteria and included playbooks for identified key FMUs or agent banks. These playbooks described potential adverse actions that could be taken by the FMU or agent bank, described possible contingency arrangements, and discussed the operational and financial impacts of such actions or arrangements, all of which were

[8] The Agencies are currently taking steps to better understand the purpose and treatment of the firms' inter-affiliate transactions. The Agencies do not expect the firms to make major changes to their RLAP and RLEN models until after the Agencies have completed this review and provided further feedback.

enhanced by the firms' direct communications with these FMUs and agent banks. The proposed PCS guidance clarifies the expectations of the Agencies with respect to a firm's capabilities to maintain continued access to PCS services through a framework. Considering the firms' earlier resolution plan submissions, the firms have the methodologies and capabilities in place to address these expectations.

*Framework.* The proposal states that firms should demonstrate capabilities for maintaining continued access to PCS services through a framework that incorporates the identification of key clients,[9] FMUs, and agent banks, using both quantitative [10] and qualitative criteria, and the development of a playbook for each key FMU and agent bank. The proposed guidance builds upon existing guidance by specifying that the framework should consider key clients (which may include affiliates of the firm) and agent banks. The Agencies note that, although the existing guidance did not expressly suggest the identification of key agent banks and playbooks for such agent banks, the firms considered agent bank relationships and each provided a playbook for at least one key agent bank in its most recent resolution plan submission. Because agent bank relationships may essentially replicate PCS services provided by FMUs, the Agencies propose to revise the PCS guidance to include the identification and development of playbooks for key agent banks.

In applying the framework, the firm would be expected to consider its role as a user and/or a provider of PCS services. The proposal refers to a user of PCS services as a firm that accesses the services of an FMU through its own membership in that FMU or through the membership of another firm that provides PCS services on an agency basis. A firm is a provider of PCS services under the proposed guidance if it provides its clients with access to an FMU or agent bank through the firm's membership in or relationship with that service provider. A firm also would be a provider if it delivers PCS services critical to a client through the firm's own operations in a manner similar to an FMU.

The proposal provides that a firm's framework should take into account the various relationships the firm and its key clients have with those key FMUs and agent banks by providing a mapping of material entities, critical operations, core business lines, and key clients to key FMUs and agent banks. This framework would be expected to consider both direct relationships (e.g., firm's direct membership in the FMU, firm provides key clients with critical PCS services through its own operations, firm's contractual relationship with an agent bank) and indirect relationships (e.g., firm provides its clients with access to the relevant FMU or agent bank through the firm's membership in or relationship with that FMU or agent bank).

By developing and evaluating these activities and relationships through a framework that incorporates the elements above, a firm should be able to consider the issue of maintaining continuity of PCS services in a systematic manner.

*Question 2: Is the guidance sufficiently clear with respect to the following concepts: Scope of PCS services, user vs. provider, direct vs. indirect relationships? What additional clarifications or alternatives concerning the proposed framework or its elements, if any, should the Agencies consider? For instance, would further examples of ways that firms may act as provider of PCS services be useful? Should the Agencies consider further distinguishing between providers based on the type of PCS service they provide?*

*Playbooks for Continued Access to PCS Services.* Firms also would be expected to provide a playbook for each key FMU and agent bank that addresses financial considerations and includes operational detail that would assist the firm in maintaining continued access to PCS services for itself and its clients in stress and in resolution. Under the proposal, each key FMU and agent bank playbook would be expected to provide analysis of the financial and operational impact to the firm's material entities and key clients due to a loss of access to the FMU or agent bank. Each playbook also should discuss any possible alternative arrangements that would allow the firm and its key clients to maintain continued access to PCS services in resolution. However, the firm is not expected to incorporate a scenario in which it loses FMU or agent bank access into its preferred resolution strategy or its RLEN/RCEN estimates.

Firms communicated with key FMUs and agent banks in preparing their most recent resolution plan submissions and indicated that such communication was helpful in refining their analysis concerning potential adverse actions and contingency arrangements. Firms would be expected to continue to engage with key FMUs, agent banks, and clients, and playbooks would be expected to reflect any feedback received during such ongoing outreach. Firms are encouraged to continue engaging with each other, key FMUs and agent banks, and other stakeholders to identify possible initiatives or additional ways to support continued access to PCS services.

The proposed guidance differentiates the type of information to be included in a firm's key FMU and agent bank playbooks based on whether a firm is a user of PCS services with respect to that FMU or agent bank, a provider of PCS services with respect to that FMU or agent bank, or both. To the extent a firm is both a user and a provider of PCS services with respect to a particular FMU or agent bank, the firm would be expected to provide the described content for both users and providers of PCS services. A firm would be able to do so either in the same playbook or in separate playbooks included in its resolution plan submission.

*Content related to Users of PCS Services.* Under the proposal, each playbook for an individual FMU or agent bank should include, at a minimum, a description of the firm's relationship as a user with the key FMU or agent bank and an identification and mapping of PCS services to the associated material entities, critical operations, and core business lines that use those PCS services, as well as a discussion of the potential range of adverse actions that could be taken by that key FMU or agent bank in a period of stress for the firm or upon the firm's resolution.[11] Playbooks submitted as part of the firms' most recent resolution plan submissions mapped the PCS services provided to material entities, critical operations, and core business lines at a fairly granular level, which enhanced the utility of these playbooks.

In discussing the potential range of adverse actions that a key FMU or agent bank could take, each playbook would be expected to address the operational and financial impact of such actions on each material entity and discuss contingency arrangements that the firm may initiate in response to such actions by the key FMU or key agent bank. Operational impacts may include effects

[9] A client is an individual or entity, including affiliates of the firm, that relies upon continued access to the firm's PCS services and any related credit or liquidity offered in connection with those services. As a result, key clients may not necessarily be limited to wholesale clients.

[10] Examples of quantitative criteria include not only the aggregate volumes and values of all transactions processed through an FMU but also assets under custody with an agent bank, the value of cash and securities settled through an agent bank, and extensions of intraday credit.

[11] Potential adverse actions may include increased collateral and margin requirements and enhanced reporting and monitoring.

on governance mechanisms or resource allocation (including human resources), as well as any expected enhanced communication with key stakeholders (*e.g.,* regulators, FMUs and agent banks). Financial impacts may include those directly associated with liquidity or any additional costs incurred by the firm as a result of such adverse actions and contingency arrangements. The proposed PCS guidance specifies that each playbook should discuss PCS-related liquidity sources and uses in business-as-usual (BAU), in stress, and in the resolution period. Each firm would be expected to determine the relevant measurement points, and this information would be presented by currency type (with U.S. dollar equivalent) and by material entity. Each playbook also would be expected to describe any account features that might restrict the firm's ready access to its intraday liquidity sources, the firm's ability to control intraday liquidity outflows, and the firm's capabilities to identify and prioritize time-specific payments.

*Content related to Providers of PCS Services.* Under the proposal, a firm that is a direct or indirect provider of PCS services would be expected to identify key clients that rely upon PCS services provided by the firm in its playbook for the relevant FMU or agent bank. Playbooks would be expected to describe the scale and manner in which the firm's material entities, critical operations, and core business lines provide PCS services and any related credit or liquidity offered by the firm in connection with such services. Similar to the playbook content expected of users of PCS services, each playbook would be expected to include a mapping of the PCS services provided to each material entity, critical operation, core business line, and key clients. In the case where a firm is a provider of PCS services through its own operations, the firm would expected to produce a playbook for the material entity that provides those services, and the playbook would focus on continuity of access for its key clients.

The proposal states that playbooks should discuss the potential range of contingency arrangements available to the firm to minimize disruption to its provision of PCS services to its clients and the financial and operational impacts of such arrangements. Contingency arrangements may include viable transfer of client activity and any related assets or any alternative arrangements that would allow the firm's key clients to maintain continued access to critical PCS services. The playbook also would be expected to describe the range of contingency actions that the firm may take concerning its provision of intraday credit to key clients and to provide analysis quantifying the potential liquidity that the firm could generate by taking each such action in stress and in the resolution period. To the extent a firm would not take any such actions as part of its preferred resolution strategy, the firm would be expected to describe its reasons for not taking any contingency action.

Under the proposal, a firm should communicate the potential impacts of implementation of any identified contingency arrangements or alternatives to its key clients, and playbooks should describe the firm's methodology for determining whether it should provide any additional communication to some or all key clients (*e.g.,* due to the client's usage of that access and/or related extensions of credit), as well as the expected timing and form of such communication. The Agencies note that in their most recent submissions, all of the firms addressed the issue of client communications and provided descriptions of planned or existing client communications, with some firms submitting specific samples of such communication. Firms would be expected to consider any benefit of communicating this information in multiple forms (*e.g.,* verbal, written) and at multiple time periods (*e.g.,* BAU, stress, some point in time in advance of taking contingency actions) in order to provide adequate notice to key clients of the action and the potential impact on the client of that action. In making decisions concerning communications to its key clients, the proposal states that firms also should consider any benefit of tailoring communications to different subsets of clients (*e.g.,* based on different levels of activity or credit usage) in form, timing, or both. Playbooks may include sample client contracts or agreements containing provisions related to the firm's provision of intraday credit or liquidity.[12] Such sample contracts or agreements may be particularly important to the extent that the firm believes those documents sufficiently convey to clients the contingency arrangements available to the firm and the potential impacts of implementing such contingency arrangements.

*Question 3: Are the Agencies' expectations with respect to playbook content for firms that are users or providers (or both) of PCS services sufficiently clear? What additional clarifications, alternatives, or additional information, if any, should the Agencies consider?*

*Question 4: Should the guidance indicate that providers of PCS activities are expected to expressly consider particular contingency arrangements (e.g., methods to transfer client activity to other firms with whom the clients have relationships, alternate agent bank relationships)? Should the guidance also indicate that firms should expressly consider particular actions they may take concerning the provision of intraday credit to affiliate and third-party clients, such as requiring pre-funding? If so, what particular actions should these firms address?*

*Question 5: Specifically for users of PCS activities, should the guidance indicate that firms are expected to expressly include particular PCS-related liquidity sources and uses such as client pre-funding, or specific abilities to control intraday liquidity inflows and outflows (e.g., throttling or prioritizing of payments)? If so, what particular sources and uses should firms be expected to include?*

*Question 6: Specifically for providers of PCS services are the Agencies' expectations concerning a firm's communication to its key clients (including affiliates as applicable) of the potential impacts of implementation of identified contingency arrangements sufficiently clear? What additional clarifications, if any, should the Agencies consider? Should the Agencies expect firms to communicate this information at specific times or in specific formats?*

*Derivatives and Trading Activities*

This section of the proposed guidance is intended to explain expectations for Bank of America Corporation, Citigroup Inc., The Goldman Sachs Group, Inc., JP Morgan Chase & Co., Morgan Stanley, and Wells Fargo & Company (each, a ''dealer firm'').[13]

The size, scope, complexity, and opacity of a firm's global derivatives and trading activities may present

[12] If these sample client contracts or agreements are included separately as part of the firm's resolution plan submission, they may be incorporated into the playbook by reference.

[13] Dealer firms share many quantitative and qualitative characteristics. For example, each dealer firm is a Covered Company that (as of December 31, 2017) (i) has total derivatives notional values greater than $5 trillion, (ii) has global gross market value of derivatives greater than $20 billion, (iii) has a sum of global trading assets and trading liabilities greater than $110 billion (each on the basis of a 3-year rolling average), (iv) is subject to the GSIB Surcharge and all components of the CCAR quantitative assessment (*i.e.,* global market shock and counterparty default scenario components), and (v) is parent to a designated primary dealer.

significant risk to resolvability. To facilitate an orderly resolution, a dealer firm should be able to demonstrate the ability to stabilize and de-risk its derivatives and trading activities during resolution without posing a threat to U.S. financial stability. Therefore, dealer firms have developed capabilities to identify and mitigate the risks associated with their derivatives and trading activities and with the implementation of their preferred resolution strategies. These capabilities seek to facilitate a dealer firm's planning, preparedness, and execution of an orderly resolution. The proposed guidance would clarify the Agencies' expectations with respect to such capabilities and a firm's analysis of its preferred strategy. The proposed guidance also would eliminate the expectations of the 2016 Guidance that a dealer firm's resolution plan include separate passive and active wind-down scenario analyses, the agency-specified data templates, and rating agency playbooks.

Over the past several years, the Agencies have engaged significantly with dealer firms to assess their resolution capabilities and to provide feedback with respect to their resolution preparedness. As a group, dealer firms have made meaningful improvements over previous resolution plan submissions. These improvements include efforts by dealer firms to enhance their resolution capabilities related to derivatives and trading activities and to integrate those capabilities with their business-as-usual practices. The expectations set out in this section of the proposed guidance reflect many of those improvements. As described in more detail below, this section of the proposed guidance is organized in five subsections. The first four of the subsections describe expectations for resolution capabilities that are commensurate with the size, scope and complexity of a firm's derivatives portfolios and should help assure that dealer firms maintain the operational preparedness to implement an orderly resolution. The fifth subsection—derivatives stabilization and de-risking strategy—describes expectations for a dealer firm's analysis of its approach to managing its derivatives portfolios in an orderly resolution.

*Booking practices.* To minimize uncertainty and avoid excessive complexity and opacity that can frustrate a firm's resolution preparedness, a dealer firm's resolution capabilities should include booking practices commensurate with the size, scope and complexity of a firm's derivatives portfolios. Dealer firms are currently developing booking practices that provide timely and up-to-date information regarding the structure, risks and resource needs associated with the management of its derivatives activities under a broad range of potential stress and failure scenarios. Therefore, the proposed guidance would clarify the capabilities a dealer firm is expected to have related to its booking practices, including descriptions of its comprehensive booking model framework and demonstrations of its ability to identify, assess, and report on each entity with derivatives portfolios (a ''derivatives entity'').[14]

*Inter-affiliate risk monitoring and controls.* Affiliates of a derivatives entity may be forced to discontinue a trading relationship with that derivatives entity during resolution, which poses risks to the orderly resolution of a firm. The proposal describes the Agencies' expectations that a dealer firm address this risk by being able to provide timely transparency into the current risk transfers between affiliates and the resolvability risks related to such transfers, including expectations regarding an inter-affiliate market risk framework that enables the firm to monitor and limit the exposures a derivatives entity that is a material entity could experience in an extreme resolution scenario.

*Portfolio segmentation and forecasting.* The ability to quickly and reliably identify problematic derivatives positions and portfolios is critical to minimizing uncertainty and forecasting resource needs to enable an orderly resolution. Each dealer firm has developed various modeling approaches that are used to evidence the adequacy of the capabilities and resources needed to execute its preferred resolution strategy. The utility of these modeled results is often affected by the scope of readily available data on the underlying characteristics of a dealer firm's derivatives portfolios. Therefore, the proposal confirms that a dealer firm should have the capabilities to produce analysis that reflects granular portfolio segmentation and differentiation of assumptions taking into account trade-level characteristics. Similarly, the proposed guidance also provides additional detail regarding other segmentation and forecasting related capabilities that the dealer firm's resolution plan should describe and demonstrate. These capabilities include (i) a method and supporting systems capabilities for categorizing and ranking the ease of exit for its derivatives positions (''*ease of exit*'' *position analysis*), (ii) the systems capabilities to apply the firm's exit cost methodology to its firm-wide derivatives portfolio (*application of exit cost methodology*), (iii) capabilities to assess the operational resources and forecast the costs related to its current derivatives activities (*analysis of operational capacity*), and (iv) a method to apply sensitivity analyses to the key drivers of the derivatives-related costs and liquidity flows under its preferred resolution strategy (*sensitivity analysis*).

*Prime brokerage customer account transfers.* The rapid withdrawal from a firm by prime brokerage clients can contribute to a disorderly resolution. Dealer firms' resolution plans should address the risk that during a resolution the firm's prime brokerage clients may seek to withdraw or transfer customer accounts balances in rates significantly higher than normal business conditions. The proposed guidance confirms that dealer firms should have the capabilities to facilitate the orderly transfer of prime brokerage account balances to peer prime brokers and describes the Agencies' related expectations in greater detail. In particular, the proposed guidance clarifies that a dealer firm's resolution plan should describe and demonstrate its ability to segment and analyze the quality and composition of such account balances and to rank account balances according to their potential transfer speed.

*Derivatives stabilization and de-risking strategy.* A key risk to the orderly resolution of a dealer firm is a volatile and risky derivatives portfolio. In the event of material financial distress or failure, the resolvability risks related to a dealer firm's derivatives and trading activities would be a key obstacle to the firm's rapid and orderly resolution. Dealer firms' resolution plans should address this obstacle. The proposed guidance confirms that a dealer firm's plan should provide a detailed analysis of the strategy to stabilize and de-risk its derivatives portfolios (''derivatives strategy'') and provides additional detail regarding the Agencies' expectations.[15] In particular, the proposed guidance clarifies that a dealer firm should incorporate into its derivatives strategy

[14] Consistent with prior guidance, ''derivatives entities'' should include both material and non-material entities, in part because non-material entities, in the aggregate, may represent significant exposures.

[15] Subject to the certain constraints, a firm's derivatives strategy may take the form of a going-concern strategy, an accelerated de-risking strategy (*e.g.,* active wind-down) or an alternative, third strategy so long as the firm's resolution plan adequately supports the executability of the chosen strategy.

assumptions consistent with the lack of access to the bilateral OTC derivatives market at the start of its resolution period. The proposed guidance also confirms or clarifies expectations related to other elements that should be addressed in the firm's analysis of its derivatives strategy, including the incorporation of resource needs into RLEN and RCEN (*forecast of resource needs*), an analysis of any potential derivatives portfolio remaining after the resolution period (*potential residual derivatives portfolio*), and the impact (including on non-U.S. jurisdictions) from the assumed failure of a material derivatives entity (*non-surviving material entity analysis*).[16]

*Question 7: Do the proposed changes relative to the 2016 Guidance provide sufficient clarity or are additional clarifications required?*

*Consolidation of Existing Guidance*

In addition to the 2016 Guidance, the Agencies have also issued: the *Guidance for 2013 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Initial Resolution Plans in 2012* (the ''2013 Guidance''); firm-specific feedback letters issued in 2014 and 2016; and the February 2015 staff communication regarding the 2016 plan submissions. The Agencies are considering consolidating all applicable guidance into a single document, which would provide the public with one source of applicable guidance to which to refer. The Agencies would also expect to incorporate aspects of the *Resolution Plan Frequently Asked Questions* issued May 2017 that may remain applicable.[17] For example, the Agencies could add a section to the proposed guidance that includes the aspects of the 2013 Guidance that should remain applicable, such as the plan format description in the ''Format of 2013 Plan'' and ''Additional Format and Content Guidance'' sections, some of the central assumptions and stress scenarios in the ''Assumptions'' and ''Stress Scenarios'' sections, the process for addressing expected global cooperation described in the ''Global Cooperation'' section, and the considerations for identifying material entities in the ''Material Entities'' section.

*Question 8: Should the Agencies consolidate all applicable guidance? If so, which aspects of the other guidance warrant inclusion, additional clarification or modification?*

## IV. Paperwork Reduction Act

Certain provisions of the Rule contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act (''PRA'') of 1995 (44 U.S.C. 3501 through 3521). In accordance with the requirements of the PRA, a 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 Agencies believe that the proposed changes to the 2016 Guidance would not result in an increase in information collection burden to the Covered Companies. The Agencies invite public comment on this assessment.

## TEXT OF PROPOSED RESOLUTION PLANNING GUIDANCE FOR EIGHT LARGE, COMPLEX U.S. BANKING ORGANIZATIONS

### Resolution Planning Guidance for Eight Large, Complex U.S. Banking Organizations

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## I. Introduction

*Resolution Plan Requirement:* Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5365(d)) requires certain financial companies (''Covered Companies'') to report periodically to the Board of Governors of the Federal Reserve System (the ''Federal Reserve'' or ''Board'') and the Federal Deposit Insurance Corporation (the ''FDIC'') (together ''the Agencies'') the Companies'[18] Plans for Rapid and Orderly Resolution in the event of Material Financial Distress or failure. On November 1, 2011, the Agencies promulgated a joint rule (the ''Rule'') implementing the provisions of Section 165(d), 12 CFR parts 243 and 381.[19] Certain Covered Companies meeting criteria set out in the Rule must file a resolution plan (''Plan'') annually or at a different time period specified by the Agencies.

*Overview of Guidance Document:* This document is intended to assist the eight current U.S. Global Systemically Important Banks (''GSIBs'' or ''firms'')[20] in further developing their preferred resolution strategies. The document describes the expectations of the Agencies regarding these firms' resolution plans, and highlights specific areas where additional detail should be provided and where certain capabilities or optionality should be developed and maintained to demonstrate that each firm has considered fully, and is able to mitigate, obstacles to the successful implementation of the preferred strategy.[21]

This document is organized around a number of key vulnerabilities in resolution (i.e., capital; liquidity; governance mechanisms; operational; legal entity rationalization and separability; and derivatives and trading activities) that apply across resolution plans. Additional vulnerabilities or

[16] From the perspective of protecting U.S. financial stability, the risk of adverse regulatory actions that could impede an orderly resolution increases where a material entity's failure would have extraordinary impacts on local markets. Therefore, analysis of non-surviving material entities located in a non-U.S. jurisdiction should contemplate the impact on local markets.

[17] *https://www.fdic.gov/resauthority/2017faqsguidance.pdf; https://www.federalreserve.gov/publications/files/resolution-plan-faqs.pdf.*

[18] Capitalized terms not defined herein have the meaning set forth in the Rule.

[19] 76 Fed. Reg. 67323 (November 1, 2011)

[20] Bank of America Corporation, the Bank of New York Mellon Corporation, Citigroup Inc., the Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation and Wells Fargo & Company.

[21] The 2013 Guidance, the 2014 Letter, and the 2015 Communication, as described in the 2016 letters to the firms, continue to be applicable (relevant dates should be updated appropriately), except to the extent superseded or supplemented by the provisions of this document. See Letters dated April 12, 2016, from the Board and FDIC to Bank of America Corporation, The Bank of New York Mellon Corporation, Citigroup Inc., the Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation, and Wells Fargo & Company, available at *https://www.federalreserve.gov/supervisionreg/resolution-plans.htm.*

obstacles may arise based on a firm's particular structure, operations, or resolution strategy. Each firm is expected to satisfactorily address these vulnerabilities in its Plan—e.g., by developing sensitivity analysis for certain underlying assumptions, enhancing capabilities, providing detailed analysis, or increasing optionality development, as indicated below.

The Agencies will review the Plan to determine if it satisfactorily addresses key potential vulnerabilities, including those detailed below. If the Agencies jointly decide that these matters are not satisfactorily addressed in the Plan, the Agencies may determine jointly that the Plan is not credible or would not facilitate an orderly resolution under the U.S. Bankruptcy Code.

## II. CAPITAL

*Resolution Capital Adequacy and Positioning (RCAP):* To help ensure that a firm's material entities [22] could operate while the parent company is in bankruptcy, the firm should have an adequate amount of loss-absorbing capacity to recapitalize those material entities. Thus, a firm should have outstanding a minimum amount of total loss-absorbing capital, as well as a minimum amount of long-term debt, to help ensure that the firm has adequate capacity to meet that need at a consolidated level (external TLAC).[23]

A firm's external TLAC should be complemented by appropriate positioning of additional loss-absorbing capacity within the firm (internal TLAC). The positioning of a firm's internal TLAC should balance the certainty associated with pre-positioning internal TLAC directly at material entities with the flexibility provided by holding recapitalization resources at the parent (contributable resources) to meet unanticipated losses at material entities. That balance should take account of both pre-positioning at material entities and holding resources at the parent, and the obstacles associated with each. Accordingly, the firm should not rely exclusively on either full pre-positioning or parent contributable resources to recapitalize any material entity. The plan should describe the positioning of internal TLAC within the firm, along with analysis supporting such positioning.

Finally, to the extent that pre-positioned internal TLAC at a material entity is in the form of intercompany debt and there are one or more entities between that material entity and the parent, the firm should mitigate uncertainty related to potential creditor challenge; for example, by ensuring that the seniority and tenor of the intercompany debt is the same between all entities in the chain.

*Resolution Capital Execution Need (RCEN):* To support the execution of the firm's resolution strategy, material entities need to be recapitalized to a level that allows them to operate or be wound down in an orderly manner following the parent company's bankruptcy filing. The firm should have a methodology for periodically estimating the amount of capital that may be needed to support each material entity after the bankruptcy filing (RCEN). The firm's positioning of internal TLAC should be able to support the RCEN estimates. In addition, the RCEN estimates should be incorporated into the firm's governance framework to ensure that the parent company files for bankruptcy at a time that enables execution of the preferred strategy.

The firm's RCEN methodology should use conservative forecasts for losses and risk-weighted assets and incorporate estimates of potential additional capital needs through the resolution period,[24] consistent with the firm's resolution strategy. However, the methodology is not required to produce aggregate losses that are greater than the amount of external TLAC that would be required for the firm under the Board's rule.[25] The RCEN methodology should be calibrated such that recapitalized material entities have sufficient capital to maintain market confidence as required under the preferred resolution strategy. Capital levels should meet or exceed all applicable regulatory capital requirements for ''well-capitalized'' status and meet estimated additional capital needs throughout resolution. Material entities that are not subject to capital requirements may be considered sufficiently recapitalized when they have achieved capital levels typically required to obtain an investment-grade credit rating or, if the entity is not rated, an equivalent level of financial soundness. Finally, the methodology should be independently reviewed, consistent with the firm's corporate governance processes and controls for the use of models and methodologies.

## III. LIQUIDITY

The firm should have the liquidity capabilities necessary to execute its preferred resolution strategy, including those described in SR Letter 14–1.[26] For resolution purposes, these capabilities should include having an appropriate model and process for estimating and maintaining sufficient liquidity at or readily available to material entities and a methodology for estimating the liquidity needed to successfully execute the resolution strategy, as described below.

*Resolution Liquidity Adequacy and Positioning (RLAP):* With respect to RLAP, the firm should be able to measure the stand-alone liquidity position of each material entity (including material entities that are non-U.S. branches)—i.e., the high-quality liquid assets (HQLA) at the material entity less net outflows to third parties and affiliates—and ensure that liquidity is readily available to meet any deficits. The RLAP model should cover a period of at least 30 days and reflect the idiosyncratic liquidity profile and risk of the firm. The model should balance the reduction in frictions associated with holding liquidity directly at material entities with the flexibility provided by holding HQLA at the parent available to meet unanticipated outflows at material entities. Thus, the firm should not rely exclusively on either full pre-positioning or the parent. The model [27] should ensure that the parent holding company holds sufficient HQLA (inclusive of its deposits at the U.S. branch of the lead bank subsidiary) to cover the sum of all stand-alone material entity net liquidity deficits. The stand-alone net liquidity position of each material entity (HQLA less net outflows) should be measured using the firm's internal liquidity stress test assumptions and should treat inter-affiliate exposures in the same manner as third-party exposures. For example, an overnight unsecured exposure to an affiliate should be assumed to mature. Finally, the firm should not assume that a net liquidity surplus at one material entity could be moved to meet net

[22] The terms ''material entities,'' ''critical operations,'' and ''core business lines'' have the same meaning as in the Agencies' Rule.

[23] 82 Fed. Reg. 8266 (January 24, 2017).

[24] The resolution period begins immediately after the parent company bankruptcy filing and extends through the completion of the preferred resolution strategy.

[25] *See* 12 CFR 252.60–.65; 82 Fed. Reg. 8266 (January 24, 2017).

[26] SR Letter 14–1, ''Heightened Supervisory Expectations for Recovery and Resolution Preparedness for Certain Large Bank Holding Companies—Supplemental Guidance on Consolidated Supervision Framework for Large Financial Institutions'' (Jan. 24, 2014), available at *http://www.federalreserve.gov/bankinforeg/srletters/sr1401.pdf.*

[27] ''Model'' refers to the set of calculations estimating the net liquidity surplus/deficit at each legal entity and for the firm in aggregate based on assumptions regarding available liquidity, e.g., HQLA, and third-party and interaffiliate net outflows.

liquidity deficits at other material entities or to augment parent resources.

Additionally, the RLAP methodology should take into account (A) the daily contractual mismatches between inflows and outflows; (B) the daily flows from movement of cash and collateral for all inter-affiliate transactions; and (C) the daily stressed liquidity flows and trapped liquidity as a result of actions taken by clients, counterparties, key financial market utilities (FMUs), and foreign supervisors, among others.

*Resolution Liquidity Execution Need (RLEN):* The firm should have a methodology for estimating the liquidity needed after the parent's bankruptcy filing to stabilize the surviving material entities and to allow those entities to operate post-filing. The RLEN estimate should be incorporated into the firm's governance framework to ensure that the firm files for bankruptcy in a timely way, i.e., prior to the firm's HQLA falling below the RLEN estimate.

The firm's RLEN methodology should:

(A) Estimate the minimum operating liquidity (MOL) needed at each material entity to ensure those entities could continue to operate post-parent's bankruptcy filing and/or to support a wind-down strategy;

(B) Provide daily cash flow forecasts by material entity to support estimation of peak funding needs to stabilize each entity under resolution;

(C) Provide a comprehensive breakout of all inter-affiliate transactions and arrangements that could impact the MOL or peak funding needs estimates; and

(D) Estimate the minimum amount of liquidity required at each material entity to meet the MOL and peak needs noted above, which would inform the firm's board(s) of directors of when they need to take resolution-related actions.

The MOL estimates should capture material entities' intraday liquidity requirements, operating expenses, working capital needs, and inter-affiliate funding frictions to ensure that material entities could operate without disruption during the resolution.

The peak funding needs estimates should be projected for each material entity and cover the length of time the firm expects it would take to stabilize that material entity. Inter-affiliate funding frictions should be taken into account in the estimation process.

The firm's forecasts of MOL and peak funding needs should ensure that material entities could operate post-filing consistent with regulatory requirements, market expectations, and the firm's post-failure strategy. These forecasts should inform the RLEN estimate, i.e., the minimum amount of HQLA required to facilitate the execution of the firm's strategy. The RLEN estimate should be tied to the firm's governance mechanisms and be incorporated into the playbooks as discussed below to assist the board of directors in taking timely resolution-related actions.

## IV. GOVERNANCE MECHANISMS

*Playbooks and Triggers:* A firm should identify the governance mechanisms that would ensure execution of required board actions at the appropriate time (as anticipated under the firm's preferred strategy) and include pre-action triggers and existing agreements for such actions. Governance playbooks should detail the board and senior management actions necessary to facilitate the firm's preferred strategy and to mitigate vulnerabilities, and should incorporate the triggers identified below. The governance playbooks should also include a discussion of (A) the firm's proposed communications strategy, both internal and external; (B) the boards of directors' fiduciary responsibilities and how planned actions would be consistent with such responsibilities applicable at the time actions are expected to be taken; (C) potential conflicts of interest, including interlocking boards of directors; and (D) any employee retention policy. All responsible parties and timeframes for action should be identified. Governance playbooks should be updated periodically for all entities whose boards of directors would need to act in advance of the commencement of resolution proceedings under the firm's preferred strategy.

The firm should demonstrate that key actions will be taken at the appropriate time in order to mitigate financial, operational, legal, and regulatory vulnerabilities. To ensure that these actions will occur, the firm should establish clearly identified triggers linked to specific actions for:

(A) The escalation of information to senior management and the board(s) to potentially take the corresponding actions at each stage of distress post-recovery leading eventually to the decision to file for bankruptcy;

(B) Successful recapitalization of subsidiaries prior to the parent's filing for bankruptcy and funding of such entities during the parent company's bankruptcy to the extent the preferred strategy relies on such actions or support; and

(C) The timely execution of a bankruptcy filing and related pre-filing actions.[28]

These triggers should be based, at a minimum, on capital, liquidity, and market metrics, and should incorporate the firm's methodologies for forecasting the liquidity and capital needed to operate as required by the preferred strategy following a parent company's bankruptcy filing. Additionally, the triggers and related actions should be specific.

Triggers linked to firm actions as contemplated by the firm's preferred strategy should identify when and under what conditions the firm, including the parent company and its material entities, would transition from business-as-usual conditions to a stress period and from a stress period to the runway and recapitalization/resolution periods. Corresponding escalation procedures, actions, and timeframes should be constructed so that breach of the triggers will allow prerequisite actions to be completed. For example, breach of the triggers needs to occur early enough to ensure that resources are available and can be downstreamed, if anticipated by the firm's strategy, and with adequate time for the preparation of the bankruptcy petition and first-day motions, necessary stakeholder communications, and requisite board actions. Triggers identifying the onset of the runway and recapitalization/resolution periods, and the associated escalation procedures and actions, should be discussed directly in the governance playbooks.

*Pre-Bankruptcy Parent Support:* The resolution plan should include a detailed legal analysis of the potential state law and bankruptcy law challenges and mitigants to planned provision of capital and liquidity to the subsidiaries prior to the parent's bankruptcy filing (Support). Specifically, the analysis should identify potential legal obstacles and explain how the firm would seek to ensure that Support would be provided as planned. Legal obstacles include claims of fraudulent transfer, preference, breach of fiduciary duty, and any other applicable legal theory identified by the firm. The analysis also should include related claims that may prevent or delay an effective recapitalization, such as equitable claims to enjoin the transfer (e.g., imposition of a constructive trust by the court). The analysis should apply the actions contemplated in the plan

[28] Key pre-filing actions include the preparation of any emergency motion required to be decided on the first day of the firm's bankruptcy. *See* ''*OPERATIONAL—Legal Obstacles Associated with Emergency Motions,*'' below.

regarding each element of the claim, the anticipated timing for commencement and resolution of the claims, and the extent to which adjudication of such claim could affect execution of the firm's preferred resolution strategy.

As noted, the analysis should include mitigants to the potential challenges to the planned Support. The plan should include the mitigant(s) to such challenges that the firm considers most effective. In identifying appropriate mitigants, the firm should consider the effectiveness of a contractually binding mechanism (CBM), pre-positioning of financial resources in material entities, and the creation of an intermediate holding company. Moreover, if the plan includes a CBM, the firm should consider whether it is appropriate that the CBM should have the following: (A) clearly defined triggers; (B) triggers that are synchronized to the firm's liquidity and capital methodologies; (C) perfected security interests in specified collateral sufficient to fully secure all Support obligations on a continuous basis (including mechanisms for adjusting the amount of collateral as the value of obligations under the agreement or collateral assets fluctuates); and (D) liquidated damages provisions or other features designed to make the CBM more enforceable. The firm also should consider related actions or agreements that may enhance the effectiveness of a CBM. A copy of any agreement and documents referenced therein (e.g., evidence of security interest perfection) should be included in the resolution plan.

The governance playbooks included in the resolution plan should incorporate any developments from the firm's analysis of potential legal challenges regarding the Support, including any Support approach(es) the firm has implemented. If the firm analyzed and addressed an issue noted in this section in a prior plan submission, the plan may reproduce that analysis and arguments and should build upon it to at least the extent described above. In preparing the analysis of these issues, firms may consult with law firms and other experts on these matters. The Agencies do not object to appropriate collaboration between firms, including through trade organizations and with the academic community, to develop analysis of common legal challenges and available mitigants.

## V. OPERATIONAL

### *Payment, Clearing, and Settlement Activities*

*Framework.* Maintaining continuity of payment, clearing, and settlement (PCS) services is critical for the orderly resolution of firms that are either users or providers,[29] or both, of PCS services. A firm should demonstrate capabilities [30] for continued access to PCS services essential to an orderly resolution through a framework to support such access by:

- Identifying key clients,[31] FMUs, and agent banks, using both quantitative (volume and value) [32] and qualitative criteria;
- Mapping material entities, critical operations, core business lines, and key clients to both key FMUs and agent banks; and
- Developing a playbook for each key FMU and agent bank reflecting the firm's role(s) as a user and/or provider of PCS services.

The framework should address both direct relationships (e.g., firm's direct membership in the FMU, firm provides key clients with critical PCS services through its own operations, firm's contractual relationship with an agent bank) and indirect relationships (e.g., firm provides its clients with access to the relevant FMU or agent bank through the firm's membership to or relationship with that FMU or agent bank).

*Playbooks for Continued Access to PCS Services.* The firm is expected to provide a playbook for each key FMU and agent bank that addresses considerations that would assist the firm and its clients in maintaining continued access to PCS services in the period leading up to and including the firm's resolution. While the firm is not expected to incorporate a scenario in which it loses FMU or agent bank access into its preferred resolution strategy or its RLEN/RCEN estimates, each playbook should provide analysis of the financial and operational impact to the firm's material entities and key clients due to loss of access to the FMU or agent bank. Each playbook also should discuss any possible alternative arrangements that would allow the firm and its key clients continued access to PCS services in resolution. The firm should continue to engage with key FMUs, agent banks and clients, and playbooks should reflect any feedback received during such ongoing outreach.

*Content Related to Users of PCS Services.* Individual FMU and agent bank playbooks should include at a minimum:

- Description of the firm's relationship as a user with the key FMU or agent bank and the identification and mapping of PCS services to material entities, critical operations, and core business lines that use those PCS services;
- Discussion of the potential range of adverse actions that may be taken by that key FMU or agent bank when the firm is in resolution,[33] the operational and financial impact of such actions on each material entity, and contingency arrangements that may be initiated by the firm in response to potential adverse actions by the key FMU or key agent bank; and
- Discussion of PCS-related liquidity sources and uses in business-as-usual (BAU), in stress, and in the resolution period, presented by currency type (with U.S. dollar equivalent) and by material entity.
  - ○ PCS Liquidity Sources: These may include the amounts of intraday extensions of credit, liquidity buffer, inflows from FMU participants, and client prefunded amounts in BAU, in stress, and in the resolution period. The playbook should also describe intraday credit arrangements (e.g., facilities of the FMU, agent bank, or a central bank) and any similar custodial arrangements that allow ready access to a firm's funds for PCS-related FMU and agent bank obligations (including margin requirements) in various currencies, including placements of firm liquidity at central banks, FMUs, and agent banks.
  - ○ PCS Liquidity Uses: These may include firm and client margin, pre-funding and intraday extensions of credit, including incremental amounts required during resolution.

[29] A firm is a user of PCS services if it uses the services of a financial market utility (FMU) through its membership in that FMU or an agent bank. A firm is a provider of PCS services if it provides its clients with access to an FMU or agent bank through the firm's membership to or relationship with that service provider (including providing PCS services to its client as an agent bank) or if it provides key clients with critical PCS services (e.g., the suspension or termination of such services would impact the key client's continued access to PCS services) through the firm's own operations.

[30] These capabilities may include those described in SR Letter 14–1.

[31] For purposes of this section V, a client is an individual or entity, including affiliates of the firm, that relies upon continued access to the firm's PCS services and any related credit or liquidity offered in connection with those services.

[32] Examples of quantitative criteria include not only the aggregate volumes and values of all transactions processed through an FMU but also assets under custody with an agent bank, the value of cash and securities settled through an agent bank, and extensions of intraday credit.

[33] Potential adverse actions may include increased collateral and margin requirements and enhanced reporting and monitoring.

○ Intraday Liquidity Inflows and Outflows: The playbook should describe the firm's ability to control intraday liquidity inflows and outflows and to identify and prioritize time-specific payments. The playbook should also describe any account features that might restrict the firm's ready access to its liquidity sources.

*Content Related to Providers of PCS Services.* Individual FMU and agent bank playbooks [34] should include at a minimum:

• Identification and mapping of PCS services to the material entities, critical operations, and core business lines that provide those PCS services, and a description of the scale and the way in which each provides PCS services;

• Identification and mapping of PCS services to key clients that rely upon the firm to provide those PCS services and any related credit or liquidity offered in connection with such services;

• Discussion of the potential range of firm contingency arrangements available to minimize disruption to the provision of PCS services to its clients, including the viability of transferring client activity and any related assets, as well as any alternative arrangements that would allow the firm's key clients continued access to critical PCS services if the firm could no longer provide such access (e.g., due to the firm's loss of FMU or agent bank access), and the financial and operational impacts of such arrangements;

• Description of the range of contingency actions that the firm may take concerning its provision of intraday credit to clients, including analysis quantifying the potential liquidity the firm could generate by taking such actions in stress and in the resolution period, such as (i) requiring clients to designate or appropriately pre-position liquidity, including through pre-funding of settlement activity, for PCS-related FMU and agent bank obligations at specific material entities of the firm (e.g., direct members of FMUs) or any similar custodial arrangements that allow ready access to clients' funds for such obligations in various currencies; (ii) delaying or restricting client PCS activity; and (iii) restricting, imposing conditions upon (e.g., requiring collateral), or eliminating the provision of intraday credit or liquidity to clients; and

• Description of how the firm will communicate to its key clients the potential impacts of implementation of any identified contingency arrangements or alternatives, including a description of the firm's methodology for determining whether any additional communication should be provided to some or all key clients (e.g., due to the client's BAU usage of that access and/or related intraday credit or liquidity), and the expected timing and form of such communication.

*Managing, Identifying, and Valuing Collateral:* The firm should have the capabilities described in SR Letter 14–1 related to managing, identifying, and valuing the collateral that it receives from and posts to external parties and its affiliates. Specifically, the firm should:

• Be able to query and provide aggregate statistics for all qualified financial contracts concerning cross-default clauses, downgrade triggers, and other key collateral-related contract terms — not just those terms that may be impacted in an adverse economic environment — across contract types, business lines, legal entities, and jurisdictions;

• Be able to track both firm collateral sources (i.e., counterparties that have pledged collateral) and uses (i.e., counterparties to whom collateral has been pledged) at the CUSIP level on at least a t+1 basis;

• Have robust risk measurements for cross-entity and cross-contract netting, including consideration of where collateral is held and pledged;

• Be able to identify CUSIP and asset class level information on collateral pledged to specific central counterparties by legal entity on at least a t+1 basis;

• Be able to track and report on inter-branch collateral pledged and received on at least a t+1 basis and have clear policies explaining the rationale for such inter-branch pledges, including any regulatory considerations; and

• Have a comprehensive collateral management policy that outlines how the firm as a whole approaches collateral and serves as a single source for governance.[35]

*Management Information Systems:* The firm should have the management information systems (MIS) capabilities to readily produce data on a legal entity basis and have controls to ensure data integrity and reliability, as described in SR Letter 14–1. The firm also should perform a detailed analysis of the specific types of financial and risk data that would be required to execute the preferred resolution strategy and how frequently the firm would need to produce the information, with the appropriate level of granularity.

*Shared and Outsourced Services:* The firm should maintain a fully actionable implementation plan to ensure the continuity of shared services that support critical operations and robust arrangements to support the continuity of shared and outsourced services. The firm should (A) maintain an identification of all shared services that support critical operations (critical services); (B) maintain a mapping of how/where these services support its core business lines and critical operations; (C) incorporate such mapping into legal entity rationalization criteria and implementation efforts; and (D) mitigate identified continuity risks through establishment of service-level agreements (SLAs) for all critical shared services. These SLAs should fully describe the services provided, reflect pricing considerations on an arm's-length basis where appropriate, and incorporate appropriate terms and conditions to (A) prevent automatic termination upon certain resolution-related events and (B) achieve continued provision of such services during resolution. The firm should also store SLAs in a central repository or repositories in a searchable format, develop and document contingency strategies and arrangements for replacement of critical shared services, and complete re-alignment or restructuring of activities within its corporate structure. In addition, the firm should ensure the financial resilience of internal shared service providers by maintaining working capital for six months (or through the period of stabilization as required in the firm's preferred strategy) in such entities sufficient to cover contract costs, consistent with the preferred resolution strategy.

The firm should identify all critical outsourced services that support critical operations and could not be promptly substituted. The firm should (A) evaluate the agreements governing these services to determine whether there are any that could be terminated despite continued performance upon the parent's bankruptcy filing, and (B) update contracts to incorporate appropriate terms and conditions to prevent automatic termination and facilitate continued provision of such services during resolution. Relying on entities projected to survive during resolution to avoid contract termination is insufficient to ensure continuity. In

[34] Where a firm is a provider of PCS services through the firm's own operations, the firm is expected to produce a playbook for the material entity that provides those services, including contingency arrangements to permit the firm's key clients to maintain continued access to PCS services.

[35] The policy may reference subsidiary or related policies already in place, as implementation may differ based on business line or other factors.

the plan, the firm should document the amendment of any such agreements governing these services.

*Legal Obstacles Associated with Emergency Motions:* The Plan should address legal issues associated with the implementation of the stay on cross-default rights described in Section 2 of the International Swaps and Derivatives Association 2015 Universal Resolution Stay Protocol (Protocol), similar provisions of any U.S. protocol,[36] or other contractual provisions that comply with the Agencies' rules regarding stays from the exercise of cross-default rights in qualified financial contracts, to the extent relevant.[37] Generally, the Protocol provides two primary methods of satisfying the stay conditions for covered agreements for which the affiliate in Chapter 11 proceedings has provided a credit enhancement (A) transferring all such credit enhancements to a Bankruptcy Bridge Company (as defined in the Protocol) (bridge transfer); or (B) having such affiliate remain obligated with respect to such credit enhancements in the Chapter 11 proceeding (elevation).[38] A firm must file a motion for emergency relief (emergency motion) seeking approval of an order to effect either of these alternatives on the first day of its bankruptcy case.

*First-day Issues*—For each alternative the firm selects, the resolution plan should present the firm's analysis of issues that are likely to be raised at the hearing on the emergency motion and its best arguments in support of the emergency motion. A firm should include supporting legal precedent and describe the evidentiary support that the firm would anticipate presenting to the bankruptcy court — e.g., declarations or other expert testimony evidencing the solvency of transferred subsidiaries and that recapitalized entities have sufficient liquidity to perform their ongoing obligations.

For either alternative, the firm should address all potential significant legal obstacles identified by the firm. For example, the firm should address due process arguments likely to be made by creditors asserting that they have not had sufficient opportunity to respond to the emergency motion given the likelihood that a creditors' committee will not yet have been appointed. The firm also should consider, and discuss in its plan, whether it would enhance the successful implementation of its preferred strategy to conduct outreach to interested parties, such as potential creditors of the holding company and the bankruptcy bar, regarding the strategy.

If the firm chooses the bridge transfer alternative, its analysis and arguments should address at a minimum the following potential issues: (A) the legal basis for transferring the parent holding company's equity interests in certain subsidiaries (transferred subsidiaries) to a Bankruptcy Bridge Company, including the basis upon which the Bankruptcy Bridge Company would remain obligated for credit enhancements; (B) the ability of the bankruptcy court to retain jurisdiction, issue injunctions, or take other actions to prevent third parties from interfering with, or making collateral attacks on (i) a Bankruptcy Bridge Company, (ii) its transferred subsidiaries, or (iii) a trust or other legal entity designed to hold all ownership interests in a Bankruptcy Bridge Company (new ownership entity); and (C) the role of the bankruptcy court in granting the emergency motion due to public policy concerns—e.g., to preserve financial stability. The firm should also provide a draft agreement (e.g., trust agreement) detailing the preferred post-transfer governance relationships between the bankruptcy estate, the new ownership entity, and the Bankruptcy Bridge Company, including the proposed role and powers of the bankruptcy court and creditors' committee. Alternative approaches to these proposed post-transfer governance relationships should also be described, particularly given the strong interest that parties will have in the ongoing operations of the Bankruptcy Bridge Company and the likely absence of an appointed creditors' committee at the time of the hearing.

If the firm chooses the elevation alternative, the analysis and arguments should address at a minimum the following potential issues: (A) The legal basis upon which the parent company would seek to remain obligated for credit enhancements; (B) the ability of the bankruptcy court to retain jurisdiction, issue injunctions, or take other actions to prevent third parties from interfering with, or making collateral attacks on, the parent in bankruptcy or its subsidiaries; and (C) the role of the bankruptcy court in granting the emergency motion due to public policy concerns—e.g., to preserve financial stability.

*Regulatory Implications*—The plan should include a detailed explanation of the steps the firm would take to ensure that key domestic and foreign authorities would support, or not object to, the emergency motion (including specifying the expected approvals or forbearances and the requisite format—i.e., formal, affirmative statements of support or, alternatively, ''non-objections''). The potential impact on the firm's preferred resolution strategy if a specific approval or forbearance cannot be timely obtained should also be detailed.

*Contingencies if Preferred Structure Fails*—The plan should consider contingency arrangements in the event the bankruptcy court does not grant the emergency motion—e.g., whether alternative relief could satisfy the Transfer Conditions and/or U.S. Parent debtor-in-possession (DIP) Conditions of the Protocol;[39] the extent to which action upon certain aspects of the emergency motion may be deferred by the bankruptcy court without interfering with the resolution; and whether, if the credit-enhancement-related protections are not satisfied, there are alternative strategies to prevent the closeout of qualified financial contracts with credit enhancements (or reduce such counterparties' incentives to closeout) and the feasibility of the alternative(s).

*Format*—If the firm analyzed and addressed an issue noted in this section in a prior plan submission, the plan may incorporate this analysis and arguments and should build upon it to at least the extent required above. A bankruptcy playbook, which includes a sample emergency motion and draft documents setting forth the post-transfer governance terms substantially in the form they would be presented to the bankruptcy court, is an appropriate vehicle for detailing the issues outlined in this section. In preparing analysis of these issues, the firm may consult with law firms and other experts on these matters. The Agencies do not object to appropriate collaboration among firms, including through trade organizations and with the academic community and bankruptcy bar, to develop analysis of common legal challenges and available mitigants.

[36] U.S. protocol has the same meaning as it does at 12 CFR 252.85(a). *See also* 12 CFR 382.5(a) (including a substantively identical definition).

[37] See 12 CFR part 47, 252.81-.88, and part 382 (together, the ''QFC stay rules''). If the firm complies with the QFC stay rules other than through adherence to the Protocol, the plan also should explain how the alternative compliance method differs from Protocol, how those differences affect the analysis and other expectations of this ''Legal Obstacles Associated with Emergency Motions'' section, and how the firm plans to satisfy any different conditions or requirements of the alternative compliance method.

[38] Under its terms, the Protocol also provides for the transfer of credit enhancements to transferees other than a Bankruptcy Bridge Company.

[39] *See* Protocol sections 2(b)(ii) and (iii) and related definitions.

## VI. LEGAL ENTITY RATIONALIZATION AND SEPARABILITY

*Legal Entity Rationalization Criteria (LER Criteria):* A firm should develop and implement legal entity rationalization criteria that support the firm's preferred resolution strategy and minimize risk to U.S. financial stability in the event of the firm's failure. LER Criteria should consider the best alignment of legal entities and business lines to improve the firm's resolvability under different market conditions. LER Criteria should govern the firm's corporate structure and arrangements between legal entities in a way that facilitates the firm's resolvability as its activities, technology, business models, or geographic footprint change over time.

Specifically, application of the criteria should:

(A) Facilitate the recapitalization and liquidity support of material entities, as required by the firm's resolution strategy. Such criteria should include clean lines of ownership, minimal use of multiple intermediate holding companies, and clean funding pathways between the parent and material operating entities;

(B) Facilitate the sale, transfer, or wind-down of certain discrete operations within a timeframe that would meaningfully increase the likelihood of an orderly resolution of the firm, including provisions for the continuity of associated services and mitigation of financial, operational, and legal challenges to separation and disposition;

(C) Adequately protect the subsidiary insured depository institutions from risks arising from the activities of any nonbank subsidiaries of the firm (other than those that are subsidiaries of an insured depository institution); and

(D) Minimize complexity that could impede an orderly resolution and minimize redundant and dormant entities.

These criteria should be built into the firm's ongoing process for creating, maintaining, and optimizing its structure and operations on a continuous basis.

*Separability:* The firm should identify discrete operations that could be sold or transferred in resolution, which individually or in the aggregate would provide meaningful optionality in resolution under different market conditions. The actionability of those options should be supported by the firm's criteria and analysis required by SR Letter 14–8.[40] Additionally, this analysis should facilitate buyer due diligence and include carve-out financial statements, valuation analysis, and a legal risk assessment. Further, the firm should establish a data room to collect and refresh annually the analyses above, as well as other information pertinent to a potential divestiture of the business.

Within the plan, the firm should demonstrate how the firm's LER Criteria and implementation efforts meet the guidance above. The plan should also provide the separability analysis noted above. Finally, the plan should include a description of the firm's legal entity rationalization governance process.

## VII. DERIVATIVES AND TRADING ACTIVITIES

*Applicability.*

This section of the proposed guidance applies to Bank of America Corporation, Citigroup Inc., Goldman Sachs Group, Inc., JP Morgan Chase & Co., Morgan Stanley, and Wells Fargo & Company (each, a ''dealer firm'').

*Booking Practices.*

A dealer firm should have booking practices commensurate with the size, scope, and complexity of a firm's derivatives portfolios,[41] including systems capabilities to track and monitor market, credit, and liquidity risk transfers between entities. The following booking practices-related capabilities should be addressed in a dealer firm's resolution plan:

*Derivatives booking framework.* A dealer firm should have a comprehensive booking model framework that articulates the principles, rationales, and approach to implementing its firm-wide booking practices. The framework and its underlying components should be documented and adequately supported by internal controls (e.g., procedures, systems, and processes). Taken together, the derivatives booking framework and its components should provide transparency with respect to (i) what is being booked (e.g., product/counterparty), (ii) where it is being booked (e.g., legal entity/geography), (iii) by whom it is booked (e.g., business/trading desk); (iv) why it is booked that way (e.g., drivers/rationales); and (v) what controls are in place to monitor and manage those practices (e.g., governance/information systems)[42]. The dealer firm's resolution plan should include detailed descriptions of the framework and each of its material components. In particular, a dealer firm's resolution plan should include descriptions of the documented booking models covering its firm-wide derivatives portfolio.[43] The descriptions should provide clarity with respect to the underlying trade flows (e.g., the mapping of trade flows based on multiple trade characteristics as decision points that determine on which entity a trade is booked, if risk is transferred, and at which entity that risk is subsequently managed). For example, a firm may choose to incorporate decision trees that depict the multiple trade flows within each documented booking model.[44] Furthermore, a dealer firm's resolution plan should describe its end-to-end trade booking and reporting processes, including a description of the current scope of automation (e.g., automated trade flows and detective monitoring) for the systems controls applied to its documented booking models. The plan should also discuss why the firm believes its current (or planned) scope of automation is sufficient for managing its derivatives activities and executing its preferred resolution strategy.[45]

[40] SR Letter 14–8, ''Consolidated Recovery Planning for Certain Large Domestic Bank Holding Companies'' (Sept. 25, 2014), available at *http://www.federalreserve.gov/bankinforeg/srletters/sr1408.pdf.*

[41] A firm's derivatives portfolios include its derivatives positions and linked non-derivatives trading positions.

[42] The description of controls should include any components of the firm-wide market, credit, and liquidity risk management framework that are material to the management of its derivatives practices.

[43] The firm should at least document booking models that, in the aggregate, represent the vast majority of the firm's derivatives transactions, e.g., booking models that represent no less than 95% of a dealer firm's derivatives transactions measured by firm-wide derivatives notional and by firm-wide gross market value of derivatives. Presumably, each asset class/product would have a booking model that is a function of the firm's regulatory and risk management requirements, client's preference, and regulatory requirements specifically for the underlying asset class, and other transaction related considerations.

[44] Some firms use trader mandates or similar controls to constrain the potential trading strategies that can be pursued by a business and to monitor the permissibility of booking activity. However, the mapping of trader mandates alone, especially those mandates that grant broad permissibility, may not provide sufficient distinction between booking model trade flows.

[45] Effective preventative (up-front) and detective (post-booking) controls embedded in a dealer firm's derivatives booking processes can help avoid and/or timely remediate trades that do not align with a documented booking model or related risk limits. Firms typically use a combination of manual and automated control functions. Although automation may not be best suited for all control functions, as compared to manual methods it can improve consistency and traceability with respect to derivatives booking practices. Nonetheless, non-automated methods can also be effective when supported by other internal controls (e.g., robust detective monitoring and escalation protocols).

*Derivatives entity analysis and reporting.* A dealer firm should have the ability to identify, assess, and report on each of its entities (material and non-material) with derivatives portfolios (a ''derivatives entity''). First, the firm's resolution plan should describe its method (that may include both qualitative and quantitative criteria) for evaluating the significance of each derivatives entity both with respect to the firm's current activities and to its preferred resolution strategy.[46] Second, a dealer firm's resolution plan should demonstrate (including through illustrative samples) its ability to readily generate current derivatives entity profiles that (i) cover all derivatives entities, (ii) are reportable in a consistent manner, and (iii) include information regarding current legal ownership structure, business activities/volume, and risk profile (including applicable risk limits).

*Inter-Affiliate Risk Monitoring and Controls.*

A dealer firm should be able to assess how the management of inter-affiliate risks can be affected in resolution, including the potential disruption in the risk transfers of trades between affiliate entities. Therefore, a dealer firm should have capabilities to provide timely transparency into the management of risk transfers between affiliates by maintaining an inter-affiliate market risk framework, consisting of at least the following two components[47]:

1. A method for measuring, monitoring, and reporting the market risk exposures for a given material derivatives entity resulting from the termination of a specific counterparty or a set of counterparties (e.g., all trades with a specific affiliate or with all affiliates in a specific jurisdiction)[48]; and

2. A method for identifying, estimating associated costs of, and evaluating the effectiveness of, a re-hedge strategy in resolution put on by the same material derivatives entity.[49]

In determining the re-hedge strategy, the firm should consider whether the instruments used (and the risk factors and risk sensitives controlled for) are sufficiently tied to the material derivatives entity's trading and risk-management practices to demonstrate its ability to execute the strategy in resolution using existing resources (e.g., existing traders and systems).

A dealer firm's resolution plan should describe and demonstrate its inter-affiliate market risk framework (discussed above). In addition, the firm's plan should provide detailed descriptions of its compression strategies used for executing its preferred strategy and how those strategies would differ from those used currently to manage its inter-affiliate derivatives activities. The plan should also include detailed descriptions of the firm's compression capabilities, the associated risks, and obstacles in resolution.

*Portfolio Segmentation and Forecasting.*

A dealer firm should have the capabilities to produce analysis that reflects derivatives portfolio segmentation and differentiation of assumptions taking into account trade-level characteristics. More specifically, a dealer firm should have the systems capabilities that would allow it to produce a spectrum of derivatives portfolio segmentation analysis using multiple segmentation dimensions, including (1) legal entity (and material entities that are branches), (2) trading desk and/or product, (3) cleared vs. clearable vs. non-clearable trades, (4) counterparty type, (5) currency, (6) maturity, (7) level of collateralization, and (8) netting set.[50] A dealer firm should also have the capabilities to segment and analyze the full contractual maturity (run-off) profile of its external and inter-affiliate derivatives portfolios. The dealer firm's resolution plan should describe and demonstrate the firm's ability to segment and analyze its firm-wide derivatives portfolio using the relevant segmentation dimensions and to report the results of such segmentation and analysis. In addition, the dealer firm's resolution plan should address the following segmentation and forecasting related capabilities:

''*Ease of exit*'' *position analysis.* A dealer firm should have, and its resolution plan should describe and demonstrate, a method and supporting systems capabilities for categorizing and ranking the ease of exit for its derivatives positions based on a set of well-defined and consistently applied segmentation criteria. These capabilities should cover the firm-wide derivatives portfolio and the resulting categories should represent a range in degree of difficulty (e.g., from easiest to most difficult to exit). The segmentation criteria should, at a minimum, reflect characteristics[51] that the firm believes could affect the level of financial incentive and operational effort required to facilitate the exit of derivatives portfolios (e.g., to motivate a potential step-in party to agree to the novation or an existing counterparty to bilaterally agree to a termination). Dealer firms should consider this methodology when separately identifying and analyzing the population of derivatives positions that it will include in the potential residual portfolio under the firm's preferred resolution strategy (discussed below).

*Application of exit cost methodology.* Each dealer firm should have a methodology for forecasting the cost and liquidity needed to exit positions (e.g., terminate/tear-up, sell, novate, and compress), and the operational resources related to those exits, under the specific scenario adopted in the firm's preferred resolution strategy. To help preserve sufficient optionality with respect to managing and de-risking its derivatives portfolios in a resolution, a dealer firm should have the systems capabilities to apply its exit cost methodology to its firm-wide derivatives portfolio, at the segmentation levels the firm would likely apply to exit the particular positions (e.g., valuation segment level). The dealer firm's plan should provide detailed descriptions of the forecasting methodology (inclusive of any challenge and validation processes) and data systems and reporting capabilities. The firm should also describe and demonstrate the application of the exit cost method and systems capabilities to the firm-wide derivatives portfolio.

[46] The firm should leverage any existing methods and criteria it uses for other entity assessments (e.g., legal entity rationalization and/or the pre-positioning of internal loss-absorbing resources). The firm's method for determining the significance of derivatives entities is allowed to diverge from the parameters for material entity designation under the Resolution Plan Rule (i.e., entities significant to the activities of a critical operation or core business line) but should be adequately supported and any differences should be explained.

[47] The inter-affiliate market risk framework is a supplement to the firm's systems capabilities to track and monitor market, credit, and liquidity risk transfers between entities.

[48] Firms may use industry market risk measures such as statistical risk measures (e.g., VaR or SVaR) or other risk measures (e.g., worst case scenario or stress test).

[49] A dealer firm's method may include an approach to identifying the risk factors and risk sensitivities, hedging instruments, and risk limits a derivatives entity would employ in its re-hedge strategy, and the quantification of any estimated basis risk that would result from hedging with only exchange-traded and centrally-cleared instruments in a severely adverse stress environment.

[50] The enumerated segmentation dimensions represent a minimum set of characteristics for differentiation of derivatives portfolios but are not intended as an exhaustive list of relevant dimensions. With respect to any product/asset class, a firm may have reasons for not capturing data on (or not using) one or more of the enumerated segmentation dimensions, but those reasons should be explained.

[51] Examples of characteristics that may affect the level of financial incentive and operational effort could include: product, size, clearability, currency, maturity, level of collateralization, and other risk characteristics.

*Analysis of operational capacity.* In resolution, a dealer firm should have the capabilities to forecast the incremental operational needs and expenses related to executing specific aspects of its preferred resolution strategy (e.g., executing timely derivatives portfolio novations). Therefore, a dealer firm should have, and its resolution plan should describe and demonstrate, the capabilities to assess the operational resources and forecast the costs (e.g., monthly expense rate) related to its current derivatives activities at an appropriately granular level and the incremental impact from executing its preferred resolution strategy.[52] In addition, a dealer firm should have the ability to manage the logistical and operational challenges related to novating (selling) derivatives portfolios during a resolution, including the design and adjustment of novation packages. A dealer firm's resolution plan should describe its methodology and demonstrate its supporting systems capabilities for timely segmenting, packaging, and novating derivatives positions. In developing its methodology, a dealer firm should consider the systems capabilities that may be needed to reliably generate preliminary novation packages tailored to the risk appetites of potential step-in counterparties (buyers), as well as the novation portfolio profile information that may be most relevant to such counterparties.

*Sensitivity analysis.* A dealer firm should have a method to apply sensitivity analyses to the key drivers of the derivatives-related costs and liquidity flows under its preferred resolution strategy. A dealer firm's resolution plan should describe its method for (i) evaluating the materiality of assumptions and (ii) identifying those assumptions (or combinations of assumptions) that constitute the key drivers for its forecasts of operational and financial resource needs under the preferred resolution strategy. In addition, using its preferred resolution strategy as a baseline, the dealer firm's resolution plan should describe and demonstrate its approach to testing the sensitivities of the identified key drivers and the potential impact on its forecasts of resource needs.[53]

*Prime Brokerage Customer Account Transfers.*

A dealer firm should have the operational capacity to facilitate the orderly transfer of prime brokerage accounts to peer prime brokers in periods of material financial distress and in resolution. The firm's plan should include an assessment of how it would transfer such accounts. This assessment should be informed by clients' relationships with other prime brokers, the use of automated and manual transaction processes, clients' overall long and short positions facilitated by the firm, and the liquidity of clients' portfolios. The assessment should also analyze the risks of and mitigants to the loss of customer-to-customer internalization (e.g., the inability to fund customer longs with customer shorts), operational challenges, and insufficient staffing to effectuate the scale and speed of prime brokerage account transfers envisioned under the firm's preferred resolution strategy.

In addition, a dealer firm should describe and demonstrate its ability to segment and analyze the quality and composition of prime brokerage customer account balances based on a set of well-defined and consistently applied segmentation criteria (e.g., size, single-prime, platform, use of leverage, non-rehypothecatable securities, and liquidity of underlying assets). The capabilities should cover the firm's prime brokerage customer account balances, and the resulting segments should represent a range in potential transfer speed (e.g., from fastest to longest to transfer, from most liquid to least liquid). The selected segmentation criteria should, at a minimum, reflect characteristics[54] that the firm believes could affect the speed at which the client account balance would be transferred to an alternate prime broker.

*Derivatives Stabilization and De-risking Strategy.*

A dealer firm's plan should provide a detailed analysis of the strategy to stabilize and de-risk its derivatives portfolios (''derivatives strategy'') that has been incorporated into its preferred resolution strategy.[55] In developing its derivatives strategy, a dealer firm should apply the following assumption constraints:

- *OTC derivatives market access:* At or before the start of the resolution period, each derivatives entity should be assumed to lack an investment-grade credit rating (e.g., unrated or downgraded below investment grade). The derivatives entity should also be assumed to have failed to establish or reestablish investment-grade status for the duration of the resolution period, unless the plan provides well-supported analysis to the contrary. As a result of the lack of investment grade status, it should be further assumed that the derivatives entity has no access to the bilateral OTC derivatives markets and must use exchange-traded and/or centrally-cleared instruments where any new hedging needs arise during the resolution period. Nevertheless, a dealer firm may assume the ability to engage in certain risk-reducing derivatives trades with bilateral OTC derivatives counterparties during the resolution period to facilitate novations with third parties and to close out inter-affiliate trades.[56]
- *Early exits (break clauses).* A dealer firm should assume that counterparties (external or affiliates) will exercise any contractual termination right, consistent with any rights stayed by the ISDA 2015 Universal Resolution Stay protocol or other applicable protocols or amendments[57], (i) that is available to the counterparty at or following the start

[52] At a minimum, a dealer firm should have separate categories for fixed and variable expenses. For example, more granular operational expenses could roll-up into categories for (i) fixed-compensation, (ii) fixed non-compensation, and (iii) variable cost.

[53] For example, key drivers of derivatives-related costs and liquidity flows might include the timing of derivatives unwind, cost of capital-related assumptions (target ROE, discount rate, WAL, capital constraints, tax rate), operational cost reduction rate, and operational capacity for novations. Other examples of key drivers likely also include CCP margin flow assumptions and risk-weighted assets forecast assumptions.

[54] For example, relevant characteristics might include: product, size, clearability, currency, maturity, level of collateralization, and other risk characteristics.

[55] Subject to the relevant constraints, a firm's derivatives strategy may take the form of a going-concern strategy, an accelerated de-risking strategy (e.g., active wind-down) or an alternative, third strategy so long as the firm's resolution plan adequately supports the execution of the chosen strategy. For example, a firm may choose a going-concern scenario (e.g., derivatives entities reestablish investment grade status and do not enter a wind-down) as its derivatives strategy. Likewise, a firm may choose to adopt a combination of going-concern and accelerated de-risking scenarios as its derivatives strategy. For example, the derivatives strategy could be a stabilization scenario for the lead bank entity and an accelerated de-risking scenario for the broker-dealer entities.

[56] A firm may engage in bilateral OTC derivatives trades with, for example, (i) external counterparties, to effect the novation of the firm's side of a derivatives contract to a new counterparty, bilateral OTC trades with the acquiring counterparty; and, (ii) inter-affiliate counterparties, where the trades with inter-affiliate counterparties (a) reduce the credit exposure of each participating counterparty and (b) do not materially increase the market risk of any such counterparty on a standalone basis, after taking into account hedging with exchange-traded and centrally-cleared instruments. The firm should demonstrate the risk-reducing nature of the trade on the basis of information that would be known to the firm at the time of the transaction.

[57] For each of the derivatives entities that have adhered to the Protocol, the dealer firm may assume that the protocol is in effect for all counterparties of that derivatives entity (except for any affiliated counterparty of the derivatives entity that has not yet adhered to the Protocol).

of the resolution period; and (ii) if exercising such right would economically benefit the counterparty (''counterparty-initiated termination'').

• *Time horizon:* The duration of the resolution period should be between 12 and 24 months. The resolution period begins immediately after the parent company bankruptcy filing and extends through the completion of the preferred resolution strategy.

A dealer firm's analysis of its derivatives strategy should, at a minimum, take into account (i) the starting profile of its derivatives portfolios (e.g., nature, concentration, maturity, clearability, and liquidity of positions); (ii) the profile and function of the derivatives entities during the resolution period; (iii) the means, challenges, and capacity for managing and de-risking its derivatives portfolios (e.g., method for timely segmenting, packaging, and selling the derivatives positions; challenges with novating less liquid positions; re-hedging strategy); (iv) the financial and operational resources required to effect the derivatives strategy; and (v) any potential residual portfolio (further discussed below). In addition, the firm's resolution plan should address the following areas in the analysis of its derivatives strategy:

*Forecasts of resource needs.* The forecasts of capital and liquidity resource needs required to adequately support the firm's derivatives strategy should be incorporated into the firm's RCEN and RLEN estimates for its overall preferred resolution strategy. These include, for example, the costs and/or liquidity flows resulting from (i) the close-out of OTC derivatives, (ii) the hedging of derivatives portfolios, (iii) the quantified losses that could be incur due to basis and other risks that would result from hedging with only exchange-traded and centrally cleared instruments in a severely adverse stress environment, and (iv) the operational costs.

*Potential residual derivatives portfolio.* A dealer firm's resolution plan should include a method for estimating the composition of any potential residual derivatives portfolio transactions remaining at the end of the resolution period under its preferred resolution strategy. The method may be a combination of approaches (e.g., probabilistic and deterministic) but should demonstrate the dealer firm's capabilities related to portfolio segmentation (discussed above). The dealer firm's plan should also provide detailed descriptions of the trade characteristics used to identify the potential residual portfolio and of the resulting trades (or categories of trades).[58] A dealer firm should assess the risk profile of the potential residual portfolio (including its anticipated size, composition, complexity, counterparties) and the potential counterparty and market impacts of non-performance on the stability of U.S. financial markets (e.g., on funding markets and the underlying asset markets and on clients and counterparties).

*Non-surviving entity analysis.* To the extent the preferred resolution strategy assumes a material derivatives entity enters its own resolution proceeding after the entry of the parent company into a bankruptcy proceeding (a ''non-surviving material derivatives entity''), the dealer firm should provide a detailed analysis of how the non-surviving material derivatives entity's resolution can be accomplished within a reasonable period of time and in a manner that substantially mitigates the risk of serious adverse effects on U.S. financial stability and to the orderly execution of the firm's preferred resolution strategy. In particular, the firm should provide an analysis of the potential impacts on funding markets and the underlying asset markets, on clients and counterparties (including affiliates), and on the preferred resolution strategy. If the non-surviving material derivatives entity is located in, or provides more than *de minimis* services to clients or counterparties located in, a non-U.S. jurisdiction, then the analysis should also specifically consider potential local market impacts.

## VIII. PUBLIC SECTION

The purpose of the public section is to inform the public's understanding of the firm's resolution strategy and how it works.

The public section should discuss the steps that the firm is taking to improve resolvability under the U.S. Bankruptcy Code. The public section should provide background information on each material entity and should be enhanced by including the firm's rationale for designating material entities. The public section should also discuss, at a high level, the firm's intra-group financial and operational interconnectedness (including the types of guarantees or support obligations in place that could impact the execution of the firm's strategy). There should also be a high-level discussion of the liquidity resources and loss-absorbing capacity of the firm.

The discussion of strategy in the public section should broadly explain how the firm has addressed any deficiencies, shortcomings, and other key vulnerabilities that the Agencies have identified in prior Plan submissions. For each material entity, it should be clear how the strategy provides for continuity, transfer, or orderly wind-down of the entity and its operations. There should also be a description of the resulting organization upon completion of the resolution process.

The public section may note that the resolution plan is not binding on a bankruptcy court or other resolution authority and that the proposed failure scenario and associated assumptions are hypothetical and do not necessarily reflect an event or events to which the firm is or may become subject.

By the Board of Governors of the Federal Reserve System, June 28, 2018.

**Ann E. Misback,**

*Secretary of the Board.*

Dated at Washington, DC on June 28, 2018.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

**Valerie Jean Best,**

*Assistant Executive Secretary.*

[FR Doc. 2018–15066 Filed 7–13–18; 8:45 am]

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[58] If under the firm's preferred resolution strategy, any derivatives portfolios are transferred during the resolution period by way of a line of business sale (or similar transaction), then those portfolios should nonetheless be included within the firm's potential residual portfolio analysis.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Meeting of the National Advisory Council for Healthcare Research and Quality

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

**DATES:** The meeting will be held on Wednesday, July 18, 2018, from 8:30 a.m. to 2:45 p.m.

**ADDRESSES:** The meeting will be held at AHRQ, 5600 Fishers Lane, Rockville, Maryland, 20857.

**FOR FURTHER INFORMATION CONTACT:** Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland 20857, (301) 427–

1456. For press-related information, please contact Alison Hunt at (301) 427–1244 or *Alison.Hunt@ahrq.hhs.gov.*

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827–4840, no later than Tuesday, July 3, 2018. The agenda, roster, and minutes will be available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Campbell's phone number is (301) 427–1554.

**SUPPLEMENTARY INFORMATION:**

## I. Purpose

The National Advisory Council for Healthcare Research and Quality is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

## II. Agenda

On Wednesday, July 18, 2018, the Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at *www.webconferences.com/ahrq.* The meeting will begin with an update on AHRQ's current research, programs, and initiatives. The agenda will also include updates on: AHRQ Data, Analytics, and Insights; Making Health Services Research Relevant to the C-Suite; and AHRQ's Opioids efforts. The final agenda will be available on the AHRQ website at *www.AHRQ.gov* no later than Friday, July 13, 2018.

**Francis D. Chesley, Jr.,**

*Acting Deputy Director.*

[FR Doc. 2018–15105 Filed 7–13–18; 8:45 am]

**BILLING CODE 4160–90–P**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Agency for Healthcare Research and Quality

## Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Database.''

**DATES:** Comments on this notice must be received by September 14, 2018.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.* Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by emails at *doris.lefkowitz@AHRQ.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## Proposed Project

*Renewal of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Database*

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. The CAHPS Database is a repository for data from selected CAHPS surveys. The primary purpose of the CAHPS Database is to facilitate comparisons of CAHPS survey results by survey users. This voluntary compilation of survey results from a large pool of data into a single database enables survey users to compare their own results to relevant Database results. The CAHPS Database also offers an important source of primary data for research related to consumer assessments of quality as measured by CAHPS surveys.

The CAHPS Clinician & Group Survey (CG–CAHPS) Database is the newest component of the CAHPS Database. It was developed in response to the growing demand for Database results for the various versions of the CG–CAHPS Survey, including the 12-month and Visit versions. In May 2011, the first set of Database results for both the 12-month and Visit versions was released through the CAHPS Database Online Reporting System.

AHRQ developed the database for CAHPS CG Survey data following the CAHPS Health Plan Database as a model. The CAHPS Health Plan Database was developed in 1998 in response to requests from health plans, purchasers, and CMS for survey data to support public reporting of health plan ratings, health plan accreditation and quality improvement (OMB Control Number 0935–0165, expiration 5/31/2020). Demand for survey results from the CG Survey has grown as well, and therefore AHRQ developed a dedicated Clinician and Group Database to support benchmarking, quality improvement, and research (OMB Control Number 0935–0197, expiration 02/28/2019).

The CAHPS Database contains data from AHRQ's standardized CAHPS Surveys which provide survey measures of quality to health care purchasers, consumers, regulators, and policy makers. The Health Plan Database also provides data for AHRQ's annual National Healthcare Quality and Disparities Reports.

The goal of this project is to renew the CAHPS CG Survey Database. This database will continue to update the CAHPS CG Database with the latest results of the CAHPS CG Survey. These results consist of 31 items that measure 5 areas or composites of patients' experiences with physicians and staff in outpatient medical practices. This database can be used to do the following:

(1) Improve care provided by individual providers, sites of care, medical groups, or provider networks.

(2) Offer several products and services, including providing survey results presented through an Online Reporting System, summary chartbooks, custom analyses, private reports in Excel format, and data for research purposes.

(3) Provides information to help identify strengths and areas with potential for improvement in patient care. The five composite measures are:

Getting Timely Appointments, Care, and Information

How Well Providers Communicate With Patients

Helpful, Courteous, and Respectful Office Staff

Providers' Use of Information to Coordinate Patient Care

Patients' Rating of the Provider

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement, and health surveys and database development. 42 U.S.C. 299a(a)(1), (2), and (8).

**Method of Collection**

To achieve the goal of this project, the following activities and data collections will be implemented:

(1) Registration Form—The purpose of this form is to determine the eligibility status and initiate the registration process for participating organizations seeking to submit their CAHPS CG survey data voluntarily to the CAHPS CG Survey Database. The point of contact (POC) at the participating organization (or parent organization) will complete the form. The POC is either a corporate-level health manager or a survey vendor who contracts with a participating organization to collect the CAHPS CG survey data.

(2) Data Use Agreement—The purpose of the Data Use Agreement (DUA) is to obtain authorization from participating organizations to use their voluntarily submitted CAHPS CG survey data for analysis and reporting according to the terms specified in the DUA. The DUA states how data submitted by participating organizations will be used and provides confidentiality assurances. The POC at the organization will complete the form. Vendors do not sign the DUA.

(3) Data Submission—The number of submissions to the database may vary each year because medical groups and practices may not administer the survey and submit data each year. Data submission is typically handled by one POC who is either a health system, a medical group or practice or a survey vendor who contracts with the medical group or practice to collect data on their behalf. After the POC has completed the Registration Form and the DUA, they will submit patient-level data collected from the CAHPS CG survey to the CAHPS CG Survey Database. Data on organizational characteristics such as ownership, number of patient visits per week, provider specialty, and information related to survey administration such as mode, dates of survey administration, sample size, and response rate, which are collected as part of CAHPS CG survey operations are also submitted.

Each submission will consist of 3 data files: (1) A Group File that contains information about the group ownership, (2) a Practice File containing the practice ownership and affiliation (*i.e.,* commercial, hospital or health system, university or academic medical center, community health center, military or county), number of providers working each week, sampling information, number of patient visits per week, contact information and (3) a Sample File that contains one record for each patient surveyed, the date of visit, survey disposition code, information about survey completion, and survey responses.

Survey data from the CAHPS CG Database is used to produce four types of products: (1) An online reporting of results available to the public on the CAHPS Database website; (2) individual participant reports (in Excel format), used for comparing a participating organization's CAHPS survey results to the database averages, that are confidential and customized for each participating organization that submits their data, (3) an annual Chartbook that presents summary-level results in a downloadable file in PDF format; and (4) a de-identified dataset that is made available to researchers for additional analyses.

Information for the CAHPS CG Database has been collected by AHRQ on an annual basis since 2010. Participating organizations are asked to submit their data voluntarily to the database each year. The data are cleaned with standardized programs, then aggregated and used to produce summarized results. In addition, reports in Excel format are produced that compare the participating organizations' results to the overall database results. These reports are sent via a secured FTP site upon the participating organization's request.

Database results and individual participant reports can serve a variety of purposes:

- Identifying areas for quality improvement at multiple levels, including medical group, practice site, and individual practitioner.
- Briefing senior leadership on patients' views of the health care they receive.
- Supporting public reporting of patients' assessments of care.
- Combining with other quality measures to examine health care outcomes.

The CAHPS CG Database supports research by providing a de-identified analytic database. Much like the CAHPS Health Plan Database developed in 1998 (OMB Control Number 0935–0165, Expiration Date 5/31/2020), researchers can use the CAHPS CG Survey Database to examine:

- Disparities in CAHPS satisfaction scores by racial and ethnic characteristics of patients.
- Comparisons of adult and child CAHPS survey results.

Analysis of case-mix factors affecting CAHPS scores, such as patient age, education, and self-reported health status.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated burden hours for the participating in the CG database. The 11 POCs in exhibit 1 are the number of estimated vendors. Survey vendors assist the Health/Medical entities with submitting data submission materials. Survey vendors generally submit all required survey data and other materials other than the DUA. The 86 POCs in exhibit 1 are the number of estimated participating Health/Medical entities based on 2017 submission.

Each vendor will register online for submission. The online Registration Form will require about 5 minutes to complete. The DUA will be completed by the 86 participating Health/Medical entities. Vendors do not sign DUAs. The DUA process requires about 15 minutes to sign and return by fax, mail or to upload directly to the submission system and includes an accompanying practice site excel file that is uploaded to the submission system. Each submitter will provide a copy of their questionnaire and the survey data file in the required file format. Survey data files must conform to the data file layout specifications provided by the CAHPS Database. The average number of data submissions per vendor is estimated to be 10. Once a data file is uploaded, the file will be automatically checked to ensure it conforms to the specifications and a data file status report will be produced and made available to the submitter. Submitters will review each report and will be expected to fix any errors in their data file and resubmit if necessary. It will take about one hour to complete each file submission. The total burden is estimated to be 133 hours annually.

| Form name | Number of respondents/ POCs | Number of responses for each POC | Hours per response | Total burden hours |
|---|---|---|---|---|
| Registration Form | 11 | 1 | 5/60 | 1 |
| Data Use Agreement | 86 | 1 | 15/60 | 22 |
| Data Submission | 11 | 10 | 1 | 110 |
| Total | 108 | NA | NA | 133 |

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete the submission process. The cost burden is estimated to be $6,602 annually.

**Exhibit 2—Estimated Annualized Cost Burden**

| Form name | Number of respondents/ POCs | Total burden hours | Average hourly wage rate * | Total cost burden |
|---|---|---|---|---|
| Registration Form | 11 | 1 | [a] 40.95 | $41 |
| Data Use Agreement | 86 | 22 | [b] 93.44 | 2,056 |
| Data Files Submission | 11 | 110 | [c] 40.95 | 4,505 |
| Total | 108 | 133 | NA | 6,602 |

* National Compensation Survey: Occupational wages in the United States May 2016, ''U.S. Department of Labor, Bureau of Labor Statistics.'' (a) and (c) Based on the mean hourly wages for Computer Programmer (15–1131). (b) Based on the mean hourly wage for Chief Executives (11–1011). *https://www.bls.gov/oes/current/oes_nat.htm.*

**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**Francis D. Chesley, Jr.,**

*Acting Deputy Director.*

[FR Doc. 2018–15104 Filed 7–13–18; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10669]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Department of Health and Human Services.

**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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and 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 August 15, 2018.

**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 the following:

1. Access CMS' website 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Health Equity Technical Assistance Monitoring and Tracking; *Use:* The Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH) developed the CMS Equity Plan for Improving Quality in Medicare (CMS Equity Plan for Medicare). The Plan outlines CMS' path to help advance health equity by improving the quality of care provided to minority and other underserved Medicare beneficiaries, particularly those with disparities in chronic diseases. CMS identified six high-impact priority areas based on a review of the evidence base and stakeholder input. These priorities encompass both system- and community-level approaches to achieve equity in Medicare. Priority 2: Evaluate Disparities Impacts and Integrate Equity Solutions Across CMS Programs, focuses on increasing understanding of the impact CMS programs have on health disparities and on identifying, developing and integrating proven solutions to improve their impact on vulnerable populations.

CMS created a Health Equity Technical Assistance (TA) email (*HealthEquityTA@cms.hhs.gov*) to support CMS programs as they integrate health equity into their programs. This TA offers guidance from health equity subject matter experts on a variety of topics including reviewing data to identify health disparities, identifying root causes of health disparities, gaining an organizational champion, building organizational capacity to address health disparities, implementing interventions, tracking success of intervention, and serves as a portal to access health equity resources. *Form Number:* CMS–10669 (OMB control number: 0938—New); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 274; *Total Annual Responses* 274; *Total Annual Hours:* 23. (For policy questions regarding this collection contact Alexandra Bryden at 410–786–2076).

Dated: July 11, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018–15146 Filed 7–13–18; 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:* U.S. Repatriation Program Forms.

*OMB No.:* 0970—NEW (two of the forms have prior OMB No: [SSA–3955 & SSA–2061])

*Description:* The United States (U.S.) Repatriation Program was established by Title XI, Section 1113 of the Social Security Act (Assistance for U.S. Citizens Returned from Foreign Countries) to provide temporary assistance to U.S. citizens and their dependents who have been identified by the Department of State (DOS) as having returned, or been brought from a foreign country to the U.S. because of destitution, illness, war, threat of war, or a similar crisis, and are without available resources immediately accessible to meet their needs. The Secretary of the Department of Health and Human Services (HHS) was provided with the authority to administer this Program. On or about 1994, this authority was delegated by the HHS Secretary to the Administration for Children and Families (ACF) and later re-delegated by ACf to the Office of Refugee Resettlement. The Repatriation Program works with States, Federal agencies, and non-governmental organizations to provide eligible individuals with temporary assistance for up to 90-days. This assistance is in the form of a loan and must be repaid to the Federal Government.

The Program was later expanded in response to legislation enacted by Congress to address the particular needs of persons with mental illness (24 U.S.C. Sections 321 through 329). Further refinements occurred in response to Executive Order (E.O.) 11490 (as amended) where HHS was given the responsibility to ''develop plans and procedures for assistance at ports of entry to U.S. personnel evacuated from overseas areas, their onward movement to final destination, and follow-up assistance after arrival at final destination.'' In addition, under E.O. 12656 (53 CFR 47491), ''Assignment of emergency preparedness responsibilities,'' HHS was given the lead responsibility to develop plans and procedures in order to provide assistance to U.S. citizens and others evacuated from overseas areas.

Overall, the Program manages two major activities, Emergency and Non-emergency Repatriation Activities. The ongoing routine arrivals of individual repatriates and the repatriation of individuals with mental illness constitute the Program Non-emergency activities. Emergency activities are comprised of group repatriations (evacuations of 50–500 individuals) and emergency repatriations (evacuations of 500 or more individuals). Operationally, these activities involve different kinds of preparation, resources, and implementation. However, the core Program policies and administrative procedures are essentially the same. The Program provides services through agreements with local repatriation service providers (*e.g.* States, federal agencies, non-governmental agencies, etc.). For the purpose of this Program, local repatriation service provider (local provider) has the same definition of ''agency'' as defined under 45 CFR 212.1 (i).

1. *The HHS Repatriation Program Emergency and Group Processing Form:* Under 45 CFR 211 and 212, ORR is to make findings setting forth the pertinent facts and conclusions according to established standards to determine whether an individual is an eligible person. This form allows authorized staff to gather necessary information to determine eligibility and needed services. This form is to be utilized during emergencies and group repatriations. Individuals interested in receiving Repatriation assistance will complete appropriate portions of this form. State personnel will utilize this form as a guide to perform an initial eligibility and needs assessment. An authorized federal staff from the ACF will make final eligibility determinations through the approval of this form.

2. *The U.S. Repatriation Program Privacy and Repayment Agreement*

*Form:* Under 45 CFR 211 and 212, individuals who receive Program assistance are required to repay the federal government for the cost associated to the services received. This form authorizes ORR to release personal identifiable information to partners for the purpose of providing services to eligible repatriates. In addition, through this form, eligible repatriates agree to accept services under the terms and conditions of the Program. Specifically, eligible repatriates commit to repay the federal government for all services received while in the Program. This form is to be completed by eligible repatriates or authorized legal custodian. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

3. *Relinquish Repatriation Services Form:* For individuals who are eligible to receive repatriation assistance but opt to relinquish services, this form is utilized to confirm and record repatriate's decision to refuse Program assistance. This form is to be completed by eligible repatriates or authorized legal custodian. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

4. *The U.S. Repatriation Program Emergency Financial Form:* Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through utilization of the services and facilities of appropriate public or private agencies and organizations, in accordance with agreements providing for payment, as may be determined by ORR. This form is to be utilized and completed by ORR local providers to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services, after emergency activities.

5. *The U.S. Repatriation Program Non-emergency Reimbursement Form:* Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through arrangements, in accordance with agreements providing for payment, as may be determined by ORR. This form is to be utilized and completed by ORR local providers to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services.

6. *The U.S. Repatriation Program Financial Waiver Request Form:* In accordance with 45 CFR 211 & 212 individuals who have received Repatriation assistance may be eligible to receive a waiver or deferral of their repatriation loan. This form is to be completed by eligible repatriates, authorized legal custodian, or the repatriation local provider. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

7. *The U.S. Repatriation Program Temporary Assistance Extension Request Form:* Under 45 CFR 211 & 212 temporary assistance may be furnished beyond the 90 days eligibility period. This form is to be completed by the eligible repatriates, authorized legal custodian, or the repatriation local provider. This form should be submitted to ORR or its authorized grantee 14 days prior to the expiration of the 90 days eligibility period.

8. *The U.S. Repatriation Program Individual Case Management Report and Financial Claim Form:* Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through agreements with public and private agencies. This form is to be utilized and completed by ORR local provider to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services. This form should also be utilized by the local repatriation provider for submit case updates. This forms is to be completed by authorized local providers.

*Respondents:* Repatriation Program local repatriation service provider and individuals repatriated or evacuated by DOS from overseas. These respondents are authorized under Title XI, Section 1113 of the Social Security Act (42 U.S.C. 1313), Executive Order 12656 (amended by E.O. 13074, February 9, 1998; E.O. 13228, October 8, 2001; E.O. 13286, February 28, 2003), and 45 CFR 211 & 212.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| U.S. Repatriation Program Emergency and Group Processing Form | 500 or more | 1 | 0.15 | 75 or more. |
| U.S. Repatriation Program Privacy and Repayment Agreement Form: | 1000 or more | 1 | 0.05 | 50 or more. |
| U.S. Repatriation Program Relinquish Temporary Assistance Form | 50 or more | 1 | 0.05 | 0.8 or more. |
| U.S. Repatriation Program Emergency and Group Financial Form | 4 or more | 1 | .20 | 4 or more. |
| U.S. Repatriation Program Non-emergency Monthly Financial Statement Form. | 53 or more | 1 | 0.20 | 10.6 or more. |
| U.S. Repatriation Program Loan Waiver Request Form | 100 or more | 1 | 1 | 100 or more. |
| U.S. Repatriation Program Temporary Assistance Extension Request Form. | 500 or more | 1 | 0.20 | 100 or more. |
| U.S. Repatriation Program Individual Case Management Report | 1000 or more | 1 or more | 0.20 | 200 or more. |

*Estimated Total Annual Burden Hours:* 540.4.

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 information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2018–15149 Filed 7–13–18; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–0341]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Use

**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 August 15, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0117. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

**New Animal Drugs for Investigational Use**

*OMB Control Number 0910–0117—Extension*

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support an NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in 21 CFR part 511 set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

*Reporting:* Our regulations require that certain information be submitted to us in a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4) (21 CFR 511.1(b)(4)). If the new animal drug is to be used in food-producing animals, *e.g.,* cattle, swine, chickens, fish, etc., certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals (§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)). We also require reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bio-Research Monitoring Program. This program permits us to monitor the validity of the studies and to ensure the proper use of the drugs is maintained by the investigators.

*Recordkeeping:* If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)). We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

*Description of Respondents:* Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

In the **Federal Register** of February 22, 2018 (83 FR 7735), 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 [1]

| 21 CFR section/activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 511.1(b)(4); submission of NCIE | 104 | 15.38 | 1,600 | 1 | 1,600 |
| 511.1(b)(5); submission of data to obtain authorization for the use of edible food products | 104 | 0.30 | 31 | 8 | 248 |
| 511.1(b)(6); submission of any additional information upon request of FDA | 104 | 0.02 | 2 | 1 | 2 |
| 511.1(b)(8)(ii); reporting of findings that may suggest significant hazards pertinent to the safety of the new animal drug | 104 | 0.14 | 15 | 2 | 30 |
| 511.1(b)(9); reporting by importers of investigational new animal drugs for clinical investigational use in animals | 104 | 0.14 | 15 | 8 | 120 |
| Total | | | 1,663 | | 2,000 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section/activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 511.1(a)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery | 104 | 2.5 | 260 | 1 | 260 |
| 511.1(b)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug or feed containing same is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery | 104 | 15.38 | 1,600 | 1 | 1,600 |
| 511.1(b)(7); maintain records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug | 104 | 15.38 | 1,600 | 3.5 | 5,600 |
| 511.1(b)(8)(i); maintain records of all reports received by a sponsor from investigators | 104 | 15.38 | 1,600 | 3.5 | 5,600 |
| Total | | | 5,060 | | 13,060 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on our informal communication with industry. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 104 respondents. We use this estimate consistently throughout the table and calculate the ''number of responses per respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from our records. The burden for this information collection has changed since the last OMB approval. We estimate an overall increase in burden that we attribute to an increase in the number of annual responses and records.

Dated: July 10, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–15087 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–2515]**

### Hypertension: Conducting Studies of Drugs To Treat Patients on a Background of Multiple Antihypertensive Drugs; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs.'' This draft guidance is intended to clarify the recommended approach for sponsors developing drugs to treat hypertension for patients who are on a background of multiple antihypertensive drugs.

**DATES:** Submit either electronic or written comments on the draft guidance by September 14, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–2515 for ''Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Stephen Grant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4160, Silver Spring, MD 20903, 301–796–2240.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs.'' This draft guidance is intended to clarify the recommended approach for sponsors developing drugs to treat hypertension for patients who are on a background of multiple antihypertensive drugs. Sponsors have approached FDA to discuss development programs for drugs intended to treat *resistant hypertension,* which sponsors have defined as hypertension not adequately controlled by maximally tolerated doses of three or more antihypertensive drugs with different mechanisms of action. FDA encourages development of additional classes of drugs for hypertension, particularly classes of drugs that demonstrate effects when added to currently available therapies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on conducting studies of drugs to treat hypertension in patients on a background of multiple antihypertensive drugs. 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. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collection of information in the guidance for industry entitled ''Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm075072.pdf*) has been approved under OMB control number 0910–0670.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: July 9, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–15092 Filed 7–13–18; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–1011]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 15, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0608. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR 111.75(a)(1)(ii)

*OMB Control Number 0910–0608—Extension*

This information collection supports Agency regulations. The Dietary Supplement Health and Education Act (Pub. L. 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if it has been prepared, packed, or held under the types of conditions that do not meet current good manufacturing practice regulations. Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

Part 111 (21 CFR part 111) establishes the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) of our regulations (21 CFR 111.75(a)(1)) establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Under § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 (21 CFR 10.30) and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95 (21 CFR 111.95). The collection of information in § 111.95 has been approved under OMB control number 0910–0606.

In the **Federal Register** of April 9, 2018 (83 FR 15159), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received suggesting that ''microbial cultures and probiotics should not be required to go through such a process to ensure exemption from the Agency's 100 percent identity testing requirement,'' but did not suggest a revision to the estimated burden. We appreciate this comment, however, we believe that the current requirements impose minimal information collection while simultaneously ensuring the safety of dietary supplements.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 111.75(a)(1)(ii); Determining whether specifications are met | 1 | 1 | 1 | 8 | 8 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since OMB's last approval of the information collection, we have received no petitions. We therefore retain the currently approved estimated burden which assumes no more than one petition will be submitted annually. We further assume it would take respondents 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition, for a total of 8 burden hours annually. These figures are based on our experience with the information collection.

Dated: July 10, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–15088 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–0001]**

### Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery—Influences of Sex and Gender; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Office of Women's Health, Center for Drug Evaluation and Research, and Center for Tobacco Products are announcing the following conference entitled ''Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery—Influences of Sex and Gender.'' The purpose of the conference is to discuss the biological (sex) and sociological (gender) influences on misuse, abuse, and cessation of opioids and tobacco. Researchers, educators, and clinicians may benefit from attending this multidisciplinary review and update on opioid and tobacco.

**DATES:** The two-day conference will be held on September 27, 2018 (8:30 a.m.–4:00 p.m.) and September 28, 2018 (8:30 a.m.–4:00 p.m.). See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The conference will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503–A), Silver Spring, MD 20993. Entrance for the conference participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

**FOR FURTHER INFORMATION CONTACT:** Gwendolyn Jones, Food and Drug Administration, Bldg. 32, Rm. 2333, 10903 New Hampshire Ave., Silver Spring, MD 20993, *OWH_OandNConf@fda.hhs.gov,* 301–796–9940.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is responsible for protecting the public health by assuring the safety and efficacy of FDA-regulated products. This conference will provide the Agency with further insight into the devastating public health crises caused by pervasive opioid and tobacco use. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Many of the drug overdose deaths (more than 6 out of 10) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Of the 63,632 drug overdose deaths in 2016, 66.4 percent (42,249) involved opioids, with increases across age groups, racial/ethnic groups, urbanization levels, and multiple states. Combustible cigarettes have been identified as the dominant cause of tobacco-related disease and are responsible for more than 20 million premature deaths since the first Surgeon General's report in 1964. Together, opioid and tobacco use are the leading causes of preventable disease and death in the United States, and women are increasingly affected. Sex and gender differences may influence susceptibility to substance abuse, which could have implications for optimal prevention and treatment. Gender influencers also impact public health from a familial and environmental perspective. Researchers, educators, and clinicians must be able to recognize and consider both sex and gender differences to identify and treat women most at risk.

#### II. Topics for Discussion at the Conference

The conference will include presentations and panel discussions by experts in the field of opioid and tobacco research, professional education, and clinical care on the biological (sex) and sociological (gender) influences on misuse, abuse, and cessation of opioids and tobacco. Each panel discussion will have a Q&A session to respond to questions from in-person attendees.

#### III. Participating in the Conference

*Registration:* To register for the Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery—Influences of Sex and Gender, please visit the following website: *https://www.eventbrite.com/e/scientific-conference-opioid-and-nicotine-use-dependence-and-recovery-influences-of-sex-and-gender-tickets-47087275308*.

Registration is free and in-person seating is limited. The conference will also be available for viewing via webcast. Persons interested in attending or viewing this conference must register online by September 24, 2018, 5:00 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please email Gwendolyn Jones at *OWH_OandNConf@fda.hhs.gov* (See **FOR FURTHER INFORMATION CONTACT**) no later than September 24, 2018.

*Streaming Webcast of the public meeting:* This public meeting will also be webcast and can only be viewed if registered. To register, please go to

*https://www.eventbrite.com/e/scientific-conference-opioid-and-nicotine-use-dependence-and-recovery-influences-of-sex-and-gender-tickets-47087275308*. Registrants will receive confirmation and information about accessing the webcast when they have been accepted. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: July 10, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–15096 Filed 7–13–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–D–4318]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities

**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 August 15, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities

*OMB Control Number—NEW*

This information collection supports the Agency guidance document entitled ''Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.''

Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that are repackaged, are subject to all applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) related to drug production. Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (21 U.S.C. 353a) (see section 503A(d)(2)), compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 of the FD&C Act (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals.

FDA developed this guidance document to describe the conditions under which the Agency generally does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State compounds or repackages radiopharmaceuticals for human use.

One of the guidance document's conditions is that the compounded radiopharmaceutical is not essentially a copy of an approved radiopharmaceutical. If a compounder intends to rely on a determination from a prescriber that there is a change between the compounded radiopharmaceutical and the comparable approved radiopharmaceutical that produces a clinical difference for an identified individual patient, either the prescribing practitioner or the compounder documents the determination on the prescription or order in writing. This documentation reflects a conversation with the prescribing practitioner, and the compounder maintains records of the prescription or order documenting this determination.

In the **Federal Register** of December 29, 2016 (81 FR 96011), FDA published a notice of availability for the draft guidance, including a 60-day notice soliciting public comment on the information collection recommendations. Several comments were received and are discussed below; however, none of the comments suggested we revise the burden estimate from our 60-day notice.

(Comment 1) One commenter said documentation of a minor deviation from an approved radiopharmaceutical should remain at the facility that performed the minor deviation.

(Response 1) The documentation condition (*i.e.,* documentation of a prescriber's determination that there is a change that produces a clinical difference between the compounded radiopharmaceutical and the comparable FDA-approved radiopharmaceutical for an identified individual patient) does not apply to compounding that consists only of minor deviations as defined in the guidance document (*i.e.,* a change from the approved labeling in radioactivity, volume, or the step-by-step procedures made when compounding the radiopharmaceutical from an FDA-approved drug product in a patient-ready dose). The documentation condition applies to compounding a radiopharmaceutical that involves manipulation other than minor deviations.

(Comment 2) One commenter supports the requirement for notating clinical differences, particularly for documenting both the change to the radiopharmaceutical and the reason that the change is important for the patient.

(Response 2) FDA concurs with this commenter's views about the importance of the documentation.

FDA's guidance document states that the documentation condition would be met if the prescription for the compounded radiopharmaceutical makes clear that the prescriber identified the relevant change between the approved radiopharmaceutical and the compounded radiopharmaceutical and the clinical difference that the change produces for the patient.

(Comment 3) One commenter recommended that the guidance document require written documentation when a commercially manufactured radiopharmaceutical is compounded for a patient because the radiopharmaceutical is unavailable due to a drug shortage.

(Response 3) The guidance document explains that FDA does not consider a compounded radiopharmaceutical to be essentially a copy of a marketed FDA-approved radiopharmaceutical if the FDA-approved radiopharmaceutical is on FDA's drug shortage list (see section 506E of the FD&C Act (21 U.S.C. 356e)) at the time of compounding and distribution. FDA maintains a database for drug shortages. If the Agency identifies a compounded radiopharmaceutical that has the characteristics of a drug that is ''essentially a copy,'' FDA intends to review its database to determine whether there was a shortage of the approved radiopharmaceutical at the time of compounding and distribution.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Type of reporting | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference. | 10 | 25 | 250 | 0.05 (3 minutes) ..... | 12.5 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The total estimated third-party disclosure burden for the guidance document is shown above.

We estimate that a total of approximately 10 compounders annually (''No. of Respondents'' in table 1, line 1) will consult a prescriber to determine whether they decided that the compounded radiopharmaceutical has a change that produces a clinical difference for an identified individual patient as compared to the comparable approved radiopharmaceutical. We estimate that compounders will document this determination on approximately 250 prescriptions or orders for compounded radiopharmaceuticals (''Total Annual Disclosures'' in table 1, line 1). We estimate that the consultation between the compounder and the prescriber and noting this determination on each prescription or order that does not already document this determination will take approximately 3 minutes per prescription or order.

In the **Federal Register** of December 29, 2016 (81 FR 96011), FDA also estimated the annual recordkeeping burden for maintaining records of prescriptions or orders documenting certain information from prescribers. While acquiring additional information from the public about State pharmacy practices since we published 81 FR 96011, FDA has determined that because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by compounders in the normal course of their activities, it is excluded from the definition of ''burden'' under 5 CFR 1320.3(b)(2). FDA understands that maintaining records of prescriptions for compounded drug products is part of the usual course of the practice of compounding and selling drugs and is required by States' pharmacy laws and other State laws governing record keeping by healthcare professionals and healthcare facilities.

Dated: July 10, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–15095 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0115]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 August 15, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0594. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle**

*OMB Control Number 0910–0594—Extension*

Under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The special control guidance serves as the special control for the automated blood cell separator device operating by centrifugal or filtration separation principle intended for the routine collection of blood and blood components (§ 864.9245 (21 CFR 864.9245)).

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Reclassification of this device from class III to class II relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e) and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under 21 CFR part 814, subpart E, including the submission of periodic reports under 21 CFR 814.84.

Collecting or transfusing facilities, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the device manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b) (21 CFR 803.50(b))). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected.

In the **Federal Register** of February 22, 2018, (83 FR 7745), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not discussed here.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Reporting activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Annual Report | 3 | 1 | 3 | 5 | 15 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA records, there are approximately three manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report. The total burden hours are reduced from previous collections due to a decrease in the number of manufacturers.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Dated: July 9, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–15089 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Declaration Regarding Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with the Federal Food, Drug and Cosmetic Act, as delegated by the Secretary of Defense, that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. More specifically, U.S. Forces are now deployed in multiple locations where they serve at

heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage.

On the basis of this determination, on July 9, 2018 the Secretary declared that circumstances exist justifying the authorization of emergency use of Freeze Dried Plasma (FDP) to treat uncontrolled hemorrhage due to agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) in emergency situations when plasma is not available for use or its use is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

**DATES:** The declaration is effective July 9, 2018.

**FOR FURTHER INFORMATION CONTACT:** Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The determination of a military emergency or significant potential for a military emergency by the Deputy Secretary of Defense, and the declaration that circumstances exist justifying emergency use of French FDP by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for FDP in emergency situations when plasma is not available for use or its use is not practical for emergency use under section 564 of the FD&C Act.

## II. Determination of a Military Emergency or Significant Potential for a Military Emergency by the Deputy Secretary of Defense

On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with section 564(b)(1)(B) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b)(1)(B), as delegated by the Secretary of Defense, that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. The Deputy Secretary further stated that, more specifically, U.S. Forces are now deployed in multiple locations where they serve at heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage.

## III. Declaration of the Secretary of Health and Human Services

On July 9, 2018, on the basis of the Deputy Secretary of Defense's determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of FDP to treat uncontrolled hemorrhage due to agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) in emergency situations when plasma is not available for use or its use is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

**Alex M. Azar II,**

*Secretary.*

[FR Doc. 2018–15152 Filed 7–13–18; 8:45 am]

BILLING CODE 4150–37–P

[1] 42 U.S.C. 247d–6b, which states: ''[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.''

# DEPARTMENT OF HOMELAND SECURITY

## U.S. Customs and Border Protection

**[Docket No. USCBP–2018–0026]**

## Commercial Customs Operations Advisory Committee (COAC)

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

**ACTION:** Committee management; notice of Federal Advisory Committee meeting.

**SUMMARY:** The Commercial Customs Operations Advisory Committee (COAC) will hold its public meeting on Wednesday, August 1, 2018 via webinar. The meeting will be open to the public.

**DATES:** The COAC will meet on Wednesday, August 1, 2018 from 1:00 p.m. to 4:00 p.m. EST. Please note that

the meeting may close early if the committee has completed its business.

**ADDRESSES:** The meeting will be held via webinar. The webinar link and conference phone number will be provided to all registrants by 5:00 p.m. on July 31, 2018. For information on services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs & Border Protection, at (202) 344–1440 as soon as possible.

*Pre-Registration:* Members of the public who plan to attend the meeting, please register online at: *https://teregistration.cbp.gov/index.asp?w=137* by 4 p.m. EST, July 31, 2018. Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered to attend via webinar and later need to cancel, please do so by 9:00 a.m. EST on August 1, 2018 utilizing the following link: *https://teregistration.cbp.gov/cancel.asp?w=137*.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than 5:00 p.m. EST on July 31, 2018, and must be identified by Docket No. USCBP–2018–0026, and may be submitted by *one (1)* of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments.
- *Email: tradeevents@dhs.gov*. Include the docket number in the subject line of the message.
- *Fax:* (202) 325–4290, Attention Florence Constant-Gibson.
- *Mail:* Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229.

*Instructions:* All submissions received must include the words ''Department of Homeland Security'' and the docket number (USCBP–2018–0026) for this action. Comments received will be posted without alteration at *https://www.regulations.gov*. Please do not submit personal information to this docket.

*Docket:* For access to the docket or to read background documents or comments, go to *https://www.regulations.gov* and search for Docket Number USCBP–2018–0026. To submit a comment, click the ''Comment Now!'' button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on August 1, 2018. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page, *https://www.cbp.gov/trade/stakeholder-engagement/coac.*

**FOR FURTHER INFORMATION CONTACT:** Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344–1440; facsimile (202) 325–4290; or Mr. Bradley Hayes, Executive Director, Office of Trade Relations and Designated Federal Officer for COAC at (202) 344–1440.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

## Agenda

The Designated Federal Officer will introduce the newly appointed, re-appointed, and alternate COAC members. The COAC will also hear from the following subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Exports Subcommittee will discuss a path forward for its work and the work of the Export Manifest Working Group for the 15th Term COAC. There will also be an update on the automated export manifest pilots, and on progress in implementing a post-departure filing pilot as part of the ocean pilot.

2. The Trusted Trader Subcommittee will present an update from the C–TPAT Minimum Security Criteria Working Group on its recommendation regarding CBP's plans to roll out new C–TPAT criteria. The subcommittee will also provide an update on the progress on the Trusted Trader Strategy and the formation of a new Trade Compliance Working Group.

3. The Trade Modernization Subcommittee will discuss the progress of the Regulatory Reform Working Group's efforts to identify and prioritize areas of regulations administered by CBP which can be reformed and the Foreign Trade Zone Regulations Working Group. In addition, the subcommittee will discuss the progress being made in the E-Commerce Working Group.

4. The Trade Enforcement and Revenue Collection (TERC) Subcommittee will provide updates from the Anti-Dumping/Countervailing Duties (AD/CVD), Bond, Forced Labor and Intellectual Property Rights Working Groups and will also speak to the lessons learned from the risk-based bonding tabletop exercise.

Meeting materials will be available by July 31, 2018 at: *http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings*.

Dated: July 11, 2018.

**Bradley F. Hayes,**

*Executive Director, Office of Trade Relations.*

[FR Doc. 2018–15107 Filed 7–13–18; 8:45 am]

**BILLING CODE 9111–14–P**

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7001–N–36]**

## 30-Day Notice of Proposed Information Collection: Human Trafficking Housing Partnership

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

**DATES:** *Comments Due Date:* August 15, 2018.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA_Submission@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Anna P. Guido, Reports Management

Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on April 27, 2018 at 83 FR 18584.

**A. Overview of Information Collection**

*Title of Information Collection:* Human Trafficking Housing Partnership.

*OMB Approval Number:* 2506–New.

*Type of Request:* New.

*Form Number:* SF 424, HUD SF 424 SUPP (if applicable), HUD–2993 (if applicable), HUD–96011 (if applicable), HUD–2880, SF–LLL.

*Description of the need for the information and proposed use:* The information to be collected will be used to rate applications, to determine eligibility for the Human Trafficking Housing Partnership and to establish grant amounts. Applicants, which must be state or local governments, nonprofit organizations, or a Federally recognized Indian Tribe or Tribally Designated Housing Entity (TDHE), will respond to narrative prompts to demonstrate their experience and expertise in providing housing and services to victims of human trafficking and to describe their intended program design, that will address the needs for housing and services that will result in permanent housing placement and sufficient income to ensure permanent housing is maintained once assistance discontinues.

ESTIMATED NUMBER OF RESPONDENTS—ESTIMATED NUMBER OF RESPONSES

| Information collection | Number of respondents | Frequency of response | Responses per annum | Burden hour per response | Annual burden hours | Hourly cost per response | Annual cost |
|---|---|---|---|---|---|---|---|
| Human Trafficking Housing Partnership Application | 20.00 | 1.00 | 20.00 | 8.00 | 160.00 | $39.07 | $6,251.20 |
| SF–424 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| SF LLL | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| HUD–2880 | 20.00 | 1.00 | 20.00 | 0.50 | 10.00 | 39.07 | 390.70 |
| HUD–50070 | 20.00 | 1.00 | 20.00 | 0.50 | 10.00 | 39.07 | 390.70 |
| Certification Regarding Lobbying | 20.00 | 1.00 | 20.00 | 0.50 | 10.00 | 39.07 | 390.70 |
| HUD–2991 | 20.00 | 1.00 | 20.00 | 0.50 | 10.00 | 39.07 | 390.70 |
| Code of Conduct | 20.00 | 1.00 | 20.00 | 0.50 | 10.00 | 39.07 | 390.70 |
| Subtotal | 20.00 | 1.00 | 20.00 | 10.50 | 210.00 | 39.07 | 8,204.70 |
| Annual Performance Reporting | 20.00 | 1.00 | 20.00 | 4.00 | 80.00 | 39.07 | 3,125.60 |
| Total | 20.00 | 1.00 | 20.00 | 14.50 | 290.00 | 39.07 | 11,330.30 |

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: June 28, 2018.

**Anna P. Guido,**

*Department Reports Management Officer, Office of the Chief Information Officer.*

[FR Doc. 2018–15131 Filed 7–13–18; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7001–N–38]**

## 30-Day Notice of Proposed Information Collection: Congregate Housing Services Program

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

**DATES:** *Comments Due Date:* August 15, 2018.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Inez C. Downs, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Inez.C.Downs@hud.gov,* or telephone 202–402–8046. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Downs.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the

information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on April 18, 2018 at 83 FR 17186.

**A. Overview of Information Collection**

*Title of Information Collection:* Congregate Housing Services Program.

*OMB Approved Number:* 2502–0485.

*Type of Request:* Extension of currently approved collection.

*Form Number:* SF–424, 425, HUD–90003, HUD–90006, HUD–90198, HUD–91180–A, HUD–91178–A.

*Description of the Need for the Information and Proposed Use:* Completion of the Annual Report by grantees provides HUD with essential information about whom the grant is serving and what sort of services the beneficiaries receive using grant funds.

The Summary Budget and the Annual Program Budget make up the budget of the grantee's annual extension request. Together the forms provide itemized expenses for anticipated program costs and a matrix of budgeted yearly costs. The budget forms show the services funded through the grant and demonstrate how matching funds, participant fees, and grant funds will be used in tandem to operate the grant program. Field staff approve the annual budget and request annual extension funds according to the budget. Field staff can also determine if grantees are meeting statutory and regulatory requirements through the evaluation of this budget.

HUD will use the Payment Voucher to monitor use of grant funds for eligible activities over the term of the grant. The Grantee may similarly use the Payment Voucher to track and record their requests for payment reimbursement for grant-funded activities.

*Respondents:* (*i.e., affected public*): Non-profit institutions.

*Estimated Number of Respondents:* 49.

*Estimated Number of Responses:* 392.

*Frequency of Response:* 8.

*Average Hours per Response:* 1.56.

*Total Estimated Burdens:* 611.52.

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond: Including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: July 3, 2018.

**Inez C. Downs,**

*Department Reports Management Officer, Office of the Chief Information Officer.*

[FR Doc. 2018–15129 Filed 7–13–18; 8:45 am]

**BILLING CODE 4210–67–P**

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7001–N–37]**

## 30-Day Notice of Proposed Information Collection: Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation Collection

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

**DATES:** *Comments Due Date:* August 15, 2018.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov*.

**FOR FURTHER INFORMATION CONTACT:** Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on March 23, 2018 at 83 FR 12806.

**A. Overview of Information Collection**

*Title of Information Collection:* Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation collection.

*OMB Approval Number:* 2528–0293.

*Type of Request:* Revision of currently approved collection.

*Form Number:* N/A.

*Description of the need for the information and proposed use:* The U.S. Department of Housing and Urban Development (HUD) is conducting a national study on the effectiveness of pre-purchase homeownership counseling services. This request covers four data collection activities: (1) Administering a final follow-up survey to study participants; (2) extending OMB approval #2528–0293 so that the study can continue to collect updated tracking information from study participants; and (3) extending OMB approval #2528–0293 so that the study can continue to collect consent from the co-borrowers of study participants; and (4) extending OMB approval #2528–0293 so that the study can continue to collect loan origination and servicing data from lenders. The final follow-up survey will be administered to study participants approximately 48 months after they completed the baseline survey. The final survey will provide a comparison of study participants' characteristics from the baseline survey and allow the study to better understand, document, and explain the impacts of first-time homebuyer education and counseling. As part of OMB approval #2528–0293, the study collects updated study participant contact information to locate study participants for the final follow-up survey. Maintaining contact with study participants over time is critical to minimizing attrition and ensuring high response rates to the follow-up surveys. Additionally, the collection of consent

from study participants' co-borrowers is necessary to allow the study to collect data related to the characteristics and performance of study participants' mortgage loans. Lastly, as part of OMB approval #2528–0293, the study collects study participants' loan origination and service tracking data from the study's three participating lenders.

*Respondents (i.e. affected public):* Up to 5,854 study participants; approximately 1,000 co-borrowers; and, staff at 3 lenders.

The average time per study participant (up to 5,854 study participants) to complete the final follow-up survey is 30 minutes. The study mails study participant tracking letters twice per year. The average time for study participants' review of the letters and return of the tracking form is 5 minutes. The collection of co-borrower consent involves including the co-borrower consent form in the study's regular tracking letters, along with a request for the co-borrower to review, sign, and return the written consent form. For co-borrowers who do not return the written form, the study will collect consent verbally at the time of the interim survey. The study estimates that approximately 1,000 study participants will have co-borrowers. The co-borrowers' review of the co-borrower consent information and completion of the consent process is estimated to require approximately 5 minutes per co-borrower. The average time for lenders to prepare study participants' loan origination and performance data for the study team is 60 minutes. The study team will ask for this data semi-annually from each lender during the next 3 years from each lender. The total burden for the study is 3,949.64 hours: 3,903 hours for study participants, 83 hours for co-borrowers, and 6 hours for lenders.

*Estimated Number of Respondents/ Estimated Number of Responses:*

| Information collection | Number of respondents | Frequency of response | Responses per annum | Burden hours per response | Annual burden hours | Hourly cost per response | Annual cost |
|---|---|---|---|---|---|---|---|
| Long-Term Follow-Up Survey | 5,854.00 | 1.00 | 5,854.00 | 0.50 | 2,927.00 | * $27.70 | $81,077.90 |
| Tracking Letter | 5,854.00 | 2.00 | 11,708.00 | 0.08 | 936.64 | * 27.70 | 25,944.92 |
| Co-borrower consent form | 1,000.00 | 1.00 | 1,000.00 | 0.08 | 80.00 | * 27.70 | 2,216.00 |
| Loan origination and performance data: Lenders | 3.00 | 2.00 | 6.00 | 1.00 | 6.00 | 35.00 | 210.00 |
| Total | 12,711.00 | | | | 3,949.64 | | 109,448.82 |

* The average income that our study participants received in the last 12 months is $57,811. This estimate of average income is based on responses to the Short-Term Follow-Up Survey and was weighted to represent the full study sample using sample weights that adjust for follow-up survey nonresponse. Thus, the hourly rate for our study participants is estimated at $27.70 (using the U.S. Office of Personnel's national standard of 2,087 hours per year for a full-time employee).

## B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: June 28, 2018.

**Anna P. Guido,**

*Department Reports Management Officer, Office of the Chief Information Officer.*

[FR Doc. 2018–15130 Filed 7–13–18; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLUTG02100/18X/L14400000.EU0000; UTU–92606]**

### Notice of Realty Action; Proposed Modified Competitive Sale of Public Land, Utah

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of realty action.

**SUMMARY:** The Bureau of Land Management (BLM) is considering the modified competitive sale of 160 acres of public land in Emery County, Utah, at not less than the appraised fair market value to the adjacent landowners Hunter Prep Plant LLC, Ross Huntington, and Clinton Price.

**DATES:** In order to ensure consideration in the environmental analysis of the proposed sale, comments must be received by August 30, 2018.

**ADDRESSES:** Address all written comments concerning this notice to the BLM, Price Field Office, Attn: Hunter Plant Public Land Disposal, 125 S. 600 W, Price, Utah, 84501. Electronic mail will also be accepted and should be sent to *BLM_UT_PR_Comments@blm.gov* with ''Hunter Plant Public Land Disposal'' inserted in the subject line.

**FOR FURTHER INFORMATION CONTACT:** Jaydon Mead, Realty Specialist, (435) 636–3646, at the above address, or email to *jmead@blm.gov.* Persons who use a telecommunication device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact the above individual. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The following described public land in Emery County, Utah, is being considered for modified competitive sale, subject to the applicable provisions of Sections 203 and 209 of the Federal Land Policy and Management Act of

1976 (FLPMA) and 43 CFR parts 2711 and 2720:

**Salt Lake Meridian, Utah**

T. 19 S, R. 8 E,
Sec. 21, E½NW¼, SW¼NW¼, and NE¼SW¼.

The area described contains 160 acres, according to the official plat of the survey of the said land, on file with the BLM.

The proposed sale is in conformance with the BLM Price Field Office Resource Management Plan (PFO RMP) that was approved in October 2008. The parcel is identified for disposal by sale under Section 203 of FLPMA in the PFO RMP on page 2 of Appendix R–11. This parcel of land was identified for disposal because it is isolated from large blocks of public land making it difficult and uneconomic to manage. The land would be offered to the adjoining land owners on a modified competitive basis, with Hunter Prep Plant, LLC, as the designated bidder, giving them the right to meet the highest bid pursuant to 43 CFR 2711.3–2(a)(1). Conveyance of the identified public land would be subject to valid existing rights and encumbrances of record. Conveyance of any mineral interests pursuant to Section 209 of FLPMA will be analyzed during processing of the proposed sale. On July 16, 2018, the above-described land will be segregated from appropriation under the public land laws, including the mining laws, except the sale provisions of FLPMA. Until completion of the sale action, the BLM is no longer accepting land use applications affecting the identified public land. The segregative effect will terminate upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or July 16, 2020, unless extended by the BLM Utah State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

For a period until August 30, 2018, interested parties and the general public may submit in writing any comments concerning the land being considered for sale, including notification of any encumbrances or other claims relating to the identified land, to the Field Manager, BLM Price Field Office, at the above address. In order to ensure consideration in the environmental analysis of the proposed sale, comments must be in writing and postmarked or delivered within 45 days of the initial date of publication of this notice. Comments, including names and street addresses of respondents, will be available for public review at the BLM Price Field Office during regular business hours, except holidays. Individual respondents may request confidentiality. Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

**Authority:** 43 CFR 2711.1–2.

**Edwin L. Roberson,**
*State Director.*

[FR Doc. 2018–15063 Filed 7–13–18; 8:45 am]

**BILLING CODE 4310–DQ–P**

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## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[L71220000.JB0000;LVTFKX899000, WYW182548]**

### Notice of Realty Action; Non-Competitive (Direct) Sale of Public Land in Park County, Wyoming

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of realty action.

**SUMMARY:** The Bureau of Land Management (BLM) proposes a non-competitive (direct) sale of 1.31 acres of public land in Park County, Wyoming, to the Jeanne S. Moeller Trust pursuant to the Federal Land Policy and Management Act of 1976 (FLPMA), as amended, to resolve an unauthorized use of public lands. The sale will be subject to the applicable provisions of Section 203 of FLPMA, and BLM regulations. The appraised fair market value for the sale parcel is $1,250.

**DATES:** Interested parties may submit written comments regarding the sale until August 30, 2018.

**ADDRESSES:** Mail written comments concerning this notice to Field Manager, BLM Cody Field Office, 1002 Blackburn Street, Cody, Wyoming 82414.

**FOR FURTHER INFORMATION CONTACT:** Cara Blank, Realty Specialist, at the above address, by email at *cblank@blm.gov,* or telephone 307–578–5912. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The following described public land in Park County, Wyoming, has been examined and found suitable for sale under the authority of Section 203 of FLPMA, as amended:

**Sixth Principle Meridian**

T. 55 N, R. 100 W,
Sec. 10, lot 4.

The areas described contains 1.31 acres in Park County, Wyoming.

The sale is in conformance with the BLM Cody Resource Management Plan, which identifies this parcel of public land as suitable for disposal on page 105 and management action 6011, approved on September 18, 2015. The parcel is not needed for any other Federal purpose. The regulations at 43 CFR 2711.3–3(a) permit the BLM to make direct sales of public lands when a competitive sale is not appropriate and the public interest would be best served by a direct sale. A competitive sale is not appropriate because these lands contain improvements owned by the Jeanne S. Moeller Trust, rendering the land not usable by the public. The public interest would be served by resolving this inadvertent unauthorized use and receiving the fair market value for the lands.

On August 30, 2018, the above-described lands will be segregated from appropriation under the public lands laws, including the mining laws, except the sale provision of the FLPMA. Until completion of the sale action, the BLM is no longer accepting land use applications affecting the public land, except applications for the amendment of previously-filed, right-of-way applications or existing authorizations to increase the term of the grants in accordance with 43 CFR 2807.15 and 2886.15. The temporary segregative effect will terminate upon the issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or on July 16, 2020, unless extended by the BLM Wyoming State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

In addition, this Notice will publish once each week for three weeks in the Powell Tribune newspaper.

The following terms, conditions, and reservations will appear on the conveyance document for the sale parcel:

1. A right-of-way is reserved for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945);

2. A reservation of all minerals to the United States, and the right to prospect for, mine, and remove such minerals under applicable law and such regulations as established by the

Secretary of the Interior, together with all necessary access and exit rights.

3. The parcel is subject to valid existing rights.

Only written comments submitted by postal service or overnight mail will be considered as properly filed. Electronic mail, facsimile, or telephone comments will not be considered.

Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask the BLM in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so. Comments, including names and street addresses of respondents, will be available for public review at the BLM Cody Field Office during regular business hours, except holidays.

Any comments regarding the sale will be reviewed by the BLM Wyoming State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action.

**Authority:** 43 CFR 2711.

**Mary Jo Rugwell,**

*Wyoming State Director.*

[FR Doc. 2018–15061 Filed 7–13–18; 8:45 am]

**BILLING CODE 4310–22–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[18X.LLAZ921000.L1440 0000.BJ0000.LXSSA2250000.241A]**

### Notice of Filing of Plats of Survey; Arizona

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of official filing.

**SUMMARY:** The plats of survey of the following described lands were officially filed in the Bureau of Land Management (BLM), Arizona State Office, Phoenix, Arizona, on the dates indicated. Surveys announced in this notice are necessary for the management of lands administered by the agencies indicated.

**ADDRESSES:** These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427. Protests of the survey should be sent to the Arizona State Director at the above address.

**FOR FURTHER INFORMATION CONTACT:** Gerald Davis, Chief Cadastral Surveyor of Arizona; (602) 417–9558; *gtdavis@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:**

**The Gila and Salt River Meridian, Arizona**

The supplemental plat, in one sheet, showing the amended lotting in section 30, Township 10 North, Range 10 East, accepted June 7, 2018, and officially filed June 8, 2018, for Group 9111, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in one sheet, representing the dependent resurvey of a portion of the north boundary of section 26, a portion of the lines of Homestead Entry Survey No. 577, and a metes-and-bounds survey, partially surveyed Township 11 North, Range 10 East, accepted January 17, 2018, and officially filed January 18, 2018, for Group 1177, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat, in one sheet, representing the Amended Protraction Diagram (APD), partially surveyed Township 11 North, Range 10 East, accepted January 17, 2018, and officially filed January 18, 2018, for Group 1177, Arizona.

This plat was prepared at the request of the United States Forest Service.

This plat supersedes the APD approved November 26, 2013.

The plat, in one sheet, representing the dependent resurvey of a portion of the west boundary of the Navajo Indian Reservation, from the southwest corner of the present reservation to the six mile corner, Township 21 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the dependent resurvey of a portion of the west boundary of the Navajo Indian Reservation, from the six mile corner to the twelve mile corner, Township 22 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the dependent resurvey of a portion of the west boundary of the Navajo Indian Reservation, from the twelve mile corner to the eighteen mile corner, a portion of the south boundary, and the establishment of the northeast township corner, partially surveyed Township 23 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the Amended Protraction Diagram (APD), partially surveyed Township 23 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

This plat supersedes that portion of Arizona Protraction Diagram No. 47 for this area.

The plat, in one sheet, representing the dependent resurvey of a portion of the west boundary of the Navajo Indian Reservation, from the eighteen mile corner to the intersection with the Little Colorado River, the meanders of the right bank of the Little Colorado River, and the establishment of the northeast township corner, partially surveyed Township 24 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the Amended Protraction Diagram (APD), partially surveyed, Township 24 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

This plat supersedes that portion of Arizona Protraction Diagram No. 47 for this area.

The plat, in five sheets, representing the dependent resurvey of a portion of the Sixth Standard Parallel North (south boundary), a portion of the west boundary, the meanders of a portion of the right bank of the Little Colorado River, and the establishment of the northeast township corner and the standard corner of Township 25 North, Ranges 11 and 12 East, partially surveyed, Township 25 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the Amended Protraction Diagram (APD), partially surveyed, Township 25 North, Range 11 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1169, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

This plat supersedes that portion of Protraction Diagram No. 47 for that area.

The plat, in one sheet, representing the Amended Protraction Diagram (APD), unsurveyed Township 3 North, Range 16 East, accepted April 26, 2018, and officially filed April 27, 2018.

This plat was prepared at the request of the Bureau of Land Management.

This plat supersedes the APD accepted November 26, 2013.

The plat, in one sheet, representing the survey of the south and east boundaries, the subdivisional lines, and the subdivision of certain sections, Township 40 North, Range 25 East, accepted April 26, 2018, and officially filed April 27, 2018, for Group 1173, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the dependent resurvey of the north boundary, Township 26 North, Range 29 East, the survey of the north boundary, the governing section line, a portion of the subdivisional lines, and the subdivision of certain sections, partially surveyed Township 27 North, Range 29 East, accepted June 11, 2018, and officially filed June 13, 2018, for Group 1178, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The supplemental plat, in one sheet, showing the amended lotting in section 34, Township 13 North, Range 2 West, accepted June 7, 2018, and officially filed June 8, 2018, for Group 9112, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat, in two sheets, representing the dependent resurvey of a portion of the east boundary, a portion of the subdivisional lines, a portion of patented mineral surveys in sections 1, 2, 11 and 12, and the metes-and-bounds survey of Tract 37, Township 2 South, Range 12 East, accepted June 28, 2018, and officially filed July 2, 2018, for Group 1168, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in three sheets, representing the dependent resurvey of portions of the south and west boundaries, a portion of the subdivisional lines, portions of certain patented mineral surveys in sections 29, 31 and 32, the survey of a portion of the center line of the right-of-way of U.S. Highway No. 60, and a metes-and-bounds survey in section 31, Township 1 South, Range 13 East, accepted June 28, 2018, and officially filed July 2, 2018, for Group 1168, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines, Township 2 South, Range 13 East, accepted June 28, 2018, and officially filed July 2, 2018, for Group 1168, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

A person or party who wishes to protest against any of these surveys must file a written notice of protest within 30 calendar days from the date of this publication with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Authority:** 43 U.S.C. Chap. 3.

**Gerald T. Davis,**

*Chief Cadastral Surveyor of Arizona.*

[FR Doc. 2018–15098 Filed 7–13–18; 8:45 am]

**BILLING CODE 4310–32–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLNVS00560.L58530000.EU0000.241A; N–94460; 12–08807; MO# 4500115809; TAS:15X5232]**

### Notice of Realty Action: Classification for Lease and/or Conveyance for Recreation and Public Purposes of Public Lands for a Park in the Northwest Portion of the Las Vegas Valley, Clark County, Nevada

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of realty action.

**SUMMARY:** The Bureau of Land Management (BLM), Las Vegas Field Office, has examined and found suitable for classification for lease and subsequent conveyance to the City of Las Vegas, approximately 10 acres of public land in the Las Vegas Valley, Clark County, Nevada, under the provisions of the Recreation and Public Purposes (R&PP) Act, as amended, and the Taylor Grazing Act. The City of Las Vegas proposes to use the 10 acres of land for a community park that will help meet future expanding needs in the northwestern part of the Las Vegas Valley.

**DATES:** Interested parties may submit written comments regarding the proposed classification for lease and conveyance of the land until August 30, 2018.

**ADDRESSES:** Mail written comments to the BLM Las Vegas Field Office, Attn: Vanessa L. Hice, Assistant Field Manager, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130, or faxed to 775–515–5010.

**FOR FURTHER INFORMATION CONTACT:** Roger Ketterling at the above address, or by telephone at 702–515–5087, or by email to *rketterling@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The parcel is located south of Kyle Canyon Road, at Iron Mountain Road and Alpine Ridge Way in northwest Las Vegas and is legally described as:

**Mount Diablo Meridian, Nevada**

T. 19 S, R. 59 E,
sec. 1, SE¼SE¼SW¼.
The area described contains 10.00 acres in Clark County, Nevada.

In accordance with the R&PP Act, the City of Las Vegas has filed an application to develop the above-described land as a community park consisting of large and small picnic shelters, ball parks, children's play area, pedestrian walkways, parking and turf open space play areas. Additional detailed information pertaining to this Notice, plan of development, and site plan is located in case file N–94460, which is available for review at the BLM Las Vegas Field Office at the above address.

The City of Las Vegas is a political subdivision of the State of Nevada and is therefore a qualified applicant under the R&PP Act.

Subject to limitations prescribed by law and regulation, prior to patent

issuance, the holder of any right-of-way grant within the lease area may be given the opportunity to amend the right-of-way grant for conversion to a new term, including perpetuity, if applicable.

The land identified is not needed for any Federal purpose. The lease and/or conveyance is in conformance with the BLM Las Vegas Resource Management Plan decision LD–1, approved on October 5, 1998, and would be in the public interest. The Las Vegas Valley Disposal Boundary Environmental Impact Statement and Record of Decision issued on December 23, 2004, analyzed the sale parcels. A parcel-specific Determination of National Environmental Policy Act Adequacy (DNA), document number DOI–BLM–NV–S010–2017–0092–DNA, was prepared in connection with this Notice of Realty Action. The City of Las Vegas has not applied for more than the 640-acre limitation for public purpose uses in a year and has submitted a statement in compliance with the regulations at 43CFR 2741.4(b).

The lease and conveyance, when issued, will be subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945); and

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove such deposits for the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

Any lease and conveyance will also be subject to valid existing rights, will contain any terms or conditions required by law (including, but not limited to, any terms or conditions required by 43 CFR 2741.4), and will contain an appropriate indemnification clause protecting the United States from claims arising out of the lessee's/patentee's use, occupancy, or operations on the leased/patented lands. It will also contain any other terms and conditions deemed necessary and appropriate by the Authorized Officer.

Upon publication of this Notice in the **Federal Register,** the land described above will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, as well as issuance of any rights-of-way, except for lease and conveyance under the R&PP Act, leasing under the mineral leasing laws, and disposals under the mineral material disposal laws.

Interested parties may submit written comments on the suitability of the land for a public park in the City of Las Vegas. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs. Interested parties may also submit written comments regarding the specific use proposed in the application and plan of development, and whether the BLM followed proper administrative procedures in reaching the decision to lease and convey under the R&PP Act.

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 the BLM in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Only written comments submitted to the Field Manager, BLM Las Vegas Field Office, will be considered properly filed. Any adverse comments will be reviewed by the BLM Nevada State Director, who may sustain, vacate, or modify this realty action.

In the absence of any adverse comments, the decision will become effective on September 14, 2018. The lands will not be available for lease and conveyance until after the decision becomes effective.

**Authority:** 43 CFR 2741.5.

**Vanessa L. Hice,**

*Assistant Field Manager, Division of Lands, Las Vegas Field Office.*

[FR Doc. 2018–15062 Filed 7–13–18; 8:45 am]

BILLING CODE 4310–HC–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLCON04000.L71220000.EU0000.LVTFC1 700130.17X; COC78146; FMV $800]**

### Notice of Realty Action: Direct Sale of Public Land in Garfield County, Colorado

**AGENCY:** Bureau of Land Management.

**ACTION:** Notice of realty action.

**SUMMARY:** The Bureau of Land Management (BLM) is proposing a non-competitive (direct) sale of 0.16 acres of public land in Garfield County, Colorado, to Ida Hoaglund, to resolve an inadvertent unauthorized use and occupancy of public land.

**DATES:** Written comments must be received no later than August 30, 2018.

**ADDRESSES:** Mail written comments to Gloria Tibbetts, Acting Field Manager, Colorado River Valley Field Office, 2300 River Frontage Road, Silt, CO 81652. Written comments may also be submitted electronically to: *blm_co_si_crvfo_webmail@blm.gov.*

**FOR FURTHER INFORMATION CONTACT:** Monte Senor, Realty Specialist, BLM Colorado River Valley Field Office, telephone: (970) 876–9053, email: *msenor@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The direct sale is a result of an IBLA-sanctioned settlement agreement to resolve an appeal of a BLM trespass decision involving an unauthorized use of public land. In addition to cash compensation for the sale, the proponent will donate two public access easements to the United States to improve public access for hunting and other recreational opportunities. The donation will be processed, separately from the subject sale, under appropriate acquisition regulations and guidelines.

The subject sale described in this notice will be processed pursuant to Section 203 of the Federal Land Policy and Management Act of 1976 (FLPMA) and BLM disposal regulations. The appraised fair market value of the sale parcel is $800. The proposed sale meets the criteria for direct sales established in FLPMA, Section 203(a)(3) and 43 CFR 2711.3–3(a). Direct sales (without competition) may be used when, in the opinion of the authorized officer, a competitive sale is not appropriate and the public interest would best be served by a direct sale. In accordance with BLM regulations, the BLM authorized officer finds the public interest would best be served by conducting a direct sale pursuant to 43 CFR 2711.3–3(a)(5). This regulation allows a direct sale when a need exists to resolve inadvertent unauthorized use or occupancy of the lands.

The subject parcel, which is located near Rulison Parachute Road and Cottonwood Creek in Garfield County, Colorado, is legally described as:

**Sixth Principal Meridian, Colorado**

T. 7 S, R. 95 W,
Sec. 2, lot 7.
The area described contains 0.16 acres.

This sale is in conformance with the BLM Colorado River Valley Field Office Record of Decision and Approved Resource Management Plan, approved in June 2015.

A parcel-specific Environmental Assessment (EA) document numbered DOI–BLM–CO–N0400–2018–0008–EA was prepared in connection with this Notice of Realty Action. A copy of the EA is available online at: *https://go.usa.gov/xQx6N.*

The proposed direct sale would be conducted in compliance with regulations contained in 43 CFR 2711.3–3, which allows the BLM to conduct direct sales of public lands when a competitive sale is not appropriate and the public interest is best served by a direct sale. Pursuant to 43 CFR 2711.1–2, the land would not be sold until after September 14, 2018, and this notice will be published once a week for 3 weeks in the *Glenwood Springs Post Independent.*

The patent, if issued, would be subject to the following terms, conditions, and reservations:

1. Reservation of a right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C 945);

2. A reservation of all mineral deposits in the land so patented, and to it, or persons authorized by it, the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe are reserved to the United States, together with all necessary access and exit rights;

3. Valid existing rights and encumbrances of record including, but not limited to, rights-of-way for roads and public utilities; and

4. An appropriate indemnification clause protecting the United States from claims arising out of the lessees/patentee's use, occupancy, or occupation on the leased/patented lands;

Information concerning the sale, appraisal, reservations, procedures and conditions, and other environmental documents that may appear in the BLM public files for this proposed action are available for review during normal business hours, Monday through Friday, at the BLM Colorado River Valley Field Office, except during Federal holidays. Submit comments on this notice to the address in the **ADDRESSES** section of this notice.

Before including your address, phone number, email address, or other personally identifiable information in your comments, be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask the BLM in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Any adverse comments regarding this sale will be reviewed by the BLM Colorado State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in whole or in part. In the absence of timely filed objections, this realty action will become the final determination of the Department of the Interior.

**Authority:** 43 CFR 2711.

**Gregory P. Shoop,**
*Acting BLM Colorado State Director.*

[FR Doc. 2018–15060 Filed 7–13–18; 8:45 am]
**BILLING CODE 4310–JB–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLUTG02100/18X/L54400000.EU0000/LVCLJ18J0760; UTU–92605]**

### Notice of Realty Action; Proposed Direct Sale of Public Land, Utah

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of realty action.

**SUMMARY:** The Bureau of Land Management (BLM) is considering the direct sale (without competition) of 200 acres of public land in Emery County, Utah, at not less than the appraised fair market value to PacifiCorp.

**DATES:** In order to ensure consideration in the environmental analysis of the proposed sale, comments must be received by August 30, 2018.

**ADDRESSES:** Send all written comments concerning this notice to the BLM, Price Field Office, Attn: Price Land Sale, 125 S 600 W, Price, Utah, 84501. Electronic mail will also be accepted and should be sent to *BLM_UT_PR_Comments@blm.gov* with ''Price Land Sale'' inserted in the subject line.

**FOR FURTHER INFORMATION CONTACT:** Jaydon Mead, Realty Specialist, (435) 636–3646, at the above address, or email to *jmead@blm.gov.* Persons who use a telecommunication device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact the above individual. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The following described public land in Emery County, Utah, is being considered for direct sale, subject to the applicable provisions of Sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (FLPMA) and 43 CFR parts 2711 and 2720:

**Salt Lake Meridian, Utah**

T. 19 S, R. 8 E,
Sec. 21, NE¼ and NE¼SE¼.
The area described contains 200 acres, according to the official plat of the survey of the said land, on file with the BLM.

The proposed sale is in conformance with the BLM Price Field Office Resource Management Plan (PFO RMP) that was approved in October 2008. The parcel is identified for disposal, by sale, under Section 203 of the FLPMA in the PFO RMP on page 2 of Appendix R–11. This parcel is isolated from large blocks of public land making it difficult and uneconomic to manage. Pursuant to 43 CFR 2711.3–3(a)(4), the land would be offered to Pacificorp on a non-competitive basis due to the lack of public access and their ownership of the surrounding lands. Conveyance of the identified public land would be subject to valid existing rights and encumbrances of record. Conveyance of any mineral interests pursuant to Section 209 of the FLPMA will be analyzed during processing of the proposed sale. On July 16, 2018, the above-described land will be segregated from appropriation under the public land laws, including the mining laws, except the sale provisions of the FLPMA. Until completion of the sale action, the BLM is no longer accepting land use applications affecting the identified public land. The segregative effect will terminate upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or July 16, 2020, unless extended by the BLM Utah State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

For a period until August 30, 2018, interested parties and the general public may submit in writing any comments concerning the land being considered for sale, including notification of any encumbrances or other claims relating to the identified land, to the Field Manager, BLM Price Field Office, at the above address. In order to ensure consideration in the environmental analysis of the proposed sale, comments

must be in writing and postmarked or delivered within 45 days of the initial date of publication of this notice. Comments, including names and street addresses of respondents, will be available for public review at the BLM Price Field Office during regular business hours, except holidays. Individual respondents may request confidentiality.

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

**Authority:** 43 CFR 2711.1–2

**Edwin L. Roberson,**

*State Director.*

[FR Doc. 2018–15065 Filed 7–13–18; 8:45 am]

**BILLING CODE 4310–DQ–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–MWR–INDU–25223; PS.SMWLA0077.00.1]**

### Minor Boundary Revision at Indiana Dunes National Lakeshore

**AGENCY:** National Park Service, Interior.

**ACTION:** Notification of boundary revision.

**SUMMARY:** The boundary of Indiana Dunes National Lakeshore is modified to include 1.30 acres of land located in Porter County, Indiana, immediately adjacent to the boundary of the national lakeshore. The United States will acquire the parcel by a land exchange.

**DATES:** The effective date of this boundary revision is July 16, 2018.

**ADDRESSES:** The map depicting this boundary revision is available for inspection at the following locations: National Park Service, Land Resources Program Center, Midwest Region, 601 Riverfront Drive, Omaha, Nebraska 68102 and National Park Service, Department of the Interior, 1849 C Street NW, Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** Chief Realty Officer Daniel L. Betts, National Park Service, Land Resources Program Center, Midwest Region, 601 Riverfront Drive, Omaha, Nebraska 68102, telephone (402) 661–1780.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, pursuant to 54 U.S.C. 100506(c), the boundary of Indiana Dunes National Lakeshore is modified to include 1.30 acres of adjacent land identified as Tract 09–131. The boundary revision is depicted on Map No. 626/140729, dated January, 2018.

54 U.S.C. 100506(c) provides that, after notifying the House Committee on Natural Resources and the Senate Committee on Energy and Natural Resources, the Secretary of the Interior is authorized to make this boundary revision upon publication of notice in the **Federal Register**. The Committees have been notified of this boundary revision. This boundary revision and subsequent acquisition will be accomplished in accordance with a settlement to a case pending in the Federal Court System regarding an encroachment onto Federal land. There will be no alienation of Federal land through the land exchange.

Dated: April 25, 2018.

**Cameron H. Sholly,**

*Regional Director, Midwest Region.*

[FR Doc. 2018–15072 Filed 7–13–18; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### Office of Natural Resources Revenue

**[Docket No. ONRR–2011–0012; DS63644000 DR2000000.CH7000 189D0102R2]**

### Major Portion Prices and Due Date for Additional Royalty Payments on Indian Gas Production in Designated Areas Not Associated With an Index Zone

**AGENCY:** Office of Natural Resources Revenue, Interior.

**ACTION:** Notice.

**SUMMARY:** Final regulations for valuing gas produced from Indian leases, published August 10, 1999, require the Office of Natural Resources Revenue (ONRR) to determine major portion prices and notify industry by publishing the prices in the **Federal Register**. The regulations also require ONRR to publish a due date for industry to pay additional royalties based on the major portion prices. Consistent with these requirements, this notice provides major portion prices for the 12 months of calendar year 2016.

**DATES:** The due date to pay additional royalties based on the major portion prices is September 28, 2018.

**FOR FURTHER INFORMATION CONTACT:**

*Calculation of Prices Information:* Robert Sudar, Manager, Market & Spatial Analytics, ONRR, at (303) 231–3511, or email to *Robert.Sudar@onrr.gov*; mailing address—Office of Natural Resources Revenue, P.O. Box 25165, MS 64310B, Denver, Colorado 80225–0165.

*Reporting Information:* Lee-Ann Martin, Program Manager, Reference & Reporting Management, ONRR, at (303) 231–3313, or email to *Leeann.Martin@onrr.gov*; mailing address—Office of Natural Resources Revenue, P.O. Box 25165, MS 63300B, Denver, Colorado 80225–0165.

**SUPPLEMENTARY INFORMATION:** On August 10, 1999, ONRR's predecessor, the Minerals Management Service, published a final rule titled ''Amendments to Gas Valuation Regulations for Indian Leases'' effective January 1, 2000 (64 FR 43506). The gas valuation regulations apply to all gas production from Indian (Tribal or allotted) oil and gas leases, except leases on the Osage Indian Reservation.

The regulations require ONRR to publish major portion prices for each designated area not associated with an index zone for each production month beginning January 2000, as well as the due date for additional royalty payments. *See* 30 CFR 1206.174(a)(4)(ii). If you owe additional royalties based on a published major portion price, you must submit to ONRR, by the due date, an amended form ONRR–2014, Report of Sales and Royalty Remittance. If you do not pay the additional royalties by the due date, ONRR will bill you late payment interest under 30 CFR 1218.54. The interest will accrue from the due date until ONRR receives your payment and an amended form ONRR–2014. The table below lists the major portion prices for all designated areas not associated with an index zone. The due date is the end of the month, following 60 days after the publication date of this notice in the **Federal Register**.

GAS MAJOR PORTION PRICES ($/MMBtu) FOR DESIGNATED AREAS NOT ASSOCIATED WITH AN INDEX ZONE

| ONRR-designated areas | Jan 2016 | Feb 2016 | Mar 2016 | Apr 2016 |
|---|---|---|---|---|
| Blackfeet Reservation | 1.28 | 1.25 | 1.06 | 1.01 |
| Fort Belknap Reservation | 4.15 | 4.24 | 3.94 | 1.10 |

GAS MAJOR PORTION PRICES ($/MMBtu) FOR DESIGNATED AREAS NOT ASSOCIATED WITH AN INDEX ZONE—Continued

| | | | | |
|---|---|---|---|---|
| Fort Berthold Reservation | 1.90 | 1.84 | 1.27 | 1.33 |
| Fort Peck Reservation | 1.34 | 1.49 | 1.56 | 1.75 |
| Navajo Allotted Leases in the Navajo Reservation | 2.16 | 2.03 | 1.52 | 1.59 |
| Turtle Mountain Reservation | 1.93 | 1.87 | 1.25 | 1.32 |
| ONRR-designated areas | May 2016 | Jun 2016 | Jul 2016 | Aug 2016 |
| Blackfeet Reservation | 1.02 | 1.13 | 1.48 | 1.01 |
| Fort Belknap Reservation | 1.26 | 1.38 | 1.56 | 1.55 |
| Fort Berthold Reservation | 1.48 | 1.51 | 2.25 | 2.16 |
| Fort Peck Reservation | 1.85 | 2.38 | 2.46 | 2.44 |
| Navajo Allotted Leases in the Navajo Reservation | 1.77 | 1.90 | 2.56 | 2.54 |
| Turtle Mountain Reservation | 1.45 | 1.49 | 2.29 | 2.20 |
| ONRR-designated areas | Sep 2016 | Oct 2016 | Nov 2016 | Dec 2016 |
| Blackfeet Reservation | 1.66 | 1.96 | 1.69 | 2.16 |
| Fort Belknap Reservation | 1.64 | 1.79 | 1.68 | 1.91 |
| Fort Berthold Reservation | 2.32 | 2.53 | 2.31 | 2.78 |
| Fort Peck Reservation | 2.34 | 2.88 | 2.68 | 3.08 |
| Navajo Allotted Leases in the Navajo Reservation | 2.62 | 2.70 | 2.42 | 3.20 |
| Turtle Mountain Reservation | 2.36 | 2.48 | 2.31 | 2.65 |

For information on how to report additional royalties due to major portion prices, please refer to our Dear Payor letter dated December 1, 1999, on the ONRR website at *http://www.onrr.gov/ReportPay/PDFDocs/991201.pdf.*

**Authorities:** : Mineral Leasing Act of 1920, 30 U.S.C. 181 *et seq.;* Indian Mineral Development Act of 1920, 30 U.S.C. 2103 *et seq.;* Federal Oil and Gas Royalty Management Act of 1982, 30 U.S.C. 1701 *et seq.*

**Gregory J. Gould,**

*Director for Office of Natural Resources Revenue.*

[FR Doc. 2018–15111 Filed 7–13–18; 8:45 am]

**BILLING CODE 4335–30–P**

## DEPARTMENT OF THE INTERIOR

### Office of Natural Resources Revenue

**[Docket No. ONRR–2016–0001; DS63644000 DR2000000.CH7000 189D0102R2]**

### Withdrawal of Temporary Physical Address Change for General Ledger Team

**AGENCY:** Office of the Secretary, Office of Natural Resources Revenue, Interior.

**ACTION:** Notice.

**SUMMARY:** The Office of Natural Resources Revenue (ONRR) is withdrawing the temporary physical address change published in the **Federal Register** on April 27, 2016 for courier services and personal deliveries.

**DATES:** The cancellation takes effect on July 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** Darrel Redford, Supervisory Accountant, at (303) 231–3085, or email to *Darrel.Redford@onrr.gov.*

**SUPPLEMENTARY INFORMATION:** As of July 16, 2018, all courier services and deliveries should be made to ONRR, at the Denver Federal Center, Building 85, Entrance N–1, West 6th Ave. and Kipling St., Denver, Colorado 80225. Visitor parking is available in the north parking lot near Entrance N–1, which is the only entrance on the north side of Building 85. To request service, please use the courtesy phone and call Janet Giron at (303) 231–3088.

**Authority:** 44 U.S.C. 1505.

**Gregory J. Gould,**

*Director for Office of Natural Resources Revenue.*

[FR Doc. 2018–15112 Filed 7–13–18; 8:45 am]

**BILLING CODE 4335–30–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Ocean Energy Management

**[Docket No. BOEM–2018–0004]**

### Commercial Leasing for Wind Power on the Outer Continental Shelf in the New York Bight—Call for Information and Nominations

**AGENCY:** Bureau of Ocean Energy Management, Interior.

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** On April 11, 2018, the Bureau of Ocean Energy Management (BOEM) issued a Call for Information and Nominations for Commercial Leasing for Wind Power on the Outer Continental Shelf (OCS) in the New York Bight (Call). BOEM invited the submission of information and nominations for commercial wind leases that would allow a lessee to propose the construction of a wind energy project in the New York Bight, and to develop one or more projects, if approved, after further environmental review. Additionally, the announcement requested comments and information from interested and affected parties about site conditions, resources, and multiple uses in close proximity to, or within, the Call Areas. Information received will help inform BOEM's identification of Wind Energy Areas, which would be further evaluated for potential commercial wind leasing. The April 11 notice had a comment period deadline of May 29, 2018. Several stakeholders have contacted BOEM and requested additional time to submit comments. BOEM agrees that it would be helpful in this instance to reopen the comment period.

**DATES:** BOEM must receive nominations describing your interest in one or more, or any portion of, the Call Areas, by a postmarked date of July 30, 2018, for your nomination to be considered. BOEM requests comments or submissions of information to be postmarked or delivered by this same date. BOEM will consider only those nominations received during the comment period.

**ADDRESSES:** If you are submitting a nomination for a lease area in response to this Call, please submit your nomination by following the instructions in the ''Required Nomination Information'' section of the Call (83 FR 15602, 15617) to the following address: BOEM, Office of Renewable Energy Programs, 45600 Woodland Road (VAM–OREP), Sterling, Virginia 20166. In addition to a paper

copy of the nomination, include an electronic copy of the nomination on a data storage device. BOEM will list the parties that submitted nominations and the location of the proposed lease areas (*i.e.,* OCS blocks nominated) on the BOEM website after the comment period has closed.

Comments and other submissions of information may be submitted by either of the following two methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* In the entry entitled, ''Enter Keyword or ID,'' enter BOEM–2018–0004, and then click ''search.'' Follow the instructions to submit public comments and view supporting and related materials available for this notice.

2. U.S. Postal Service or other delivery service. Send your comments and information to the following address: Bureau of Ocean Energy Management, Office of Renewable Energy Programs, 45600 Woodland Road (VAM–OREP), Sterling, Virginia 20166.

All responses will be reported on *http://www.regulations.gov.*

If you wish to protect the confidentiality of your nominations or comments, clearly mark the relevant sections and request that BOEM treat them as confidential. Please label privileged or confidential information ''Contains Confidential Information,'' and consider submitting such information as a separate attachment. Treatment of confidential information is addressed in the section of this Call entitled, ''Protection of Privileged or Confidential Information.'' Information that is not labeled as privileged or confidential will be regarded by BOEM as suitable for public release.

**FOR FURTHER INFORMATION CONTACT:** Luke Feinberg, BOEM, Office of Renewable Energy Programs, 45600 Woodland Road (VAM–OREP), Sterling, Virginia 20166, (703) 787–1705 or *luke.feinberg@boem.gov.*

**SUPPLEMENTARY INFORMATION:**

Authority: This Call is published pursuant to subsection 8(p)(3) of the OCS Lands Act, 43 U.S.C. 1337(p)(3), which was added by section 388 of the Energy Policy Act of 2005 (EPAct), as well as the implementing regulations at 30 CFR part 585.

*Background and Purpose:* The OCS Lands Act requires BOEM to award leases competitively, unless BOEM makes a determination that there is no competitive interest (43 U.S.C. 1337(p)(3)). BOEM will make this determination after reviewing the nominations received in response to this Call. This Call also requests information from interested and affected parties on issues relevant to potential leasing within the Call Areas.

The responses to this Call could lead to the initiation of a competitive leasing process in some parts of the Call Areas (*i.e.,* where competition exists), and a noncompetitive process in other parts of the Call Areas (*i.e.,* where no competitive interest exists). The Call, described in detail in the **Federal Register** (83 FR 15602 (April 11, 2018)), had an initial comment deadline of May 29, 2018, but several stakeholders have requested additional time to comment. BOEM agrees that it would be helpful in this instance to reopen the comment period until July 30, 2018.

*Protection of Privileged or Confidential Information:* BOEM will protect privileged or confidential information that you submit as provided in the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to trade secrets and commercial or financial information that you submit that is privileged or confidential. If you wish to protect the confidentiality of such information, clearly mark it and request that BOEM treat it as confidential. BOEM will not disclose such information if it qualifies for exemption from disclosure under FOIA. Please label privileged or confidential information ''Contains Confidential Information'' and consider submitting such information as a separate attachment.

BOEM will not treat as confidential any aggregate summaries of such information or comments not containing such information. Additionally, BOEM will not treat as confidential (1) the legal title of the nominating entity (for example, the name of your company), or (2) the list of whole or partial blocks that you are nominating. Information that is not labeled as privileged or confidential will be regarded by BOEM as suitable for public release.

Dated: July 11, 2018.

**Walter D. Cruickshank,**

*Acting Director, Bureau of Ocean Energy Management.*

[FR Doc. 2018–15133 Filed 7–13–18; 8:45 am]

BILLING CODE 4310–MR–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Ocean Energy Management

**[Docket No. BOEM–2018–0035]**

### Gulf of Mexico Outer Continental Shelf Region-Wide Oil and Gas Lease Sale 251

**AGENCY:** Bureau of Ocean Energy Management, Interior.

**ACTION:** Final notice of sale.

**SUMMARY:** On Wednesday, August 15, 2018, the Bureau of Ocean Energy Management (BOEM) will open and publicly announce bids received for blocks offered in the Gulf of Mexico (GOM) Outer Continental Shelf (OCS) Region-wide Oil and Gas Lease Sale 251 (GOM Region-wide Sale 251), in accordance with the provisions of the Outer Continental Shelf Lands Act (OCSLA), as amended, and the implementing regulations issued pursuant thereto. The GOM Region-wide Sale 251 Final Notice of Sale (NOS) package contains information essential to potential bidders.

**DATES:** BOEM will hold GOM Region-wide Sale 251 at 9:00 a.m. on Wednesday, August 15, 2018. All times referred to in this document are Central Standard Time, unless otherwise specified.

*Bid submission deadline:* BOEM accepts sealed bids between 8:00 a.m. and 4:00 p.m. on normal working days prior to the sale with the exception of Tuesday, August 14th, the day before the sale. BOEM must receive all bids for GOM Region-wide Sale 251 by 10:00 a.m. on Tuesday, August 14, 2018. For more information on bid submission, see Section VII, ''Bidding Instructions,'' of this document.

**ADDRESSES:** Bids will be accepted prior to the bid receipt deadline at 1201 Elmwood Park Boulevard, New Orleans, Louisiana. Public bid reading for GOM Region-wide Sale 251 will be held at 1201 Elmwood Park Boulevard, New Orleans, Louisiana, but the venue will not be open to the general public, media, or industry during bid opening or reading. Bid opening will be available for public viewing on BOEM's website at *www.boem.gov* via live-streaming video beginning at 9:00 a.m. on the date of the sale. BOEM will also post the results on its website after bid opening and reading are completed. Interested parties may download the Final NOS package from BOEM's website at *http://www.boem.gov/Sale-251/.* Copies of the sale maps may be obtained by contacting the BOEM GOM Region at: Gulf of Mexico Region Public Information Office, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394, (504) 736–2519 or (800) 200–GULF.

For more information on bid submission, see Section VII, ''Bidding Instructions,'' of this document.

**FOR FURTHER INFORMATION CONTACT:** Ann Glazner, Deputy Regional Supervisor, Office of Leasing and Plans, 504–736–

2607, *ann.glazner@boem.gov* or Wright Jay Frank, Acting Chief, Leasing Policy and Management Division, 703–787–1325, *wright.frank@boem.gov.*

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I. Lease Sale Area
II. Statutes and Regulations
III. Lease Terms and Economic Conditions
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## I. Lease Sale Area

*Blocks Offered for Leasing:* BOEM will offer for bid in this lease sale all of the available unleased acreage in the GOM, except those blocks listed in ''Blocks Not Offered for Leasing'' below.

*Blocks Not Offered for Leasing:* The following whole, segregated, and partial blocks are not offered for lease in this sale. The BOEM Official Protraction Diagrams (OPDs) and Supplemental Official Block Diagrams are available online at *https://www.boem.gov/Maps-and-GIS-Data/.*

Whole and partial blocks that lie within the current boundaries of the Flower Garden Banks National Marine Sanctuary (in the East and West Flower Garden Banks and the Stetson Bank), identified in the following list:

*High Island, East Addition, South Extension (Leasing Map TX7C)*
Whole Block: A–398
Partial Blocks: A–366, A–367, A–374, A–375, A–383, A–384, A–385, A–388, A–389, A–397, A–399, A–401
*High Island, South Addition (Leasing Map TX7B)*
Partial Blocks: A–502, A–513
*Garden Banks (OPD NG15–02)*
Partial Blocks: 134, 135

Blocks that are adjacent to or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap:

*Lund South (OPD NG 16–07)*
Whole Blocks: 128, 129, 169 through 173, 208 through 217, 248 through 261, 293 through 305, and 349
*Henderson (OPD NG 16–05)*
Whole Blocks: 466, 508 through 510, 551 through 554, 594 through 599, 637 through 643, 679 through 687, 722 through 731, 764 through 775, 807 through 819, 849 through 862, 891 through 905, 933 through 949, and 975 through 992
Partial Blocks: 467, 511, 555, 556, 600, 644, 688, 732, 776, 777, 820, 821, 863, 864, 906, 907, 950, 993, and 994
*Florida Plain (OPD NG 16–08)*
Whole Blocks: 5 through 24, 46 through 67, 89 through 110, 133 through 154, 177 through 197, 221 through 240, 265 through 283, 309 through 327, and 363 through 370

All whole and portions of blocks deferred by the Gulf of Mexico Energy Security Act of 2006, Public Law 109–432:

*Pensacola (OPD NH 16–05)*
Whole Blocks: 751 through 754, 793 through 798, 837 through 842, 881 through 886, 925 through 930, and 969 through 975
*Destin Dome (OPD NH 16–08)*
Whole Blocks: 1 through 7, 45 through 51, 89 through 96, 133 through 140, 177 through 184, 221 through 228, 265 through 273, 309 through 317, 353 through 361, 397 through 405, 441 through 450, 485 through 494, 529 through 538, 573 through 582, 617 through 627, 661 through 671, 705 through 715, 749 through 759, 793 through 804, 837 through 848, 881 through 892, 925 through 936, and 969 through 981
*DeSoto Canyon (OPD NH 16–11)*
Whole Blocks: 1 through 15, 45 through 59, and 92 through 102
Partial Blocks: 16, 60, 61, 89 through 91, 103 through 105, and 135 through 147
*Henderson (OPD NG 16–05)*
Partial Blocks: 114, 158, 202, 246, 290, 334, 335, 378, 379, 422, and 423

Depth restricted, segregated block portion(s):

Block 299, Main Pass Area, South and East Addition (Louisiana Leasing Map LA10A), containing 1,125 acres, from the surface of the earth down to a subsea depth of 1,900 feet with respect to the following described portions:
SW¼NE¼; NW¼SE¼NE¼; W½NE¼SE¼NE¼; S½S½NW¼NE¼; S½SW¼NE¼NE¼; S½SW¼SE¼NE¼NE¼; N½SW¼SE¼NE¼; SW¼SW¼SE¼NE¼; NW¼SE¼SE¼ NE¼; N½NW¼SW¼SE¼SE¼NE¼; N½SE¼SW¼SE¼NE¼; N½S½SE¼SW¼SE¼NE¼; S½NE¼NW¼; S½S½N½NE¼NW¼; N½SE¼NW¼; S½SE¼NW¼NW¼; NE¼SE¼NW¼NW¼; E½NE¼SW¼NW¼; N½SE¼SE¼NW¼; NE¼SW¼SE¼NW¼; N½NW¼SW¼SE¼NW¼; SE¼SE¼SE¼NW¼; E½SW¼SE¼SE¼NW¼; N½NW¼NE¼SW¼NW¼; N½S½NW¼NE¼SW¼NW¼; N½N½NE¼NE¼NE¼SW¼; N½N½N½NW¼NW¼SE¼; N½N½NW¼NE¼NW¼SE¼.

The following blocks, whose lease status is currently under appeal:

Keathley Canyon (*Leasing Map NG15–05*) Blocks 290, 291, and 292
Keathley Canyon (*Leasing Map NG15–05*) Blocks 246 and 247
Keathley Canyon (*Leasing Map NG15–05*) Blocks 335 and 336
Vermilion Area (*Leasing Map LA3*) Partial Block 179

## II. Statutes and Regulations

Each lease is issued pursuant to OCSLA, 43 U.S.C. 1331–1356, as amended, and is subject to OCSLA implementing regulations promulgated pursuant thereto in 30 CFR part 556, and other applicable statutes and regulations in existence upon the effective date of the lease. Each lease is also subject to those applicable statutes enacted and regulations promulgated thereafter, except to the extent that the after-enacted statutes and regulations explicitly conflict with an express provision of the lease. Additionally, each lease is subject to amendments to statutes and regulations, including but not limited to OCSLA, that do not explicitly conflict with an express provision of the lease. The lessee expressly bears the risk that such new or amended statutes and regulations (*i.e.,* those that do not explicitly conflict with an express provision of the lease) may increase or decrease the lessee's obligations under the lease.

## III. Lease Terms and Economic Conditions

*Lease Terms*

OCS Lease Form

BOEM will use Form BOEM–2005 (February 2017) to convey leases resulting from this sale. This lease form may be viewed on BOEM's website at *http://www.boem.gov/BOEM-2005.* The lease form will be amended to conform with the specific terms, conditions, and stipulations applicable to the individual lease. The terms, conditions, and stipulations applicable to this sale are set forth below.

Primary Term

Primary Terms are summarized in the following table:

| Water depth (meters) | Primary term |
|---|---|
| 0 to <400 | The primary term is five years; the lessee may earn an additional three years (*i.e.,* for an eight-year extended primary term) if a well is spudded targeting hydrocarbons below 25,000 feet True Vertical Depth Subsea (TVDSS) during the first five years of the lease. |
| 400 to <800 | The primary term is five years; the lessee will earn an additional three years (*i.e.,* for an eight-year extended primary term) if a well is spudded during the first five years of the lease. |
| 800 to <1,600 | The primary term is seven years; the lessee will earn an additional three years (*i.e.,* for a ten-year extended primary term) if a well is spudded during the first seven years of the lease. |
| 1,600+ | Ten years. |

(1) The primary term for a lease in water depths less than 400 meters issued as a result of this sale is five years. If the lessee spuds a well targeting hydrocarbons below 25,000 feet TVDSS within the first five years of the lease, then the lessee may earn an additional three years, resulting in an eight-year primary term. The lessee will earn the eight-year primary term when the well is drilled to a target below 25,000 feet TVDSS, or the lessee may earn the eight-year primary term in cases where the well targets, but does not reach, a depth below 25,000 feet TVDSS due to mechanical or safety reasons, where sufficient evidence is provided that it did not reach that target for reasons beyond the lessee's control.

In order to earn the eight-year extended primary term, the lessee is required to submit to the BOEM GOM Regional Supervisor for Leasing and Plans, as soon as practicable, but in no instance more than 30 days after completion of the drilling operation, a letter providing the well number, spud date, information demonstrating a target below 25,000 feet TVDSS and whether that target was reached, and if applicable, any safety, mechanical, or other problems encountered that prevented the well from reaching a depth below 25,000 feet TVDSS. This letter must request confirmation that the lessee earned the eight-year primary term. The BOEM GOM Regional Supervisor for Leasing and Plans will confirm in writing, within 30 days of receiving the lessee's letter, whether the lessee has earned the extended primary term and update BOEM records accordingly. The extended primary term is not effective unless and until the lessee receives confirmation from BOEM.

A lessee that has earned the eight-year primary term by spudding a well with a hydrocarbon target below 25,000 feet TVDSS during the standard five-year primary term of the lease will not be granted a suspension for that same period under the regulations at 30 CFR 250.175 because the lease is not at risk of expiring.

(2) The primary term for a lease in water depths ranging from 400 to less than 800 meters issued as a result of this sale is five years. If the lessee spuds a well within the five-year primary term of the lease, the lessee will earn an additional three years, resulting in an eight-year primary term.

In order to earn the eight-year primary term, the lessee is required to submit to the BOEM GOM Regional Supervisor for Leasing and Plans, as soon as practicable, but in no instance more than 30 days after spudding a well, a letter providing the well number and spud date, and requesting confirmation that the lessee earned the eight-year extended primary term. Within 30 days of receipt of the request, the BOEM GOM Regional Supervisor for Leasing and Plans will provide written confirmation of whether the lessee has earned the extended primary term and update BOEM records accordingly. The extended primary term is not effective unless and until the lessee receives confirmation from BOEM.

(3) The standard primary term for a lease in water depths ranging from 800 to less than 1,600 meters issued as a result of this sale is seven years. If the lessee spuds a well within the standard seven-year primary term, the lessee will earn an additional three years, resulting in a ten-year extended primary term.

In order to earn the ten-year primary term, the lessee is required to submit to the BOEM GOM Regional Supervisor for Leasing and Plans, as soon as practicable, but in no instance more than 30 days after spudding a well, a letter providing the well number and spud date, and requesting confirmation that the lessee earned the ten-year primary term. Within 30 days of receipt of the request, the BOEM GOM Regional Supervisor for Leasing and Plans will provide written confirmation of whether the lessee has earned the extended primary term and update BOEM records accordingly. The extended primary term is not effective unless and until the lessee receives confirmation from BOEM.

(4) The primary term for a lease in water depths 1,600 meters or greater issued as a result of this sale will be ten years.

*Economic Conditions*

Minimum Bonus Bid Amounts

- $25.00 per acre or fraction thereof for blocks in water depths less than 400 meters; and
- $100.00 per acre or fraction thereof for blocks in water depths 400 meters or deeper.

BOEM will not accept a bonus bid unless it provides for a cash bonus in an amount equal to, or exceeding, the specified minimum bid of $25.00 per acre or fraction thereof for blocks in water depths less than 400 meters, and $100.00 per acre or fraction thereof for blocks in water depths 400 meters or deeper.

Rental Rates

Annual rental rates are summarized in the following table:

Rental Rates

RENTAL RATES PER ACRE OR FRACTION THEREOF

| Water depth (meters) | Years 1–5 | Years 6, 7, & 8+ |
|---|---|---|
| 0 to <200 | $7.00 | $14.00, $21.00, & $28.00. |
| 200 to <400 | 11.00 | $22.00, $33.00, & $44.00. |
| 400+ | 11.00 | $16.00. |

Escalating Rental Rates for Leases With an Eight-Year Primary Term in Water Depths Less Than 400 Meters

Any lessee with a lease in less than 400 meters water depth who earns an eight-year primary term will pay an escalating rental rate as shown above. The rental rates after the fifth year for blocks in less than 400 meters water depth will become fixed and no longer escalate, if another well is spudded targeting hydrocarbons below 25,000 feet TVDSS after the fifth year of the lease, and BOEM concurs that such a well has been spudded. In this case, the rental rate will become fixed at the rental rate in effect during the lease year in which the additional well was spudded. Royalty Rate

Royalty Rate

- 12.5 percent for leases situated in water depths less than 200 meters; and,
- 18.75 percent for leases situated in water depths of 200 meters and deeper.

Minimum Royalty Rate

- $7.00 per acre or fraction thereof per year for blocks in water depths less than 200 meters; and
- $11.00 per acre or fraction thereof per year for blocks in water depths 200 meters and deeper.

Royalty Suspension Provisions

The issuance of leases with Royalty Suspension Volumes (RSVs) or other forms of royalty relief is authorized under existing BOEM regulations at 30 CFR part 560. The specific details relating to eligibility and implementation of the various royalty relief programs, including those involving the use of RSVs, are codified in Bureau of Safety and Environmental Enforcement (BSEE) regulations at 30 CFR part 203.

In this sale, the only royalty relief program being offered that involves the provision of RSVs relates to the drilling of ultra-deep wells in water depths of less than 400 meters, as described in the following section.

Royalty Suspension Volumes on Gas Production From Ultra-Deep Wells

Leases issued as a result of this sale may be eligible for RSV incentives on gas produced from ultra-deep wells pursuant to 30 CFR part 203. These regulations implement the requirements of the Energy Policy Act of 2005 (42 U.S.C. 13201 *et seq.*). Under this program, wells on leases in less than 400 meters water depth and completed to a drilling depth of 20,000 feet TVDSS or deeper receive a RSV of 35 billion cubic feet on the production of natural gas. This RSV incentive is subject to applicable price thresholds set forth in the regulations at 30 CFR part 203.

## IV. Lease Stipulations

Consistent with the Record of Decision for the Final Programmatic Environmental Impact Statement for the 2017–2022 Five Year OCS Oil and Gas Leasing Program, Stipulation No. 5 (Topographic Features) and Stipulation No. 8 (Live Bottom) will apply to every lease sale in the GOM Program Area. One or more of the remaining eight stipulations listed below may be applied to leases issued as a result of this sale. The blocks to which particular stipulations will apply is identified on the map ''Final, Gulf of Mexico Region-wide Oil and Gas Lease Sale 251, August 15, 2018, Stipulations and Deferred Blocks'' included in the Final NOS package. The detailed text of the following stipulations is contained in the ''Lease Stipulations'' section of the Final NOS package.

(1) Military Areas
(2) Evacuation
(3) Coordination
(4) Protected Species
(5) Topographic Features
(6) United Nations Convention on the Law of the Sea Royalty Payment
(7) Agreement between the United States of America and the United Mexican States Concerning Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico
(8) Live Bottom
(9) Blocks South of Baldwin County, Alabama
(10) Restrictions due to Rights-of-Use and Easement for Floating Production Facilities

## V. Information to Lessees

Information to Lessees (ITLs) provides detailed information on certain issues pertaining to specific oil and gas lease sales. The detailed text of the ITLs for this sale is contained in the ''Information to Lessees'' section of the Final NOS package and covers the following topics:

(1) Navigation Safety
(2) Ordnance Disposal Areas
(3) Existing and Proposed Artificial Reefs/Rigs-to-Reefs
(4) Lightering Zones
(5) Indicated Hydrocarbons List
(6) Military Areas
(7) Bureau of Safety and Environmental Enforcement (BSEE) Inspection and Enforcement of Certain U.S. Coast Guard (USCG) Regulations
(8) Significant Outer Continental Shelf Sediment Resource Areas
(9) Notice of Arrival on the Outer Continental Shelf
(10) Bidder/Lessee Notice of Obligations Related to Criminal/Civil Charges and Offenses, Suspension, or Debarment; Disqualification Due to a Conviction under the Clean Air Act or the Clean Water Act
(11) Protected Species
(12) Proposed Expansion of the Flower Garden Banks National Marine Sanctuary
(13) Communication Towers
(14) Deepwater Port Applications for Offshore Oil and Liquefied Natural Gas Facilities
(15) Ocean Dredged Material Disposal Sites
(16) Rights-of-Use and Easement
(17) Industrial Waste Disposal Areas
(18) Gulf Islands National Seashore
(19) Air Quality Permit/Plan Approvals

## VI. Maps

The maps pertaining to this lease sale may be viewed on BOEM's website at *http://www.boem.gov/Sale-251/*. The following maps also are included in the Final NOS package:

*Lease Terms and Economic Conditions Map*

The lease terms and economic conditions associated with leases of certain blocks are shown on the map entitled, ''Final, Gulf of Mexico Region-wide Oil and Gas Lease Sale 251, August 15, 2018, Lease Terms and Economic Conditions.''

*Stipulations and Deferred Blocks Map*

The lease stipulations and the blocks to which they apply are shown on the map entitled, ''Final, Gulf of Mexico Region-wide Oil and Gas Lease Sale 251, August 15, 2018, Stipulations and Deferred Blocks Map.''

## VII. Bidding Instructions

Bids may be submitted in person or by mail at the address below in the ''Mailed Bids'' section. Bidders submitting their bid(s) in person are advised to email *boemgomrleasesales@boem.gov* to provide the names of the company representative(s) that will submit the bid(s). Instructions on how to submit a bid, secure payment of the advance bonus bid deposit (if applicable), and what information must be included with the bid are as follows:

*Bid Form*

For each block bid upon, a separate sealed bid must be submitted in a sealed envelope (as described below) and include the following:

- Total amount of the bid in whole dollars only;
- Sale number;
- Sale date;

• Each bidder's exact name;
• Each bidder's proportionate interest, stated as a percentage, using a maximum of five decimal places (*e.g.,* 33.33333%);
• Typed name and title, and signature of each bidder's authorized officer;
• Each bidder's qualification number;
• Map name and number or Official Protraction Diagram (OPD) name and number;
• Block number; and
• Statement acknowledging that the bidder(s) understand that this bid legally binds the bidder(s) to comply with all applicable regulations, including those requiring it to post a deposit in the amount of one-fifth of the bonus bid amount for any tract bid upon and make payment of the balance of the bonus bid and first year's rental upon BOEM's acceptance of high bids.

The information required to accompany the bid(s) is specified in the document ''Bid Form'' that is available in the Final NOS package. A blank bid form is provided in the Final NOS package for convenience and may be copied and completed with the necessary information described above.

*Bid Envelope*

Each bid must be submitted in a separate sealed envelope labeled as follows:
• ''Sealed Bid for GOM Region-wide Sale 251, not to be opened until 9 a.m. Wednesday, August 15, 2018;''
• Map name and number or OPD name and number;
• Block number for block bid upon; and
• The exact name and qualification number of the submitting bidder only.

The Final NOS package includes a sample bid envelope for reference.

*Mailed Bids*

If bids are mailed, please address the envelope containing the sealed bid envelope(s) as follows: Attention: Leasing and Financial Responsibility Section, BOEM Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard GM 266A, New Orleans, Louisiana 70123–2394. Contains Sealed Bids for GOM Region-wide Sale 251. Please Deliver to Mr. Greg Purvis, 2nd Floor, Immediately.

*Please Note:* Bidders mailing bid(s) are advised to inform BOEM by email to *boemgomrleasesales@boem.gov* immediately after putting their bid(s) in the mail. This is to ensure receipt of bids prior to the Bid Submission Deadline. If BOEM receives bids later than the Bid Submission Deadline, the BOEM GOM Regional Director (RD) will return those bids unopened to bidders. Please see ''Section XI. Delay of Sale'' regarding BOEM's discretion to extend the Bid Submission Deadline in the case of an unexpected event (*e.g.,* flooding or travel restrictions) and how bidders can obtain more information on such extensions.

*Advance Bonus Bid Deposit Guarantee*

Bidders that are not currently an OCS oil and gas lease record title holder or designated operator, or those that ever have defaulted on a one-fifth bonus bid deposit, by Electronic Funds Transfer (EFT) or otherwise, must guarantee (secure) the payment of the one-fifth bonus bid deposit prior to bid submission using one of the following four methods:
• Provide a third-party guarantee;
• Amend an area-wide development bond via bond rider;
• Provide a letter of credit; or
• Provide a lump sum payment in advance via EFT.

For more information on EFT procedures, see Section X of this document entitled, ''The Lease Sale.'' Please allow sufficient time for your EFT payment to process so that it can be confirmed prior to your bid submission.

*Affirmative Action*

Prior to bidding, each bidder should file the Equal Opportunity Affirmative Action Representation Form BOEM–2032 (October 2011, *https://www.boem.gov/BOEM-2032/*) and Equal Opportunity Compliance Report Certification Form BOEM–2033 (October 2011, *https://www.boem.gov/BOEM-2033/*) with the BOEM GOM Adjudication Section, Attention: BOEM Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, GM 276A, New Orleans, Louisiana 70123–2394. This certification is required by 41 CFR part 60 and Executive Order No. 11246, issued September 24, 1965, as amended by Executive Order No. 11375, issued October 13, 1967, and by Executive Order 13672, issued July 21, 2014. Both forms must be on file for the bidder(s) in the GOM Adjudication Section prior to the execution of any lease contract.

*Geophysical Data and Information Statement (GDIS)*

The GDIS is composed of three parts:

(1) The ''Statement'' page includes the company representatives' information and lists of blocks bid on that used proprietary data and those blocks bid on that did not use proprietary data;

(2) The ''Table'' listing the required data about each proprietary survey used (see below); and

(3) The ''Maps'' being the live trace maps for each proprietary survey that is identified in the GDIS statement and table.

Every bidder, including joint bidders, must provide all applicable parts of the GDIS at the time of bid submission. If the data you are using has been reprocessed in any way, externally or ''in-house,'' it is considered proprietary data and is no longer considered speculative. All three parts of the GDIS must be submitted for proprietary data.

The GDIS must be submitted in a separate and sealed envelope, and must identify all proprietary data, which includes reprocessed speculative data, and/or any Controlled Source Electromagnetic surveys, Amplitude Versus Offset (AVO), Gravity, or Magnetic data; or other information used as part of the decision to bid or participate in a bid on the block. The bidder and joint bidder must also include a live trace map (*e.g.,* .pdf and ArcGIS shape file) for each proprietary survey that they identify in the GDIS illustrating the actual areal extent of the proprietary geophysical data in the survey (see the ''Example of Preferred Format'' that is included the Final NOS package for additional information). The shape file must not include cultural information; only the live trace map of the survey itself.

The GDIS statement must include the name, phone number, and full address of a contact person and an alternate who are both knowledgeable about the geophysical information and data listed and who are available for 30 days after the sale date. The GDIS statement also must include a list of all blocks bid upon that did not use proprietary or reprocessed pre- or post-stack geophysical data and information as part of the decision to bid or to participate as a joint bidder in the bid. The GDIS statement must be submitted even if no proprietary geophysical data and information were used in bid preparation for the block.

The GDIS table should have columns that clearly state:
• The sale number;
• The bidder company's name;
• The Joint Bidder Company (if applicable);
• The block area and block number bid on;
• The owner of the original data set (*i.e.,* who initially acquired the data);
• The industry's original name of the survey (*e.g.,* E Octopus);
• The BOEM permit number for the survey;
• Whether the data set is a fast track version;

• Whether the data is speculative or proprietary;

• The data type (*e.g.,* 2–D, 3–D, or 4–D; pre-stack or post-stack; and time or depth, etc.);

• The Migration algorithm (*e.g.,* Kirchhoff Migration, Wave Equation Migration, Reverse Migration, Reverse Time Migration) of the data and areal extent of bidder survey (*i.e.,* number of line miles for 2–D or number of blocks for 3–D);

• The Live Proprietary Survey Coverage (2–D miles 3–D Blocks);

• The computer storage size, to the nearest gigabyte, of each seismic data and velocity volume used to evaluate the lease block;

• The name of the party that reprocessed the data and the date the final reprocessing was completed (month and year);

• If data was previously sent to BOEM, list the sale number and date of the sale for which it was used; and

• Whether proprietary or Speculative AVO/AVA (PROP/SPEC) was used.

The computer storage size information will be used in estimating the reproduction costs for each data set, if applicable. The availability of reimbursement of production costs will be determined consistent with 30 CFR 551.13.

BOEM reserves the right to query about alternate data sets, to quality check, and to compare the listed and alternative data sets to determine which data set most closely meets the needs of the fair market value determination process. For an example of the preferred format of the table, see ''Example of Preferred Format'' that is included in the Final NOS package. A blank digital version of the preferred table can be accessed on the GOM Region-wide Sale 251 web page at *http://www.boem.gov/Sale-251.*

The GDIS maps are live trace maps (*e.g.,* .pdf and ArcGIS shape files) that should be submitted for each proprietary survey that is identified in the GDIS table. They should illustrate the actual areal extent of the proprietary geophysical data in the survey. See the ''Example of Preferred Format'' that is included in the Final NOS package for additional information. As previously stated, the shape file must not include cultural information; only the live trace map of the survey itself.

Pursuant to 30 CFR 551.12 and 30 CFR 556.501, as a condition of the sale, the BOEM Gulf of Mexico requires that all bidders and joint bidders submit the proprietary data identified on their GDIS within 30 days after the lease sale (unless they are notified after the lease sale that BOEM has withdrawn the request). This requirement only pertains to proprietary data that is not commercially available. Commercially available data is not required to be submitted to BOEM, and reimbursement will not be provided if such data is submitted by a bidder. The BOEM Gulf of Mexico Regional Director will notify bidders and joint bidders of any withdrawal of the request, for all or some of the proprietary data identified on the GDIS, within 15 days of the lease sale. Pursuant to 30 CFR part 551 and 30 CFR 556.501, as a condition of this sale, all bidders that are required to submit data must ensure that the data is received by BOEM no later than the 30th day following the lease sale, or the next business day if the submission deadline falls on a weekend or Federal holiday.

The data must be submitted to BOEM at the following address: Bureau of Ocean Energy Management, Resource Studies, GM 881A, 1201 Elmwood Park Blvd., New Orleans, LA 70123–2304.

BOEM recommends that bidders mark the submission's external envelope as ''Deliver Immediately to DASPU.'' BOEM also recommends that the data be submitted in an internal envelope, or otherwise marked, with the following designation: ''Proprietary Geophysical Data Submitted Pursuant to GOM Region-wide Sale 251 and used during <Bidder Name's> evaluation of Block <Block Number>.''

In the event a person supplies any type of data to BOEM, that person must meet the following requirements to qualify for reimbursement:

(1) The person must be registered with the System for Award Management (SAM), formerly known as the Central Contractor Registration (CCR). CCR usernames will not work in SAM. A new SAM User Account is needed to register or update an entity's records. The website for registering is *https://www.sam.gov.*

(2) The persons must be enrolled in the Department of Treasury's Invoice Processing Platform (IPP) for electronic invoicing. The person must enroll in the IPP at *https://www.ipp.gov/.* Access then will be granted to use the IPP for submitting requests for payment. When a request for payment is submitted, it must include the assigned Purchase Order Number on the request.

(3) The persons must have a current Online Representations and Certifications Application (ORCA) at *https://www.sam.gov.*

*Please Note:* The GDIS Information Table must be submitted digitally, preferably as an Excel spreadsheet, on a CD, DVD, or any USB external drive (formatted for Windows), along with the seismic data map(s). If bidders have any questions, please contact Ms. Dee Smith at (504) 736–2706, or Mr. John Johnson at (504) 736–2455.

Bidders should refer to Section X of this document, ''The Lease Sale: Acceptance, Rejection, or Return of Bids,'' regarding a bidder's failure to comply with the requirements of the Final NOS, including any failure to submit information as required in the Final NOS or Final NOS package.

*Telephone Numbers/Addresses of Bidders*

BOEM requests that bidders provide this information in the suggested format prior to, or at the time of, bid submission. The suggested format is included in the Final NOS package. The form must not be enclosed inside the sealed bid envelope.

*Additional Documentation*

BOEM may require bidders to submit other documents in accordance with 30 CFR 556.107, 30 CFR 556.401, 30 CFR 556.501, and 30 CFR 556.513.

## VIII. Bidding Rules and Restrictions

*Restricted Joint Bidders*

On May 15, 2018, BOEM published the most recent List of Restricted Joint Bidders in the **Federal Register** at 83 FR 22513. Potential bidders are advised to refer to the **Federal Register**, prior to bidding, for the most current List of Restricted Joint Bidders in place at the time of the lease sale. Please refer to the joint bidding provisions at 30 CFR 556.511–515.

*Authorized Signatures*

All signatories executing documents on behalf of bidder(s) must execute the same in conformance with the BOEM qualification records. Bidders are advised that BOEM considers the signed bid to be a legally binding obligation on the part of the bidder(s) to comply with all applicable regulations, including that requiring payment of one-fifth of the bonus bid on all high bids. A statement to this effect is included on each bid form (see the document ''Bid Form'' that is included in the Final NOS package).

*Unlawful Combination or Intimidation*

BOEM warns bidders against violation of 18 U.S.C. 1860, prohibiting unlawful combination or intimidation of bidders.

*Bid Withdrawal*

Bids may be withdrawn only by written request delivered to BOEM prior to the Bid Submission Deadline. The withdrawal request must be on company letterhead and must contain the bidder's name, its BOEM

qualification number, the map name/number, and the block number(s) of the bid(s) to be withdrawn. The withdrawal request must be executed in conformance with the BOEM qualification records. The name and title of the authorized signatory must be typed under the signature block on the withdrawal request. The BOEM Gulf of Mexico RD, or the RD's designee, will indicate their approval by signing and dating the withdrawal request.

*Bid Rounding*

Minimum bonus bid calculations, including rounding, for all blocks are shown in the document ''List of Blocks Available for Leasing'' included in the Final NOS package. The bonus bid amount must be stated in whole dollars. If the acreage of a block contains a decimal figure, then prior to calculating the minimum bonus bid, BOEM rounded up to the next whole acre. The appropriate minimum rate per acre was then applied to the whole (rounded up) acreage. The bonus bid amount must be greater than or equal to the minimum bonus bid in whole dollars.

**IX. Forms**

The Final NOS package includes instructions, samples, and/or the preferred format for the following items. BOEM strongly encourages bidders to use the recommended formats. If bidders use another format, they are responsible for including all the information specified for each item in the Final NOS package.

(1) Bid Form
(2) Sample Completed Bid
(3) Sample Bid Envelope
(4) Sample Bid Mailing Envelope
(5) Telephone Numbers/Addresses of Bidders Form
(6) GDIS Form
(7) GDIS Envelope Form

**X. The Lease Sale**

*Bid Opening and Reading*

Sealed bids received in response to the Final NOS will be opened at the place, date, and hour specified under the **DATES** and **ADDRESSES** sections of the Final NOS. The venue will not be open to the public. Instead, the bid opening will be available for the public to view on BOEM's website at *www.boem.gov* via live-streaming. The opening of the bids is for the sole purpose of publicly announcing and recording the bids received; no bids will be accepted or rejected at that time.

*Bonus Bid Deposit for Apparent High Bids*

Each bidder submitting an apparent high bid must submit a bonus bid deposit to the Office of Natural Resources Revenue (ONRR) equal to one-fifth of the bonus bid amount for each such bid. A copy of the notification of the high bidder's one-fifth bonus bid amount may be obtained on the BOEM website at *http://www.boem.gov/Sale-251* under the heading ''Notification of EFT 1/5 Bonus Liability'' after 1:00 p.m. on the day of the sale. All payments must be deposited electronically into an interest-bearing account in the U.S. Treasury by 11:00 a.m. Eastern Time (10 a.m. Central Time) the day following the bid reading (no exceptions). Account information is provided in the ''Instructions for Making Electronic Funds Transfer Bonus Payments'' found on the BOEM website identified above.

BOEM requires bidders to use EFT procedures for payment of one-fifth bonus bid deposits for GOM Region-wide Sale 251 following the detailed instructions contained on the ONRR Payment Information web page at *http://www.onrr.gov/ReportPay/Payments.htm.* Acceptance of a deposit does not constitute, and will not be construed as, acceptance of any bid on behalf of the United States.

*Withdrawal of Blocks*

The United States reserves the right to withdraw any block from this lease sale prior to issuance of a written acceptance of a bid for the block.

*Acceptance, Rejection, or Return of Bids*

The United States reserves the right to reject any and all bids. No bid will be accepted, and no lease for any block will be awarded to any bidder, unless:

(1) The bidder has complied with all requirements of the Final NOS, including those set forth in the documents contained in the Final NOS package, and applicable regulations;

(2) The bid is the highest valid bid; and

(3) The amount of the bid has been determined to be adequate by the authorized officer.

Any bid submitted that does not conform to the requirements of the Final NOS and Final NOS package, OCSLA, or other applicable statute or regulation will be rejected and returned to the bidder. The U.S. Department of Justice and the Federal Trade Commission will review the results of the lease sale for antitrust issues prior to the acceptance of bids and issuance of leases.

*Bid Adequacy Review Procedures for GOM Region-Wide Sale 251*

To ensure that the U.S. Government receives a fair return for the conveyance of leases from this sale, high bids will be evaluated in accordance with BOEM's bid adequacy procedures, which are available at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Leasing/Regional-Leasing/Gulf-of-Mexico-Region/Bid-Adequacy-Procedures.aspx.*

*Lease Award*

BOEM requires each bidder awarded a lease to:

(1) Execute all copies of the lease (Form BOEM–2005 (February 2017), as amended);

(2) Pay by EFT the balance of the bonus bid amount and the first year's rental for each lease issued in accordance with the requirements of 30 CFR 218.155 and 556.520(a); and

(3) Provide to BOEM the bonding required by 30 CFR part 556, subpart I.

ONRR requests that bidders use only one transaction to pay the balance of the bonus bid amount and the first year's rental. When ONRR receives such payment, the bidder awarded the lease may not request a refund of the balance bonus bid amount or first year's rental payment.

**XI. Delay of Sale**

The BOEM Gulf of Mexico RD has the discretion to change any date, time, and/or location specified in the Final NOS package in the case of an event that the BOEM Gulf of Mexico RD deems may interfere with the carrying out of a fair and orderly lease sale process. Such events could include, but are not limited to, natural disasters (*e.g.,* earthquakes, hurricanes, and floods), wars, riots, acts of terrorism, fires, strikes, civil disorder, or other events of a similar nature. In case of such events, bidders should call (504) 736–0557, or access the BOEM website at *http://www.boem.gov,* for information regarding any changes.

Dated: July 11, 2018.

**Walter D. Cruickshank,**

*Acting Director, Bureau of Ocean Energy Management.*

[FR Doc. 2018–15180 Filed 7–13–18; 8:45 am]

BILLING CODE 4310–MR–P

## DEPARTMENT OF THE INTERIOR

## Bureau of Ocean Energy Management

**[Docket No. BOEM–2018–0035]**

## Gulf of Mexico, Outer Continental Shelf (OCS), Oil and Gas Lease Sale 251

**AGENCY:** Bureau of Ocean Energy Management, Interior.

**ACTION:** Notice of availability of a Record of Decision.

**SUMMARY:** The Bureau of Ocean Energy Management (BOEM) is announcing the availability of a Record of Decision for proposed Gulf of Mexico (GOM) regionwide oil and gas Lease Sale 251. This Record of Decision identifies BOEM's selected alternative for proposed Lease Sale 251, which is analyzed in the *Gulf of Mexico Outer Continental Shelf Lease Sale: Final Supplemental Environmental Impact Statement 2018* (2018 GOM Supplemental EIS).

**ADDRESSES:** The Record of Decision is available on BOEM's website at *http://www.boem.gov/nepaprocess/.*

**FOR FURTHER INFORMATION CONTACT:** For more information on the Record of Decision, you may contact Mr. Greg Kozlowski, Deputy Regional Supervisor, Office of Environment, by telephone at 504–736–2512 or by email at *greg.kozlowski@boem.gov.*

**SUPPLEMENTARY INFORMATION:** In the 2018 GOM Supplemental EIS, BOEM evaluated five alternatives in regard to proposed Lease Sale 251. These alternatives are summarized below:

*Alternative A—Regionwide OCS Lease Sale:* This is BOEM's preferred alternative. This alternative would allow for a proposed GOM regionwide lease sale encompassing all three planning areas: The Western Planning Area (WPA); the Central Planning Area (CPA); and a small portion of the Eastern Planning Area (EPA) not under Congressional moratorium. Under this alternative, BOEM would offer for lease all available unleased blocks within the proposed regionwide lease sale area for oil and gas operations with the following exceptions: Whole and portions of blocks deferred by the Gulf of Mexico Energy Security Act of 2006; blocks that are adjacent to or beyond the United States' Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap; whole and partial blocks within the current boundary of the Flower Garden Banks National Marine Sanctuary; and blocks where the lease status is currently under appeal. The unavailable blocks are listed in Section I of the Final Notice of Sale for proposed Lease Sale 251 and at *www.boem.gov/Sale-251.* The proposed regionwide lease sale area encompasses about 91.93 million acres (ac). As of June 2018, approximately 78.2 million ac of the proposed regionwide lease sale area are available for lease. As described in the Final 2018 GOM Supplemental EIS, the estimated amounts of resources projected to be leased, discovered, developed, and produced as a result of the proposed regionwide lease sale are between 0.211 and 1.118 billion barrels of oil (BBO) and 0.547 and 4.424 trillion cubic feet (Tcf) of natural gas.

*Alternative B—Regionwide OCS Lease Sale Excluding Available Unleased Blocks in the WPA Portion of the Proposed Lease Sale Area:* This alternative would offer for lease all available unleased blocks within the CPA and EPA portions of the proposed lease sale area for oil and gas operations, with the following exceptions: Whole and portions of blocks deferred by the Gulf of Mexico Energy Security Act of 2006; and blocks that are adjacent to or beyond the United States' Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap. The proposed CPA/EPA lease sale area encompasses about 63.35 million ac. As of February 2018, approximately 51.2 million ac of the proposed CPA/EPA lease sale area are available for lease. The estimated amounts of resources projected to be leased, discovered, developed, and produced as a result of the proposed lease sale under Alternative B are 0.185–0.970 BBO and 0.441–3.672 Tcf of gas.

*Alternative C—Regionwide OCS Lease Sale Excluding Available Unleased Blocks in the CPA and EPA Portions of the Proposed Lease Sale Area:* This alternative would offer for lease all available unleased blocks within the WPA portion of the proposed lease sale area for oil and gas operations, with the following exception: Whole and partial blocks within the current boundary of the Flower Garden Banks National Marine Sanctuary. The proposed WPA lease sale area encompasses about 28.58 million ac. As of February 2018, approximately 26.2 million ac of the proposed WPA lease sale area are available for lease. The estimated amounts of resources projected to be leased, discovered, developed, and produced as a result of the proposed lease sale under Alternative C are 0.026–0.148 BBO and 0.106–0.752 Tcf of gas.

*Alternative D—Alternative A, B, or C, with the Option to Exclude Available Unleased Blocks Subject to the Topographic Features, Live Bottom (Pinnacle Trend), and/or Blocks South of Baldwin County, Alabama, Stipulations:* This alternative could be combined with any of the Action alternatives above (*i.e.,* Alternative A, B, or C) and would allow the flexibility to offer leases under any alternative with additional exclusions. Under Alternative D, the decisionmaker could exclude from leasing any available unleased blocks subject to any one and/or a combination of the following stipulations: Topographic Features Stipulation; Live Bottom Stipulation; and Blocks South of Baldwin County, Alabama, Stipulation (not applicable to Alternative C). This alternative considered blocks subject to these stipulations because these areas have been emphasized in scoping, can be geographically defined, and adequate information exists regarding their ecological importance and sensitivity to OCS oil- and gas-related activities.

A total of 207 blocks within the CPA and 160 blocks in the WPA are affected by the Topographic Features Stipulation. There are currently no identified topographic features protected under this stipulation in the EPA. The Live Bottom Stipulation covers the pinnacle trend area of the CPA, affecting a total of 74 blocks. Under Alternative D, the number of blocks that would become unavailable for lease represents only a small percentage of the total number of blocks to be offered under Alternative A, B, or C (<4%, even if blocks subject to all three stipulations were excluded). Therefore, Alternative D could reduce offshore infrastructure and activities in the pinnacle trend area, but Alternative D also shifts the location of offshore infrastructure and activities farther from these sensitive zones and would not lead to a reduction in overall offshore infrastructure and activities.

*Alternative E—No Action:* This alternative is not holding proposed regionwide Lease Sale 251 and is identified as the environmentally preferred alternative.

*Lease Stipulations*—The 2018 GOM Supplemental EIS describes all lease stipulations, which are included in the Final Notice of Sale Package. In the Record of Decision for the 2017–2022 Five-Year Program, the Secretary of the Interior required the protection of biologically sensitive underwater features in all Gulf of Mexico oil and gas lease sales as programmatic mitigation; therefore, the application of the Topographic Features Stipulation and Live Bottom Stipulation are being adopted and applied for applicable designated lease blocks in Lease Sale 251.

The additional eight lease stipulations for proposed regionwide Lease Sale 251 are the Military Areas Stipulation; the Evacuation Stipulation; the Coordination Stipulation; the Blocks South of Baldwin County, Alabama, Stipulation; the Protected Species Stipulation; the United Nations Convention on the Law of the Sea Royalty Payment Stipulation; the Below Seabed Operations Stipulation; and the Stipulation on the Agreement between the United States of America and the United Mexican States Concerning

Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico. These eight stipulations will be added as lease terms where applicable and will be enforceable as part of the lease. Appendix B of the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2017–2022; Gulf of Mexico Lease Sales 249, 250, 251, 252, 253, 254, 256, 257, 259, and 261; Final Multisale Environmental Impact Statement* provides a list and description of standard post-lease conditions of approval that may be required by BOEM or the Bureau of Safety and Environmental Enforcement as a result of plan and permit review processes for the Gulf of Mexico OCS Region.

After careful consideration, BOEM has selected the preferred alternative (Alternative A) in the 2018 GOM Supplemental EIS for proposed Lease Sale 251. BOEM's selection of the preferred alternative meets the purpose and need for the proposed action, as identified in the 2018 GOM Supplemental EIS, and provides for orderly resource development with protection of the human, marine, and coastal environments while also ensuring that the public receives an equitable return for these resources and that free-market competition is maintained.

**Authority:** This Notice of Availability of a Record of Decision is published pursuant to the regulations (40 CFR part 1505) implementing the provisions of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Dated: July 11, 2018.

**Walter D. Cruickshank,**

*Acting Director, Bureau of Ocean Energy Management.*

[FR Doc. 2018–15181 Filed 7–13–18; 8:45 am]

**BILLING CODE 4310–MR–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–1374–1376 (Final)]**

## Citric Acid and Certain Citrate Salts From Belgium, Colombia, and Thailand

### Determination

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of citric acid and certain citrate salts from Belgium, Colombia, and Thailand that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2] [3] [4]

### Background

The Commission, pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)), instituted these investigations effective June 2, 2017, following receipt of a petition filed with the Commission and Commerce by Archer Daniels Midland Company, Decatur, Illinois; Cargill, Incorporated, Minneapolis, Minnesota; and Tate & Lyle Ingredients Americas, LLC, Hoffman Estates, Illinois. The Commission scheduled the final phase of the investigations following notification of a preliminary determination by Commerce that imports of citric acid and certain citrate salts from Belgium, Colombia, and Thailand were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 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 February 2, 2018 (83 FR 4922). The hearing was held in Washington, DC, on May 14, 2018, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on July 10, 2018. The views of the Commission are contained in USITC Publication 4799 (July 2018), entitled *Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand: Investigation Nos. 731–TA–1374–1376 (Final).*

By order of the Commission.

Issued: July 10, 2018.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2018–15067 Filed 7–13–18; 8:45 am]

**BILLING CODE 7020–02–P**

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] *Citric Acid and Certain Citrate Salts from Thailand: Affirmative Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances in Part,* 82 FR 25998, June 5, 2018; *Citric Acid and Certain Citrate Salts from Belgium: Affirmative Final Determination of Sales at Less Than Fair Value,* 82 FR 26001, June 5, 2018; *Citric Acid and Certain Citrate Salts from Colombia: Affirmative Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances,* 82 FR 26002, June 5, 2018.

[3] The Commission also finds that imports subject to Commerce's affirmative critical circumstances determination are not likely to undermine seriously the remedial effect of the antidumping duty order on Thailand.

[4] Commissioner Jason E. Kearns did not participate in these investigations.

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

## Bulk Manufacturer of Controlled Substances Application: Siegfried USA, LLC

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 14, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on November 2, 2017, Siegfried USA, LLC, 33 Industrial Park Rd., Pennsville, NJ 08070 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Gamma Hydroxybutyric Acid. | 2010 | I |
| Dihydromorphine .... | 9145 | I |
| Hydromorphinol ..... | 9301 | I |

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Methylphenidate | 1724 | II |
| Amobarbital | 2125 | II |
| Pentobarbital | 2270 | II |
| Secobarbital | 2315 | II |
| Codeine | 9050 | II |
| Oxycodone | 9143 | II |
| Hydromorphone | 9150 | II |
| Hydrocodone | 9193 | II |
| Methadone | 9250 | II |
| Methadone intermediate. | 9254 | II |
| Morphine | 9300 | II |
| Oripavine | 9330 | II |
| Thebaine | 9333 | II |
| Opium tincture | 9630 | II |
| Oxymorphone | 9652 | II |

The company plans to manufacture the listed controlled substances in bulk for sale to its customers.

Dated: July 10, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–15138 Filed 7–13–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

**[Docket No. DEA–392]**

## Importer of Controlled Substances Application: Cerilliant Corporation

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 15, 2018. Such persons may also file a written request for a hearing on the application on or before August 15, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on June 12, 2018, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665 applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| 3-Fluoro-N-methylcathinone (3–FMC) | 1233 | I |
| Cathinone | 1235 | I |
| Methcathinone | 1237 | I |
| 4-Fluoro-N-methylcathinone (4–FMC) | 1238 | I |
| Pentedrone (α-methylaminovalerophenone) | 1246 | I |
| Mephedrone (4-Methyl-N-methylcathinone) | 1248 | I |
| 4-Methyl-N-ethylcathinone (4–MEC) | 1249 | I |
| Naphyrone | 1258 | I |
| N-Ethylamphetamine | 1475 | I |
| N,N-Dimethylamphetamine | 1480 | I |
| Fenethylline | 1503 | I |
| Methaqualone | 2565 | I |
| JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole) | 6250 | I |
| SR–18 (Also known as RCS–8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole) | 7008 | I |
| 5-Fluoro-UR-144 and XLR11 [1-(5-Fluoropentyl)1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone | 7011 | I |
| AB–FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide) | 7012 | I |
| JWH–019 (1-Hexyl-3-(1-naphthoyl)indole) | 7019 | I |
| AB–PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide) | 7023 | I |
| THJ–2201 [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone | 7024 | I |
| AB–CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide | 7031 | I |
| ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide) | 7035 | I |
| APINACA and AKB48 N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide | 7048 | I |
| JWH–081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole) | 7081 | I |
| SR–19 (Also known as RCS–4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole | 7104 | I |
| JWH–018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole) | 7118 | I |
| JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole) | 7122 | I |
| UR–144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone | 7144 | I |
| JWH–073 (1-Butyl-3-(1-naphthoyl)indole) | 7173 | I |
| JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole) | 7200 | I |
| AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole) | 7201 | I |
| JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl) indole) | 7203 | I |
| PB–22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate) | 7222 | I |
| 5F–PB–22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate) | 7225 | I |
| Alpha-ethyltryptamine | 7249 | I |
| Ibogaine | 7260 | I |
| CP–47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol) | 7297 | I |
| CP–47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol) | 7298 | I |

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Lysergic acid diethylamide | 7315 | I |
| 2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7) | 7348 | I |
| Marihuana | 7360 | I |
| Parahexyl | 7374 | I |
| Mescaline | 7381 | I |
| 2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine (2C–T–2) | 7385 | I |
| 3,4,5-Trimethoxyamphetamine | 7390 | I |
| 4-Bromo-2,5-dimethoxyamphetamine | 7391 | I |
| 4-Bromo-2,5-dimethoxyphenethylamine | 7392 | I |
| 4-Methyl-2,5-dimethoxyamphetamine | 7395 | I |
| 2,5-Dimethoxyamphetamine | 7396 | I |
| JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole) | 7398 | I |
| 3,4-Methylenedioxyamphetamine | 7400 | I |
| 5-Methoxy-3,4-methylenedioxyamphetamine | 7401 | I |
| N-Hydroxy-3,4-methylenedioxyamphetamine | 7402 | I |
| 3,4-Methylenedioxy-N-ethylamphetamine | 7404 | I |
| 3,4-Methylenedioxymethamphetamine | 7405 | I |
| 4-Methoxyamphetamine | 7411 | I |
| 5-Methoxy-N–N-dimethyltryptamine | 7431 | I |
| Alpha-methyltryptamine | 7432 | I |
| Bufotenine | 7433 | I |
| Diethyltryptamine | 7434 | I |
| Dimethyltryptamine | 7435 | I |
| Psilocybin | 7437 | I |
| Psilocyn | 7438 | I |
| 5-Methoxy-N,N-diisopropyltryptamine | 7439 | I |
| N-Ethyl-1-phenylcyclohexylamine | 7455 | I |
| 1-(1-Phenylcyclohexyl)pyrrolidine | 7458 | I |
| 1-[1-(2-Thienyl)cyclohexyl]piperidine | 7470 | I |
| N-Benzylpiperazine | 7493 | I |
| 4-Methyl-alphapyrrolidinopropiophenone (4-MePPP) | 7498 | I |
| 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (2C–D) | 7508 | I |
| 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (2C–E) | 7509 | I |
| 2-(2,5-Dimethoxyphenyl) ethanamine (2C–H) | 7517 | I |
| 2-(4-iodo-2,5-dimethoxyphenyl) ethanamine (2C–I) | 7518 | I |
| 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C–C) | 7519 | I |
| 2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (2C–N) | 7521 | I |
| 2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (2C–P) | 7524 | I |
| 2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine (2C–T–4) | 7532 | I |
| MDPV (3,4-Methylenedioxypyrovalerone) | 7535 | I |
| 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25B–NBOMe) | 7536 | I |
| 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25C–NBOMe) | 7537 | I |
| 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25I–NBOMe) | 7538 | I |
| Methylone (3,4-Methylenedioxy-N-methylcathinone) | 7540 | I |
| Butylone | 7541 | I |
| Pentylone | 7542 | I |
| alpha-pyrrolidinopentiophenone (α-PVP) | 7545 | I |
| alpha-pyrrolidinobutiophenone (α-PBP) | 7546 | I |
| AM–694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole) | 7694 | I |
| Desomorphine | 9055 | I |
| Etorphine (except HCl) | 9056 | I |
| Codeine methylbromide | 9070 | I |
| Heroin | 9200 | I |
| Morphine-N-oxide | 9307 | I |
| Normorphine | 9313 | I |
| Pholcodine | 9314 | I |
| U–47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide) | 9547 | I |
| AH–7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide)) | 9551 | I |
| Acetylmethadol | 9601 | I |
| Allylprodine | 9602 | I |
| Alphacetylmethadol except levo-alphacetylmethadol | 9603 | I |
| Alphameprodine | 9604 | I |
| Alphamethadol | 9605 | I |
| Betacetylmethadol | 9607 | I |
| Betameprodine | 9608 | I |
| Betamethadol | 9609 | I |
| Betaprodine | 9611 | I |
| Dextromoramide | 9613 | I |
| Dipipanone | 9622 | I |
| Hydroxypethidine | 9627 | I |
| Noracymethadol | 9633 | I |
| Norlevorphanol | 9634 | I |
| Normethadone | 9635 | I |
| Racemoramide | 9645 | I |

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Trimeperidine | 9646 | I |
| 1-Methyl-4-phenyl-4-propionoxypiperidine | 9661 | I |
| Tilidine | 9750 | I |
| Para-Fluorofentanyl | 9812 | I |
| 3-Methylfentanyl | 9813 | I |
| Alpha-methylfentanyl | 9814 | I |
| Acetyl-alpha-methylfentanyl | 9815 | I |
| Beta-hydroxyfentanyl | 9830 | I |
| Beta-hydroxy-3-methylfentanyl | 9831 | I |
| Alpha-methylthiofentanyl | 9832 | I |
| 3-Methylthiofentanyl | 9833 | I |
| Thiofentanyl | 9835 | I |
| Methamphetamine | 1105 | II |
| Methylphenidate | 1724 | II |
| Amobarbital | 2125 | II |
| Pentobarbital | 2270 | II |
| Secobarbital | 2315 | II |
| Glutethimide | 2550 | II |
| Nabilone | 7379 | II |
| 1-Phenylcyclohexylamine | 7460 | II |
| Phencyclidine | 7471 | II |
| Phenylacetone | 8501 | II |
| 1-Piperidinocyclohexanecarbonitrile | 8603 | II |
| Alphaprodine | 9010 | II |
| Dihydrocodeine | 9120 | II |
| Ecgonine | 9180 | II |
| Ethylmorphine | 9190 | II |
| Levomethorphan | 9210 | II |
| Levorphanol | 9220 | II |
| Meperidine | 9230 | II |
| Dextropropoxyphene, bulk (non-dosage forms) | 9273 | II |
| Levo-alphacetylmethadol | 9648 | II |
| Noroxymorphone | 9668 | II |
| Racemethorphan | 9732 | II |
| Alfentanil | 9737 | II |
| Remifentanil | 9739 | II |
| Sufentanil | 9740 | II |
| Carfentanil | 9743 | II |
| Tapentadol | 9780 | II |

The company plans to import small quantities of the listed controlled substances for the manufacture of analytical reference standards and distribution to their research and forensic customers.

Dated: July 10, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–15139 Filed 7–13–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

**[OMB Number 1121–NEW]**

### Agency Information Collection Activities; Proposed eCollection eComments Requested; Approval of a New Collection; Comments Requested: National Survey of Victim Service Providers (NCVSP)

**AGENCY:** Bureau of Justice Statistics, Department of Justice.

**ACTION:** 60-day notice.

**SUMMARY:** The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** Comments are encouraged and will be accepted for 60 days until September 14, 2018.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Barbara Oudekerk, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Barbara.a.oudekerk@usdoj.gov*; telephone: 202–616–3904).

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* New collection.

(2) *The Title of the Form/Collection:* National Survey of Victim Service Providers

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number for the collection is NSVSP–1 (note, there will be no hard copy of the NSVSP instrument, the survey will be completed online or over the phone). The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* A sample of agencies serving crime victims as their primary function or through dedicated staff or programs will be asked to respond. The National Survey of Victim Service Providers will gather data on the number of victims served by type of crime, victim characteristics, types of services provided, criminal justice and community relationships, service gaps, and VSP staff size, turnover, and characteristics. BJS plans to publish information from the NSVSP in reports and reference it when responding to queries from the U.S. Congress, Executive Office of the President, the U.S. Supreme Court, partner federal agencies (*e.g.,* Office for Victims of Crime), state officials, international organizations, researchers, students, the media, and others interested in criminal justice statistics.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* A total of 8,067 victim service providers will be asked to respond to the survey. An estimated 5% of entities will no longer be in business or no longer serving victims. For ineligible respondents the survey will take less than 5 minutes to complete. Among active victim service providers, the expected response rate is 70%. For these 5,365 active victim service providers that decide to participate, it will take an average of 45 minutes to complete the survey.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 4,058 total burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: July 10, 2018.

**Melody Braswell,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2018–15056 Filed 7–13–18; 8:45 am]

**BILLING CODE 4410–18–P**

## LEGAL SERVICES CORPORATION

### Sunshine Act Meeting

**DATE AND TIME:** The Legal Services Corporation's Board of Directors and its six committees will meet July 25–26, 2018. On Wednesday, July 25, the first meeting will commence at 3:00 p.m., Mountain Daylight Time (MDT), with the meetings thereafter commencing promptly upon adjournment of the immediately preceding meeting. On Thursday, July 26, the first meeting will commence at 9:00 a.m., (MDT), with the next meeting commencing promptly upon adjournment of the immediately preceding meeting. The closed session meeting of the Board of Directors will commence promptly upon adjournment of the open session of the Board of Directors meeting.

**LOCATION:** The Grove Hotel, 245 South Capitol Blvd., Boise, Idaho 83702.

**PUBLIC OBSERVATION:** Unless otherwise noted herein, the Board and all committee meetings will be open to public observation. Members of the public who are unable to attend in person but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below.

### Call-In Directions for Open Sessions

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348
- Once connected to the call, your telephone line will be *automatically* ''MUTED''.
- To participate in the meeting during public comment press #6 to ''UNMUTE'' your telephone line, once you have concluded your comments please press *6 to ''MUTE'' your line.

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. From time to time, the presiding Chair may solicit comments from the public.

MEETING SCHEDULE

| | Time * |
|---|---|
| Wednesday, July 25, 2018: | |
| 1. Governance and Performance Review Committee. | 3:00 p.m. |
| 2. Operations & Regulations Committee. | |
| 3. Audit Committee. | |
| 4. Institutional Advancement Committee. | |
| 5. Communications Subcommittee Committee. | |
| Thursday, July 26, 2018 | |
| 1. Finance Committee ... | 9:00 a.m. |
| 2. Delivery of Legal Services Committee. | |
| 3. Board of Directors. | |

*Status of Meeting:* Open, except as noted below.

*Board of Directors*—Open, except that, upon a vote of the Board of Directors, a portion of the meeting may be closed to the public to hear briefings by management and LSC's Inspector General, and to consider and act on the General Counsel's report on potential and pending litigation involving LSC, and on a list of prospective funders.**

*Audit Committee*—Open, except that the meeting may be closed to the public to hear a briefing on the Office of Compliance and Enforcement's active enforcement matters.**

*Institutional Advancement Committee*—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to consider and act on recommendation of new Leaders Council invitees and to receive a briefing on the development activities.**

A verbatim written transcript will be made of the closed session of the Board, Institutional Advancement Committee, and Audit Committee meetings. The transcript of any portions of the closed sessions falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6) and (10), will not be available for public inspection.

A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

* Please note that all times in this notice are in *Mountain Daylight Time.*

** Any portion of the closed session consisting solely of briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to such portion of the closed session. 5 U.S.C. 552b(a)(2) and (b). *See also* 45 CFR 1622.2 & 1622.3.

**Matters To Be Considered**

**July 25, 2018**

*Governance and Performance Review Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on April 9, 2018
3. Approval of minutes of the Committee's Closed Session meeting on April 9, 2018
4. Report on status of LSC's implementation of the U. S. Government Accountability Office's 2007 and 2010 recommendations
   - Jim Sandman, President
   - Carol Bergman, Vice President for Government Relations & Public Affairs
   - Lynn Jennings, Vice President for Grants Management
5. Report on foundation grants and LSC's research agenda
   - Jim Sandman, President
6. Report on transition planning
   - Carol Bergman, Vice President for Government Relations & Public Affairs
7. Consider and act on other business
8. Public comment
9. Consider and act on adjournment of meeting

*Operations & Regulations Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting of April 8, 2018
3. Consider and act on Notice of Proposed Rulemaking for 45 CFR Part 1607—Governing Bodies
   - Stefanie Davis, Assistant General Counsel
4. Consider and act on the 2018–2019 Rulemaking Timeline
   - Stefanie Davis, Assistant General Counsel
5. Public comment
6. Consider and act on other business
7. Consider and act on adjournment of meeting

**July 25, 2018**

*Audit Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on April 9, 2018
3. Briefing of Office of Inspector General
   - Jeffrey Schanz, Inspector General
   - Roxanne Caruso, Assistant Inspector General for Audits
4. Pursuant to Section VIII(C)(1) of the Committee Charter, review LSC's systems of internal controls that are designed to minimize the risk of fraud, theft, corruption, or misuse of funds
   - Jim Sandman, President
   - David Richardson, Treasurer and Comptroller
   - Jeffrey Schanz, Inspector General
5. Management update regarding risk management
   - Jim Sandman, President
6. Briefing about follow-up by the Office of Compliance and Enforcement on referrals by the Office of Inspector General regarding audit reports and annual Independent Public audits of grantees
   - Lora Rath, Director of Compliance and Enforcement
   - Roxanne Caruso, Assistant Inspector General for Audits
7. Public comment
8. Consider and act on other business
9. Consider and act on motion to adjourn the open session meeting and proceed to a closed session

Closed Session

10. Approval of minutes of the Committee's Closed Session meeting of April 9, 2018
11. Briefing by the Office of Compliance and Enforcement on active enforcement matter(s) and follow-up to open investigation referrals from the Office of Inspector General
    - Lora Rath, Director of Compliance and Enforcement
12. Consider and act on adjournment of meeting

**July 25, 2018**

*Institutional Advancement Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting of April 9, 2018
3. Update on Leaders Council
   - John G. Levi, Chairman of the Board
4. Development report
   - Nadia Elguindy, Director of Institutional Advancement
5. Public Comment
6. Consider and act on other business
7. Consider and act on motion to adjourn the open session meeting and proceed to a closed session

Closed Session

8. Approval of minutes of the Committee's Closed Session meeting of April 9, 2018
9. Development activities report
10. Consider and act on motion to approve Leaders Council invitees
11. Consider and act on other business
12. Consider and act on motion to adjourn the meeting

**July 25, 2018**

*Communications Subcommittee of the Institutional Advancement Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Subcommittee's Open Session meeting of April 9, 2018
3. Communications and Social Media update
   - Carl Rauscher, Director of Communications and Media Relations
4. Public comment
5. Consider and act on other business
6. Consider and act on motion to adjourn the meeting

**July 26, 2018**

*Finance Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session telephonic meeting on June 11, 2018
3. Approval of minutes of the Committee's Open Session telephonic meeting on June 19, 2018
4. Presentation of LSC's Financial Reports for the first eight months of FY 2018
   - David Richardson, Treasurer/Comptroller
5. Review of Internal Budgetary Adjustments for the FY 2018 Consolidated Operating Budget, and consider and act on FY 2018 Revised Consolidated Operating Budget, *Resolution 2018–XXX*
   - David Richardson, Treasurer/Comptroller
6. Report on the FY 2019 appropriations process
   - Carol Bergman, Director of Government Relations & Public Affairs
7. Consider and act on Temporary Operating Budget for FY 2019, *Resolution 2018–XXX*
   - David Richardson, Treasurer and Comptroller
8. Consider and act on FY 2020 Budget Request, *Resolution 2018–XXX*
   - Jim Sandman, President
   - Carol Bergman, Director of Government Relations & Public Affairs
   - Jeffrey Schanz, Inspector General
   - David Maddox, Assistant Inspector General for Management and Evaluation
9. Public comment
10. Consider and act on other business
11. Consider and act on adjournment of meeting

**July 26, 2018**

*Delivery of Legal Services Committee*

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on April 9, 2018
3. Report on revisions to LSC Performance Criteria
4. Panel presentation on developing and expanding effective pro bono programs
   - Raphael Ramos, Project Director, Legal Action of Wisconsin
   - Ann Porath, Managing Attorney, Legal Aid Society of Cleveland
   - Kate White, Access to Services Director, Legal Aid of West Virginia
   - Moderator: Ed Caspar, Office of Program Performance
5. Public comment
6. Consider and act on other business
7. Consider and act on motion to adjourn the meeting

**July 26, 2018**

*Board of Directors*

Open Session

1. Pledge of Allegiance
2. Approval of agenda
3. Approval of minutes of the Board's Open Session meeting of April 9 and April 10, 2018
4. Approval of minutes of the Board's Open Session telephonic meeting of May 24, 2018
5. Chairman's Report
6. Members' Report
7. President's Report
8. Inspector General's Report
9. Consider and act on the report of the Governance and Performance Review Committee
10. Consider and act on the report of the Operations and Regulations Committee
11. Consider and act on the Audit Committee
12. Consider and act on the report of the Institutional Advancement Committee
13. Consider and act on the report of the Finance Committee
14. Consider and act on the report of the Delivery of Legal Services Committee
15. Public comment
16. Consider and act on other business
17. Consider and act on whether to authorize an executive session of the Board to address items listed below, under Closed Session

Closed Session

18. Approval of minutes of the Board's Closed Session meeting of April 10, 2018
19. Briefing by Management
20. Briefing by Inspector General
21. Consider and act on list of prospective Leaders Council members
22. Consider and act on General Counsel's report on potential and pending litigation involving LSC
23. Consider and act on motion to adjourn meeting

*Contact Person for Information:* Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

*Non-Confidential Meeting Materials:* Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *http://www.lsc.gov/board-directors/meetings/board-meeting-notices/non-confidential-materials-be-considered-open-session.*

*Accessibility:* LSC complies with the American's 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 Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@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: July 11, 2018.

**Katherine Ward,**

*Executive Assistant to the Vice President for Legal Affairs, General Counsel & Corporate Secretary.*

[FR Doc. 2018–15175 Filed 7–12–18; 11:15 am]

BILLING CODE 7050–01–P

## NATIONAL SCIENCE FOUNDATION

### Sunshine Act Meetings; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of a revision to an announcement of meetings for the transaction of National Science Board business.

**FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:** 83 FR 32330–31, published on July 12, 2018.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETINGS:**

**Committee on Strategy (CS)**

*Tuesday, July 17, 2018*

Open Session: 1:00–1:30 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- FY 2018 Appropriations and FY 2019 Budget Request Update

*Wednesday, July 18, 2018*

Closed Session: 9:30–10:30 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- FY 2020 Budget Discussion

**Plenary Board**

*Tuesday, July 17, 2018*

Open Session 10:15 a.m.–12:00 p.m.

Presentation and Panel Discussion—''Being Smart About Artificial Intelligence (AI)''

- Chair's Opening Remarks and Introductions
- Presentation, Dr. Andrew Moore, Carnegie Mellon University
- Panel Presentations and Discussion
  - Dr. Michael Jordan, University of California, Berkeley
  - Dr. Daniela Rus, Massachusetts Institute of Technology
  - Dr. Charles Isbell, Georgia Institute of Technology
  - Dr. James Kurose, Assistant Director, Computer & Information Science & Engineering

*Wednesday, July 18, 2018*

Open Session: 11:50 a.m.–2:15 p.m.

- Board Chair's Opening Remarks
- Introduction of Presentation on the National Academies and Board of International Scientific Organizations

(Break for lunch from 12:20–1:15 p.m.)

- Board Chair's Opening Remarks
- NSF Director's Remarks
- Approval of Prior Minutes
- Vote: NSB Calendar for CY 2019
- Open Committee Reports
- NSF INCLUDES Presentation
- Board Chair's Closing Remarks

**CHANGES IN THE MEETINGS:**

**Committee on Strategy (CS)**

*Tuesday, July 17, 2018*

Open Session: 1:00–1:30 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- FY 2019 Budget Request Update

*Wednesday, July 18, 2018*

Closed session: 9:30–10:30 a.m.

- Committee Chair's Opening Remarks

- Approval of Prior Minutes
- FY 2020 Budget Discussion
- FY 2018 Appropriations

**Plenary Board**

*Tuesday, July 17, 2018*

Open Session 10:15 a.m.–12:00 p.m.

Presentation and Panel Discussion—''Being Smart About Artificial Intelligence (AI)''

- Chair's Opening Remarks and Introductions
- Presentation, Dr. Andrew Moore, Carnegie Mellon University
- Panel Presentations and Discussion
  - Dr. Michael Jordan, University of California, Berkeley
  - Dr. Daniela Rus, Massachusetts Institute of Technology
  - Dr. Charles Isbell, Georgia Institute of Technology
  - Dr. James Kurose, Assistant Director, Computer & Information Science & Engineering; Assistant Director for Artificial Intelligence, Whites House Office of Science and Technology Policy

*Wednesday, July 18, 2018*

Open Session: 11:50 a.m.–2:15 p.m.

- Board Chair's Opening Remarks
- Introduction of Presentation on the National Academies and Board of International Scientific Organizations

(Break for lunch from 12:20–1:15 p.m.)

- Board Chair's Opening Remarks
- NSF Director's Remarks
- Approval of Prior Minutes
- Vote: NSB Calendar for CY 2019
- Open Committee Reports
- NSF Learning Agenda Presentation
- Board Chair's Closing Remarks

Open meetings in the boardroom are webcast. In addition to the regular link for the July 2018 meetings at *http://www.tvworldwide.com/events/nsf/180717/,* members of the public may also watch open meetings on You Tube. On July 17, the video can be accessed at: *https://www.youtube.com/watch?v=hdGXXO_pMzQ&feature=youtu.be.* On July 18, the video can be accessed at: *https://www.youtube.com/watch?v=bg9Tf020B0Q&feature=youtu.be.*

**CONTACT PERSON FOR MORE INFORMATION:** Brad Gutierrez, *bgutierr@nsf.gov,* 703/292–7000. Please refer to the National Science Board website for additional information. Meeting information and schedule updates (time, place, subject matter, and status of meeting) may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

**Chris Blair,**

*Executive Assistant, National Science Board Office.*

[FR Doc. 2018–15229 Filed 7–12–18; 4:15 pm]

**BILLING CODE 7555–01–P**

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50–390; NRC–2018–0144]**

## Watts Bar Nuclear Plant, Unit 1

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** License amendment request; opportunity to comment, request a hearing, and petition for leave to intervene.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. NPF–90 for the Watts Bar Nuclear Plant (Watts Bar or WBN), Unit 1. The proposed amendment would modify the Watts Bar, Unit 1, Technical Specifications (TSs) to extend Surveillance Requirements (SRs) 3.3.1.5, 3.3.2.2, and 3.3.6.2.

**DATES:** Comments must be filed by August 15, 2018. Requests for a hearing or petitions for leave to intervene must be filed by September 14, 2018.

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

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0144. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, 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:** Natreon Jordan, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7410; email: *Natreon.Jordan@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Obtaining Information and Submitting Comments

*A. Obtaining Information*

Please refer to Docket ID NRC–2018–0144 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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0144.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *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–2018–0144 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. Introduction

The NRC is considering issuance of an amendment to Facility Operating

License No. NPF–90 for Watts Bar, Unit 1, located in Rhea County, Tennessee.

The proposed amendment would amend the Watts Bar, Unit 1, TS SR 3.0.2 and certain SRs in Table SR 3.0.2–1 to permit the extension of the above SRs, so that Tennessee Valley Authority (the licensee) can perform the SRs listed in Table 1 of the enclosure to the licensee's application during the Unit 1 outage (U1R15). Further, the licensee will perform these SRs if Unit 1 enters Mode 5 prior to its U1R15 outage.

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

The NRC has made a proposed determination that the license amendment request involves no significant hazards consideration. Under the NRC's regulations in section 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; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. 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 requested action is an extension to the performance interval of a limited number of TS surveillance requirements. The performance of these surveillances, or the extension of these surveillances, is not a precursor to an accident. Performing these surveillances or failing to perform these surveillances does not affect the probability of an accident. Therefore, the proposed delay in performance of the SRs in this amendment request does not increase the probability of an accident previously evaluated.

A delay in performing these surveillances does not result in a system being unable to perform its required function. In the case of this one-time extension request, the short period of additional time that the systems and components will be in service before the next performance of the surveillance will not affect the ability of those systems to operate as designed. Therefore, the systems required to mitigate accidents will remain capable of performing their required function. No new failure modes have been introduced because of this action and the consequences remain consistent with previously evaluated accidents. On this basis, the proposed delay in performance of the SRs in this amendment request does not involve a significant increase in 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 amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed amendment does not involve a physical alteration of any system, structure, or component (SSC) or a change in the way any SSC is operated. The proposed amendment does not involve operation of any SSCs in a manner or configuration different from those previously recognized or evaluated. No new failure mechanisms will be introduced by the one-time SR extensions being requested.

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 amendment is a one-time extension of the performance interval of a limited number of TS SRs. Extending these SRs does not involve a modification of any TS limiting condition for operation. Extending these SRs does not involve a change to any limit on accident consequences specified in the license or regulations. Extending these SRs does not involve a change in how accidents are mitigated or a significant increase in the consequences of an accident. Extending these SRs does not involve a change in a methodology used to evaluate consequences of an accident. Extending these SRs does not involve a change in any operating procedure or process.

Operating history has demonstrated that the WBN Units 1 and 2 SSPS [solid state protection system] is highly reliable. A review of the test results has not revealed any automatic logic failures. Based on the limited additional period of time that the systems and components will be in service before the surveillances are next performed, as well as the operating experience that these surveillances are typically successful when performed, it is reasonable to conclude that the margins of safety associated with these SRs will not be affected by the requested extension.

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 license amendment request involves no significant hazards consideration.

The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. 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 notice period if the Commission concludes 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 if 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. If the Commission takes 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. If the Commission makes 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.

## III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of

the 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 petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in 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 petitioner must 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 petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) 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. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the 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). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

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 establish 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 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 the 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 no later than 60 days from the date of publication of this notice. 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 set forth in this section, except that under 10 CFR 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. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at 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 his or her 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. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

## IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), 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 that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). 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. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* 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,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (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 website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is 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 document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 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 stating why there is good cause for not filing electronically and 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, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents 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 *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. 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.

For further details with respect to this action, see the application for license amendment dated July 8, 2018 (ADAMS Accession No. ML18189A001).

*Attorney for Licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

*NRC Acting Branch Chief:* Booma Venkataraman.

Dated at Rockville, Maryland, this 11th day of July 2018.

For the Nuclear Regulatory Commission.

**Natreon J. Jordan,**

*Project Manager, Plant Licensing Branch 2–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2018–15100 Filed 7–13–18; 8:45 am]

BILLING CODE 7590–01–P

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## NUCLEAR REGULATORY COMMISSION

**[NRC–2018–0009]**

## Information Collection: Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of submission to the Office of Management and Budget; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.''

**DATES:** Submit comments by August 15, 2018.

**ADDRESSES:** Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0143), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Obtaining Information and Submitting Comments

*A. Obtaining Information*

Please refer to Docket ID NRC–2018–0009 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 Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0009.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML18165A415.
- *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.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without

charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

*B. Submitting Comments*

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''10 CFR [*Code of Federal Regulations*] Part 62, Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on April 24, 2018 (83 FR 18353).

1. *The title of the information collection:* 10 CFR part 62, ''Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.''
2. *OMB approval number:* 3150–0143.
3. *Type of submission:* Revision.
4. *The form number if applicable:* Not applicable.
5. *How often the collection is required or requested:* On occasion.
6. *Who will be required or asked to respond:* Part 62 of 10 CFR sets out the information that must be provided to the NRC by any low-level waste generator or governor of a State on behalf of generators seeking emergency access to an operating low-level waste disposal facility. The information is required to allow the NRC to determine if denial of disposal constitutes a serious and immediate threat to public health and safety or common defense and security. Part 62 of 10 CFR also provides that the Commission may grant an exemption from the requirements in this part upon application of an interested person or upon its own initiative.
7. *The estimated number of annual responses:* 2.
8. *The estimated number of annual respondents:* 1.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 233.
10. *Abstract:* Part 62 of 10 CFR sets out the information that must be provided to the NRC by any low-level waste generator or governor of a State on behalf of generators seeking emergency access to an operating low-level waste disposal facility. The information is required to allow the NRC to determine if denial of disposal constitutes a serious and immediate threat to public health and safety or common defense and security. Part 62 of 10 CFR also provides that the Commission may grant an exemption from the requirements in this part upon application of an interested person or upon its own initiative.

Dated at Rockville, Maryland, this 10th day of July 2018.

For the Nuclear Regulatory Commission.

**Kristen Benney,**

*Acting NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 2018–15081 Filed 7–13–18; 8:45 am]

**BILLING CODE 7590–01–P**

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## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50–397; NRC–2018–0146]**

## Energy Northwest; Columbia Generating Station

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Environmental assessment and finding of no significant impact; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Renewed Facility Operating License No. NPF–21, issued on May 22, 2012, and held by Energy Northwest (the licensee) for the operation of Columbia Generating Station (Columbia), located in Benton County, Washington. The proposed amendment would revise the Environmental Protection Plan (Non-Radiological) (EPP), contained in Appendix B to the Columbia renewed facility operating license. The NRC is issuing a final environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed license amendment.

**DATES:** The EA and FONSI referenced in this document is available on July 16, 2018.

**ADDRESSES:** Please refer to Docket ID NRC–2018–0146 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0146. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** John Klos, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5136; email: *John.Klos@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

The NRC is considering issuance of an amendment to Renewed Facility Operating License No. NPF–21 issued to

Energy Northwest for operation of Columbia, located in Benton County, Washington. The licensee submitted its license amendment request by letter dated December 18, 2017 (ADAMS Accession No. ML17352B255). If approved, the license amendment would add Section 4.2.2, ''Aquatic Issues,'' to the Columbia EPP to require Energy Northwest to adhere to the specific requirements within the Incidental Take Statement (ITS) in the currently applicable biological opinion. The NRC prepared an EA to document its findings related to the proposed license amendment request in accordance with Section 51.21 of title 10 of the *Code of Federal Regulations* (10 CFR). Based on the results of the EA documented herein, the NRC did not identify any significant environmental impacts associated with the proposed amendment and is, therefore, issuing a FONSI in accordance with 10 CFR 51.32.

## II. Environmental Assessment

*Plant Site and Environs*

Columbia is a single unit plant with a boiling water reactor and a closed-cycle cooling system that withdraws water from and discharges water to the Columbia River. The facility occupies approximately 1,089 acres (441 hectares) of land leased from the U.S. Department of Energy within the Hanford Reservation. The leased land is located in Benton County, Washington, 12 miles (19 kilometers) northwest of Richland and approximately 160 miles (257 kilometers) southeast of Seattle. The Columbia River borders the site to the east and flat rolling hills surround the site.

The U.S. Atomic Energy Commission, the NRC's predecessor agency, and the NRC have previously conducted environmental reviews of Columbia operations in several documents, which contain more detailed descriptions of the plant site and environs. Those documents include the Final Environmental Statement related to construction of the facility in December 1972 (ADAMS Accession No. ML101870543); the Final Environmental Statement related to initial operation of the facility in December 1981 (ADAMS Accession No. ML100570374); and NUREG–1437, ''Generic Environmental Impact Statement [GEIS] for License Renewal of Nuclear Plants, Supplement 47, Regarding Columbia Generating Station—Final Report,'' dated April 2012 and its associated GEIS documents (ADAMS Package Accession No. ML12097A267).

*Description of the Proposed Action*

The proposed action would add language in Section 4.2, ''Environmental Monitoring,'' of the Columbia EPP to require Energy Northwest to adhere to the specific requirements within the ITS in the currently applicable biological opinion. The proposed action would be in accordance with the licensee's application dated December 18, 2017.

By amending Section 4.2 of the EPP to state that Energy Northwest must adhere to the ITS in the currently applicable biological opinion, the proposed action would require Energy Northwest's compliance with the National Marine Fisheries Service's (NMFS) biological opinion, dated March 10, 2017 (ADAMS Accession No. ML17072A036). This biological opinion applies to Upper Columbia River spring run Chinook salmon (*Oncorhynchus tshawytscha*) and Upper Columbia River steelhead (*Oncorhynchus mykiss*), and concludes that the continued operation of Columbia is not likely to jeopardize the continued existence of these species or destroy or adversely modify the designated critical habitat of these species. The ITS included in the biological opinion exempts the incidental take of these species from the prohibitions of Section 9 of the Endangered Species Act of 1973, as amended (ESA), provided that the specified Reasonable and Prudent Measures (RPMs) are implemented. The RPMs are:

1. Minimize the potential for incidental take of ESA-listed species as a result of elevated concentrations of chemical constituents in the mainstem Columbia River.
2. Minimize the potential for incidental take of ESA-listed species as a result of entrainment and impingement associated with the cooling water intake structure for Columbia.
3. Minimize the potential for incidental take [1] of ESA-listed species as a result of biological monitoring.
4. Ensure completion of a monitoring and reporting program to confirm that the terms and conditions in this ITS were effective in avoiding and minimizing incidental take from permitted activities and ensuring incidental take is not exceeded.

In order to implement the RPMs, the ITS prescribes a number of Terms and Conditions (T&Cs). The T&Cs require Energy Northwest to conduct effluent monitoring (RPM1), conduct impingment and entrainment studies (RPM 2), implement various best practices while conducting biological monitoring studies to minimize impacts to listed species (RPM 3), and submit a report to NMFS regarding all biological monitoring activites (RPM 4). Specificially, to minimize chemical exposures to ESA-listed species as described in RPM 1, Energy Northwest must conduct physical and chemical monitoring of the Columbia effluent, as specified in its National Pollutant Discharge Elimination System (NPDES) Permit No. WA002515–1, to ensure that effluent water quality controls are functioning as intended. To minimize potential impingment and entrainment as described in RPM 2, Energy Northwest must prepare and conduct an impingment study and an entrainment study for NMFS's review and comment, as described in its NPDES permit.

To minimize the potential for a take during biological monitoring as described in RPM 3, the ITS prescribes several best practices and reporting requirements for Energy Northwest to implement, including:

- Fish handling practices.
- Requirements to stop sampling when water temperatures reach specified limits, or if any ESA-listed adult salmon or steelhead or steelhead redds are observed at the site.
- Reporting requirments if Energy Northwest unintentionally captures any ESA-listed adult salmon or steelhead while angling for resident fish, if a take is likely, or if any authorized level of take is exceeded than the levels specied in the ITS.

To ensure completion of a monitoring and reporting program and to ensure that incidental take is not exceeded as described in RPM 4, Energy Northwest must submit to NMFS, with a copy to NRC, an annual post-season report describing the biological monitoring activities that occurred and a summary of each take including the ESA-listed species affected, the type of take, the location where the take occurred, and the date of occurrence. The annual report must also summarize any operational changes to Columbia that affect the effluent discharge and have the potential to affect ESA-listed resources.

Notably, because the proposed amendment would require Energy Northwest's compliance with the ''currently applicable'' biological opinion, if NMFS were to issue a new biological opinion in the future, the proposed amendment would require Energy Northwest to adhere to the specific requirements in the ITS of that

[1] The ESA prohibits the take of any federally listed species without a special exemption and states that the term ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.

new biological opinion, and Energy Northwest would no longer be required to adhere to the March 10, 2017, biological opinion upon issuance of a new biological opinion.

*Need for the Proposed Action*

The proposed action is needed to reflect the biological opinion issued by NMFS on March 10, 2017, and to require Energy Northwest's compliance with the ITS and related RPMs and T&Cs contained therein. The proposed action is administrative in nature.

*Environmental Impacts of the Proposed Action*

The NRC has completed its evaluation of the proposed action and concludes that the proposed changes are administrative in nature, would have no direct effects on plant equipment or plant operation, and would not involve any changes to the design bases for Columbia.

With regard to potential radiological impacts, the proposed action would not increase the probability or consequences of accidents, would not change the types or increase the amount of effluent that may be released offsite, and would result in no increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, because the proposed action is administrative in nature, it would not have any direct impacts on land, air, or water resources, including impacts to terrestrial biota. In addition, the NRC staff identified no socioeconomic or environmental justice impacts associated with the proposed action. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

An indirect effect of the proposed action is that Energy Northwest's impingement and entrainment studies (RPM 1 and 2) would likely require in-water work and the collection of larvae and eggs. In-water work could cause minor disturbances to nearby biota. However, the activity would be temporary and fish could swim away to avoid the area and return once the temporary work is completed. Removal of larvae and eggs of resident fish species could occur during collection periods for the entrainment study. However, the amount of individuals that would be collected for the study would be negliable when compared to the size of local resident fish populations. In addition, RPM 3 requires Energy Northwest to modify some of its collection practices while conducting biological monitoring studies. In general, these practices will result in beneficial effects to ESA-listed species because the purpose of the modifications are to minimize impacts. For example, during electrofishing, where fish are temporarily stunned for biologists to collect and measure them, RPM 3 requires Energy Northwest to handle ESA-listed fish with extreme care and keep them in cold water to the maximum extent possible during sampling and processing procedures. The NRC staff concludes that the indirect effects from the impingement and entrainment studies as well as the modified collection practices will not result in significant environmental impacts to the radiological or non-radiological environment.

Based on the foregoing analysis, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

*Environmental Impacts of the Alternatives to the Proposed Action*

As an alternative to the proposed action, the NRC staff considered denial of the proposed license amendment (*i.e.,* the ''no-action'' alternative). Denial of the application would result in no change in current environmental conditions or impacts. Accordingly, the environmental impacts of the proposed action and the no-action alternative are similar.

*Alternative Use of Resources*

The proposed action does not involve the use of any different resources than those previously considered in NUREG–1437, Supplement 47, prepared for the license renewal of Columbia.

*Agencies and Persons Consulted*

The NRC did not enter into consultation with any other Federal Agency or with the State of Washington regarding the environmental impact of the proposed action. However, on June 6, 2018, the NRC notified the Washington State official, Mr. Richard Cowley, Washington State Department of Health, Office of Radiation Protection of the proposed amendment. The State official had no comments.

**III. Finding of No Significant Impact**

The NRC is considering issuance of an amendment to Renewed Facility Operating License No. NPF–21, issued to Energy Northwest for operation of Columbia. The proposed amendment would revise the Columbia EPP to require Energy Northwest to adhere to the specific requirements within the ITS in the currently applicable biological opinion. On the basis of the EA included in Section II of this document and incorporated by reference into this finding, the NRC concludes that the proposed action would not have significant effects on the quality of the human environment. The NRC's evaluation considered information provided in the licensee's application as well as the NRC's independent review of other relevant environmental documents. Based on its findings, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Dated at Rockville, Maryland, this 11th day of July 2018.

For the Nuclear Regulatory Commission.

**L. John Klos,**

*Project Manager, Plant Licensing Branch IV–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2018–15091 Filed 7–13–18; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

**[NRC–2018–0050]**

## Information Collection: 10 CFR Part 140, Financial Protection Requirements and Indemnity Agreements

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of submission to the Office of Management and Budget; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''10 CFR part 140, Financial Protection Requirements and Indemnity Agreements.''

**DATES:** Submit comments by August 15, 2018.

**ADDRESSES:** Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0039), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Obtaining Information and Submitting Comments

*A. Obtaining Information*

Please refer to Docket ID NRC–2018–0050 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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0050.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML18127B276.

• *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.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

*B. Submitting Comments*

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''10 CFR part 140, Financial Protection Requirements and Indemnity Agreements.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on April 10, 2018 (83 FR 15422).

1. *The title of the information collection:* ''10 CFR part 140, Financial Protection Requirements and Indemnity Agreements.''
2. *OMB approval number:* 3150–0039.
3. *Type of submission:* Revision.
4. *The form number, if applicable:* N/A.
5. *How often the collection is required or requested:* On occasion, as needed for applicants and licensees to meet their responsibilities called for in Sections 170 and 193 of the Atomic Energy Act of 1954.
6. *Who will be required or asked to respond:* Each applicant for or holder of a license issued under parts 50 or 54 of title 10 of the *Code of Federal Regulations* (10 CFR) to operate a nuclear reactor, or the applicant for or holder of a combined license issued under parts 52 or 54 of 10 CFR, as well as licensees authorized to possess and use plutonium in a plutonium processing and fuel fabrication plant. In addition, licensees authorized to construct and operate a uranium enrichment facility in accordance with parts 40 and 70 of 10 CFR.
7. *The estimated number of annual responses:* 102.
8. *The estimated number of annual respondents:* 102.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 796.
10. *Abstract:* 10 CFR part 140 specifies the information to be submitted by licensees that enables the NRC to assess (a) financial protection required by licensees and for the indemnification and limitation of liability of certain licensees and other persons pursuant to Section 170 of the Atomic Energy Act of 1954, as amended, and (b) the liability insurance required of plutonium processing and fuel fabrication plants, as well as uranium enrichment facility licensees pursuant to Section 193 of the Atomic Energy Act of 1954, as amended.

Dated at Rockville, Maryland, this 10th day of July, 2018.

For the Nuclear Regulatory Commission.

**Kristen Benney,**

*Acting NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 2018–15080 Filed 7–13–18; 8:45 am]

BILLING CODE 7590–01–P

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## NUCLEAR REGULATORY COMMISSION

**[Docket No. 72–1051; NRC–2018–0055]**

## Holtec International's HI–STORE Consolidated Interim Storage Facility for Interim Storage of Spent Nuclear Fuel

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** License application; opportunity to request a hearing and to petition for leave to intervene; order.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) received a license application from Holtec International (Holtec), by letter dated March 30, 2017, as supplemented on April 13, October 6, December 21, and 22, 2017; and February 22, 2018. By this application, Holtec is requesting authorization to construct and operate the HI–STORE Consolidated Interim Storage (CIS) Facility, in Lea County, New Mexico. If the NRC approves the application and issues a license to Holtec, Holtec intends to store up to 8,680 metric tons of uranium (MTU) of commercial spent nuclear fuel in the HI–STORM UMAX Canister Storage System for a 40-year license term.

**DATES:** A request for a hearing or petition for leave to intervene must be filed by September 14, 2018.

**ADDRESSES:** Please refer to Docket ID NRC–2018–0055 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0055. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' 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.

**FOR FURTHER INFORMATION CONTACT:** Jose R. Cuadrado, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0606; email: *Jose.Cuadrado@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

The NRC received an application from Holtec for a specific license pursuant to part 72 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste.'' On March 19, 2018, notice of the NRC's acceptance and docketing of the application and the public availability of the application was provided in the **Federal Register** (83 FR 12034).

Holtec is proposing to construct and operate the HI–STORE Consolidated Interim Storage (CIS) Facility on a large parcel of presently unused land owned by the Eddy-Lea Energy Alliance (ELEA), LLC. The ELEA was formed in 2006 in accordance with enabling legislation passed in New Mexico and consists of an alliance of the city of Carlsbad, Eddy County, the city of Hobbs, and Lea County. The proposed site for the CIS facility is located in southeastern New Mexico in Lea County, 32 miles east of Carlsbad, New Mexico, and 34 miles west of Hobbs, New Mexico.

Holtec is proposing to construct and operate Phase 1 of the CIS facility within an approximately 1,040 acre parcel. Holtec is currently requesting authorization to possess and store 500 canisters of spent nuclear fuel (SNF) containing up to 8,680 metric tons of uranium (MTUs), which includes spent uranium-based fuel from commercial nuclear reactors, as well as a small quantity of spent mixed-oxide fuel. If the NRC issues the requested license, Holtec expects to subsequently request additional amendments to the initial license to expand the storage capacity of the facility. In its plans, Holtec proposes expanding the facility in 19 subsequent expansion phases, each for an additional 500 canisters, to be completed over the course of 20 years. Ultimately, Holtec anticipates that approximately 10,000 canisters of SNF would be stored at the CIS facility upon completion of 20 phases. Each phase would require NRC review and approval.

According to its application, Holtec intends to only use the HI–STORM UMAX Canister Storage System for storage of spent nuclear fuel canisters at the facility. The HI–STORM UMAX Canister Storage System stores the canister containing SNF entirely below-ground, providing a clear, unobstructed view of the entire CIS facility from any location.

## II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR part 2. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* A copy of the regulations is also available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (First Floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the 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 petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in 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 petitioner must 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 petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) 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. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the 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). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

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 no later than 60 days from the date of publication of this notice. 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 set forth in this section. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at 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 his or her 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. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

**III. Electronic Submissions (E-Filing)**

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), 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 that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). 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. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* 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,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (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 website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is 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 document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 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 stating why there is good cause for not filing electronically and 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, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents 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 *https://adams.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 personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. 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.

**IV. Availability of Documents**

The documents identified in this **Federal Register** notice are accessible to interested persons in ADAMS under the accession numbers identified in the table below.

| Title | ADAMS accession No. |
|---|---|
| Holtec International HI–STORE CIS License Application | ML17115A431 |
| NRC request for supplemental information | ML17191A356, ML17191A478 |
| Holtec letter with schedule for response to NRC request for supplemental information | ML17206A203 |
| Holtec's October 6, 2017, information submittal in response to NRC request for supplemental information | ML17310A21 |
| Holtec's December 21, 2017, information submittal in response to NRC request for supplemental information | ML17362A097 |
| Holtec's December 22, 2017, information submittal in response to NRC request for supplemental information | ML18011A158 |
| Holtec's February 22, 2018, information submittal in response to proprietary information determination | ML18058A617 |
| NRC letter accepting application for review | ML18059A251 |
| NRC **Federal Register** Notice of docketing Holtec license application | ML18058A171 |

## V. Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing sensitive unclassified information (including Sensitive Unclassified Non-Safeguards Information (SUNSI) and Safeguards Information (SGI)). Requirements for access to SGI are primarily set forth in 10 CFR parts 2 and 73. Nothing in this Order is intended to conflict with the SGI regulations.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI or SGI is necessary to respond to this notice may request access to SUNSI or SGI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI or SGI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI, SGI, or both to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Hearings and Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1);

(3) If the request is for SUNSI, the identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention; and

(4) If the request is for SGI, the identity of each individual who would have access to SGI if the request is granted, including the identity of any expert, consultant, or assistant who will aid the requestor in evaluating the SGI. In addition, the request must contain the following information:

(a) A statement that explains each individual's ''need to know'' the SGI, as required by 10 CFR 73.2 and 10 CFR 73.22(b)(1). Consistent with the definition of ''need to know'' as stated in 10 CFR 73.2, the statement must explain:

(i) Specifically why the requestor believes that the information is necessary to enable the requestor to proffer and/or adjudicate a specific contention in this proceeding;[2] and

(ii) The technical competence (demonstrable knowledge, skill, training or education) of the requestor to effectively utilize the requested SGI to provide the basis and specificity for a proffered contention. The technical competence of a potential party or its counsel may be shown by reliance on a qualified expert, consultant, or assistant who satisfies these criteria.

(b) A completed Form SF–85, ''Questionnaire for Non-Sensitive Positions,'' for each individual who would have access to SGI. The completed Form SF–85 will be used by the Office of Administration to conduct the background check required for access to SGI, as required by 10 CFR part 2, subpart C, and 10 CFR 73.22(b)(2), to determine the requestor's trustworthiness and reliability. For security reasons, Form SF–85 can only be submitted electronically through the electronic questionnaire for investigations processing (e-QIP) website, a secure website that is owned and operated by the Office of Personnel Management. To obtain online access to the form, the requestor should contact the NRC's Office of Administration at 301–415–3710.[3]

(c) A completed Form FD–258 (fingerprint card), signed in original ink, and submitted in accordance with 10 CFR 73.57(d). Copies of Form FD–258 may be obtained by writing the Office of Administrative Services, Mail Services Center, Mail Stop P1–37, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by email to *MAILSVC.Resource@nrc.gov.* The fingerprint card will be used to satisfy the requirements of 10 CFR part 2, subpart C, 10 CFR 73.22(b)(1), and Section 149 of the Atomic Energy Act of 1954, as amended, which mandates that

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI and/or SGI under these procedures should be submitted as described in this paragraph.

[2] Broad SGI requests under these procedures are unlikely to meet the standard for need to know; furthermore, NRC staff redaction of information from requested documents before their release may be appropriate to comport with this requirement. These procedures do not authorize unrestricted disclosure or less scrutiny of a requestor's need to know than ordinarily would be applied in connection with an already-admitted contention or non-adjudicatory access to SGI.

[3] The requestor will be asked to provide his or her full name, social security number, date and place of birth, telephone number, and email address. After providing this information, the requestor usually should be able to obtain access to the online form within one business day.

all persons with access to SGI must be fingerprinted for an FBI identification and criminal history records check.

(d) A check or money order payable in the amount of $324.00[4] to the U.S. Nuclear Regulatory Commission for each individual for whom the request for access has been submitted.

(e) If the requestor or any individual(s) who will have access to SGI believes they belong to one or more of the categories of individuals that are exempt from the criminal history records check and background check requirements in 10 CFR 73.59, the requestor should also provide a statement identifying which exemption the requestor is invoking and explaining the requestor's basis for believing that the exemption applies. While processing the request, the Office of Administration, Personnel Security Branch, will make a final determination whether the claimed exemption applies. Alternatively, the requestor may contact the Office of Administration for an evaluation of their exemption status prior to submitting their request. Persons who are exempt from the background check are not required to complete the SF–85 or Form FD–258; however, all other requirements for access to SGI, including the need to know, are still applicable.

**Note:** Copies of documents and materials required by paragraphs C.(4)(b), (c), and (d) of this Order must be sent to the following address: U.S. Nuclear Regulatory Commission, ATTN: Personnel Security Branch, Mail Stop TWFN–07–D04M, 11555 Rockville Pike, Rockville, MD 20852.

These documents and materials should *not* be included with the request letter to the Office of the Secretary, but the request letter should state that the forms and fees have been submitted as required.

D. To avoid delays in processing requests for access to SGI, the requestor should review all submitted materials for completeness and accuracy (including legibility) before submitting them to the NRC. The NRC will return incomplete packages to the sender without processing.

E. Based on an evaluation of the information submitted under paragraphs C.(3) or C.(4) above, as applicable, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI or need to know the SGI requested.

F. For requests for access to SUNSI, if the NRC staff determines that the requestor satisfies both E.(1) and E.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.[5]

G. For requests for access to SGI, if the NRC staff determines that the requestor has satisfied both E.(1) and E.(2) above, the Office of Administration will then determine, based upon completion of the background check, whether the proposed recipient is trustworthy and reliable, as required for access to SGI by 10 CFR 73.22(b). If the Office of Administration determines that the individual or individuals are trustworthy and reliable, the NRC will promptly notify the requestor in writing. The notification will provide the names of approved individuals as well as the conditions under which the SGI will be provided. Those conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[6] by each individual who will be granted access to SGI.

H. Release and Storage of SGI. Prior to providing SGI to the requestor, the NRC staff will conduct (as necessary) an inspection to confirm that the recipient's information protection system is sufficient to satisfy the requirements of 10 CFR 73.22. Alternatively, recipients may opt to view SGI at an approved SGI storage location rather than establish their own SGI protection program to meet SGI protection requirements.

I. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI or SGI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI or SGI contentions by that later deadline.

J. Review of Denials of Access.

(1) If the request for access to SUNSI or SGI is denied by the NRC staff either after a determination on standing and requisite need, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) Before the Office of Administration makes a final adverse determination regarding the trustworthiness and reliability of the proposed recipient(s) for access to SGI, the Office of Administration, in accordance with 10 CFR 2.336(f)(1)(iii), must provide the proposed recipient(s) any records that were considered in the trustworthiness and reliability determination, including those required to be provided under 10 CFR 73.57(e)(1), so that the proposed recipient(s) have an opportunity to correct or explain the record.

(3) The requestor may challenge the NRC staff's adverse determination with respect to access to SUNSI or with respect to standing or need to know for SGI by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(4) The requestor may challenge the Office of Administration's final adverse determination with respect to trustworthiness and reliability for access to SGI by filing a request for review in accordance with 10 CFR 2.336(f)(1)(iv).

(5) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

K. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of

[4] This fee is subject to change pursuant to the Office of Personnel Management's adjustable billing rates.

[5] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[6] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SGI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 180 days of the deadline for the receipt of the written access request.

the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[7]

L. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI or SGI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

*It is so ordered.*

Dated at Rockville, Maryland, this 10th of July 2018.

For the Nuclear Regulatory Commission.

**Annette L. Vietti-Cook,**

*Secretary of the Commission.*

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION AND SAFEGUARDS INFORMATION IN THIS PROCEEDING

| Day | Event/activity |
|---|---|
| 0 | Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests. |
| 10 | Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) and/or Safeguards Information (SGI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding; demonstrating that access should be granted (*e.g.,* showing technical competence for access to SGI); and, for SGI, including application fee for fingerprint/background check. |
| 60 | Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI and/or SGI (+25 Answers to petition for intervention; +7 requestor/petitioner reply). |
| 20 | U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows (1) need for SUNSI or (2) need to know for SGI. (For SUNSI, NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents). If NRC staff makes the finding of need to know for SGI and likelihood of standing, NRC staff begins background check (including fingerprinting for a criminal history records check), information processing (preparation of redactions or review of redacted documents), and readiness inspections. |
| 25 | If NRC staff finds no "need," no "need to know," or no likelihood of standing, the deadline for requestor/petitioner to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access. |
| 30 | Deadline for NRC staff reply to motions to reverse NRC staff determination(s). |
| 40 | (Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI. |
| 190 | (Receipt +180) If NRC staff finds standing, need to know for SGI, and trustworthiness and reliability, deadline for NRC staff to file motion for Protective Order and draft Non-disclosure Affidavit (or to make a determination that the proposed recipient of SGI is not trustworthy or reliable). Note: Before the Office of Administration makes a final adverse determination regarding access to SGI, the proposed recipient must be provided an opportunity to correct or explain information. |
| 205 | Deadline for petitioner to seek reversal of a final adverse NRC staff trustworthiness or reliability determination under 10 CFR 2.336(f)(1)(iv). |
| A | If access granted: Issuance of a decision by a presiding officer or other designated officer on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff. |
| A + 3 | Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI and/or SGI consistent with decision issuing the protective order. |
| A + 28 | Deadline for submission of contentions whose development depends upon access to SUNSI and/or SGI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI or SGI contentions by that later deadline. |
| A + 53 | (Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI and/or SGI. |
| A + 60 | (Answer receipt +7) Petitioner/Intervenor reply to answers. |
| >A + 60 | Decision on contention admission. |

[7] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI/SGI request submitted to the NRC staff under these procedures.

[FR Doc. 2018–15079 Filed 7–13–18; 8:45 am]

BILLING CODE 7590–01–P

## OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

### Privacy Act of 1974; System of Records.

**AGENCY:** Occupational Safety and Health Review Commission.

**ACTION:** Rescindment of System of Records Notices.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Occupational Safety and Health Review Commission (OSHRC) is rescinding the Privacy Act system-of-records notices for following systems of records: Travel Records, OSHRC–1; and Mailing Lists for News Releases, Speeches, Booklets, Reports, OSHRC–2.

**DATES:** Comments must be received by OSHRC on or before August 15, 2018. The rescindment of OSHRC–1 and OSHRC–2 will become effective on that date, without any further notice in the **Federal Register**, unless comments or government approval procedures necessitate otherwise.

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

- *Email: rbailey@oshrc.gov*. Include ''PRIVACY ACT SYSTEM OF RECORDS'' in the subject line of the message.
- *Fax:* (202) 606–5417.
- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.
- *Hand Delivery/Courier:* Same as mailing address.

*Instructions:* All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as ''PRIVACY ACT SYSTEM OF RECORDS.''

**FOR FURTHER INFORMATION CONTACT:** Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606–5410, or via email at *rbailey@oshrc.gov*.

**SUPPLEMENTARY INFORMATION:** Following OSHRC's review of its systems of records, the agency is rescinding two of its system-of-records notices: (1) Travel Records, OSHRC–1; and (2) Mailing Lists for News Releases, Speeches, Booklets, Reports, OSHRC–2.

The records included in OSHRC–1 are fully covered by the following Privacy Act notices for governmentwide systems of records: GSA/GOVT–4, see 74 FR 26700, July 6, 2009, and GSA/GOVT–3, see 78 FR 20108, May 3, 2013. OSHRC–1 is therefore being rescinded to avoid duplicative notices.

Additionally, based on a comprehensive review of OSHRC's records, the agency has determined that mailing lists for news releases, speeches, booklets, and reports are no longer maintained by the agency. As this system of records, OSHRC–2, no longer exists, its notice is being rescinded.

The notices rescinding OSHRC–1 and OSHRC–2 are as follows.

#### OSHRC–1

**SYSTEM NAME AND NUMBER:**

Travel Records, OSHRC–1.

**HISTORY:**

April 14, 2006, 71 FR 19556; August 4, 2008, 73 FR 45256; October 5, 2015, 80 FR 60182; and September 28, 2017, 82 FR 45324.

#### OSHRC–2

**SYSTEM NAME AND NUMBER:**

Mailing Lists for News Releases, Speeches, Booklets, Reports, OSHRC–2.

**HISTORY:**

April 14, 2006, 71 FR 19556; August 4, 2008, 73 FR 45256; October 5, 2015, 80 FR 60182; and September 28, 2017, 82 FR 45324.

Dated: July 9, 2018.

**Nadine N. Mancini,**

*General Counsel, Senior Agency Official for Privacy.*

[FR Doc. 2018–15069 Filed 7–13–18; 8:45 am]

BILLING CODE 7600–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 33156; 812–14884]**

### DMS ETF Trust I, et al.

July 10, 2018.

**AGENCY:** Securities and Exchange Commission (''Commission'').

**ACTION:** Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements''). The requested exemption would permit an investment adviser to hire and replace certain sub-advisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers.

**APPLICANTS:** DMS ETF Trust I, DMS ETF Trust II, and DMS Mutual Fund Trust (each, a ''Trust'' and collectively, the ''Trusts''), each a Delaware statutory trust that will be registered under the Act as an open-end management investment company, and DMS ETF Solutions, LLC (the ''Initial Adviser''), a Delaware limited liability company that will be registered as an investment adviser under the Investment Advisers Act of 1940 (collectively with the Trusts, the ''Applicants'').

**FILING DATES:** The application was filed on March 12, 2018.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 6, 2018, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. Applicants, 130 West 42nd Street, Ste. 1050, New York, NY 10036.

**FOR FURTHER INFORMATION CONTACT:** Christine Y. Greenlees, Senior Counsel, at (202) 551–6879, or Andrea Ottomanelli Magovern, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

#### Summary of the Application

1. An Adviser will serve as the investment adviser to each Subadvised Series pursuant to an investment advisory agreement with the applicable Trust (the ''Investment Management

Agreement'').[1] An Adviser will provide each Subadvised Series with continuous investment management services, subject to the supervision of, and policies established by, the board of trustees of each Trust (each, a ''Board''). Each Investment Management Agreement permits the Adviser, subject to the approval of the applicable Board, to delegate to one or more sub-advisers (each, a ''Sub-Adviser'' and collectively, the ''Sub-Advisers'') the responsibility to provide the day-to-day portfolio investment management of each Subadvised Series, subject to the supervision and direction of the Adviser.[2] The primary responsibility for managing each Subadvised Series will remain vested in the Adviser. The Adviser will hire, evaluate, allocate assets to and oversee the Sub-Advisers, including determining whether a Sub-Adviser should be terminated, at all times subject to the authority of the applicable Board.

2. Applicants request an exemption to permit the Adviser, subject to Board approval, to hire certain Sub-Advisers pursuant to Sub-Advisory Agreements and materially amend existing Sub-Advisory Agreements without obtaining the shareholder approval required under section 15(a) of the Act and rule 18f–2 under the Act.[3] Applicants also seek an exemption from the Disclosure Requirements to permit a Subadvised Series to disclose (as both a dollar amount and a percentage of the Subadvised Series' net assets): (a) The aggregate fees paid to the Adviser and any Wholly-Owned Sub-Adviser; (b) the aggregate fees paid to Non-Affiliated Sub-Advisers; and (c) the fee paid to each Affiliated Sub-Adviser (collectively, ''Aggregate Fee Disclosure'').

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Subadvised Series shareholders and notification about sub-advisory changes and enhanced Board oversight to protect the interests of the Subadvised Series' shareholders.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the application, the Investment Management Agreements will remain subject to shareholder approval while the role of the Sub-Advisers is substantially similar to that of individual portfolio managers, so that requiring shareholder approval of Sub-Advisory Agreements would impose unnecessary delays and expenses on the Subadvised Series.

Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Adviser's ability to negotiate fees paid to the Sub-Advisers that are more advantageous for the Subadvised Series.

For the Commission, by the Division of Investment Management, under delegated authority.

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–15068 Filed 7–13–18; 8:45 am]

**BILLING CODE 8011–01–P**

[1] Applicants request relief with respect to the named Applicants, as well as to any future series of the Trusts and any other registered open-end management investment company or series thereof that: (a) Is advised by the Initial Adviser, its successors, or any entity controlling, controlled by or under common control with the Initial Adviser or its successors (each, an ''Adviser''); (b) uses the multi-manager structure described in the application; and (c) complies with the terms and conditions set forth in the application (each, a ''Subadvised Series''). For purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] A ''Sub-Adviser'' for a Subadvised Series is (1) an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the Adviser for that Subadvised Series, or (2) a sister company of the Adviser for that Subadvised Series that is an indirect or direct ''wholly-owned subsidiary'' of the same company that, indirectly or directly, wholly owns the Adviser (each of (1) and (2) a ''Wholly-Owned Sub-Adviser'' and collectively, the ''Wholly-Owned Sub-Advisers''), or (3) not an ''affiliated person'' (as such term is defined in section 2(a)(3) of the Act) of the Subadvised Series or the Adviser, except to the extent that an affiliation arises solely because the Sub-Adviser serves as a sub-adviser to a Subadvised Series (''Non-Affiliated Sub-Advisers'').

[3] The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Adviser, who is an affiliated person, as defined in Section 2(a)(3) of the Act, of the Subadvised Series, any Trust or of the Adviser, other than by reason of serving as a sub-adviser to one or more of the Subadvised Series (''Affiliated Sub-Adviser'').

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 33157; File No. 812–14926]**

## Charles Schwab & Co. Inc. and Charles Schwab Investment Management, Inc.

July 10, 2018.

**AGENCY:** Securities and Exchange Commission (''Commission'').

**ACTION:** Temporary order and notice of application for a permanent order under section 9(c) of the Investment Company Act of 1940 (''Act'').

**SUMMARY OF APPLICATION:** Applicants have received a temporary order (''Temporary Order'') exempting them from section 9(a) of the Act, with respect to an injunction entered against Charles Schwab & Co. Inc. (''CS&Co.'') on July 9, 2018 by the U.S. District Court for the Northern District of California (''District Court''), in connection with a consent order between CS&Co. and the Commission, until the Commission takes final action on an application for a permanent order (the ''Permanent Order,'' and with the Temporary Order, the ''Orders''). Applicants also have applied for a Permanent Order.

**APPLICANTS:** CS&Co. and Charles Schwab Investment Management, Inc. (''CSIM'') (each an ''Applicant'' and together, the ''Applicants'').

**FILING DATE:** The application was filed on July 2, 2018.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 6, 2018 and should be accompanied by proof of service on Applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090; Applicants: Charles Schwab & Co. Inc.: 211 Main Street, San Francisco, CA 94105; Charles Schwab Investment

Management, Inc.: 211 Main Street, San Francisco, CA 94105.

**FOR FURTHER INFORMATION CONTACT:** Thankam A. Varghese, Attorney-Adviser, Kyle R. Ahlgren, Senior Counsel, or Holly L. Hunter-Ceci, Assistant Chief Counsel, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:** The following is a temporary order and a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

## Applicants' Representations

1. CS&Co. is a California corporation registered as a broker-dealer under the Securities Exchange Act of 1934, as amended (''Exchange Act''), and as an investment adviser under the Investment Advisers Act of 1940, as amended (the ''Advisers Act''). CS&Co. serves as the principal underwriter for 85 open-end management investment companies registered under the Act (''Open-End Funds''). CSIM is a Delaware corporation registered as an investment adviser under the Advisers Act that serves as investment adviser to 107 Open-End Funds. A list of the funds to which CS&Co. and CSIM served as investment adviser or principal underwriter, individual adviser or sub-adviser as of June 1, 2018 (the ''Funds'') is appended to the Application.

2. CS&Co. and CSIM are wholly-owned subsidiaries of The Charles Schwab Corporation (''CS''), a Delaware corporation headquartered in San Francisco, California and listed on the New York Stock Exchange. CS is a savings and loan holding company incorporated in 1986 that engages through its subsidiaries in wealth management, securities brokerage, banking, asset management, custody, and financial advisory services.

3. While no existing company of which CS&Co. is an ''affiliated person'' within the meaning of section 2(a)(3) of the Act (''Affiliated Person''), other than CS&Co. and CSIM (the ''Fund Servicing Applicants'') currently serves as an investment adviser (as defined in section 2(a)(20) of the Act) to, or depositor of, any registered investment company under the Act, employees' securities company or investment company that has elected to be treated as a business development company under the Act, or as a principal underwriter (as defined in section 2(a)(29) of the Act) for any Open-End Fund, unit investment trust registered under the Act (''UIT''), or face-amount certificate company registered under the Act (''FACC'') (such activities, the ''Fund Servicing Activities''), Applicants request that any relief granted by the Commission pursuant to the application also apply to any existing company of which CS&Co. is an Affiliated Person and to any other company of which CS&Co. may become an Affiliated Person in the future (together with the Fund Servicing Applicants, the ''Covered Persons'') with respect to any activity contemplated by section 9(a) of the Act.[1]

4. On July 2, 2018, the Commission filed a complaint in the District Court (the ''Complaint'') alleging violations of section 17(a) of the Exchange Act and rule 17a–8 thereunder. CS&Co. agreed to consent to the entry of a judgment by the District Court against CS&Co. (the ''Final Judgment''). The Complaint alleges that, in violation of section 17(a) of the Exchange Act and rule 17a–8 thereunder, CS&Co. failed to file Suspicious Activity Reports (''SARs'') on suspicious transactions by independent advisers that CS&Co. terminated from its custodial platform (''Advisers''). Such Advisers were not affiliated or associated with CS&Co. CS&Co. terminated the Advisers for engaging in activity CS&Co. determined violated its internal policies and presented risk to CS&Co. or its customers. The Complaint alleges that: (1) CS&Co.'s failure to file SARs during the 2012–2013 time period resulted from its inconsistent implementation of policies and procedures for identifying reportable transactions under the SAR rule (31 CFR 1023.320(a)) when CS&Co. investigated and terminated Advisers from its custodial platform; (2) although CS&Co. took steps to investigate and terminate Advisers, CS&Co. did not have clear or consistent policies for the types of activities for which SARs need to be filed; and (3) in a number of cases in which Advisers were terminated and there was reason for CS&Co. to suspect fraudulent activity, CS&Co. applied an unreasonably high standard for determining whether to file a SAR on the suspicious transactions.

5. Concurrently with the filing of the Complaint, CS&Co. presented to the District Court an executed Consent of the Defendant Charles Schwab & Co. Inc. to Entry of Final Judgment (the ''Consent''), consenting to the Final Judgment. The Final Judgment permanently restrains and enjoins CS&Co from violating section 17(a) of the Exchange Act and rule 17a–8 thereunder (the ''Injunction'') and ordered CS&Co. to pay a civil penalty in the amount of $2,800,000.

## Applicants' Legal Analysis

1. Section 9(a)(2) of the Act provides, in pertinent part, that a person may not serve or act as, among other things, an investment adviser or depositor of any registered investment company or as principal underwriter for any registered open-end investment company, UIT, or FACC, if such person ''. . . by reason of any misconduct, is permanently or temporarily enjoined by order, judgment, or decree of any court of competent jurisdiction from acting as an underwriter, broker, dealer, investment adviser, municipal securities dealer, bank, transfer agent, credit rating agency or entity or person required to be registered under the Commodity Exchange Act, or as an affiliated person, salesman, or employee of any investment company, bank, insurance company, or entity or person required to be registered under the Commodity Exchange Act, or from engaging in or continuing any conduct or practice in connection with any such activity or in connection with the purchase or sale of any security.'' Section 9(a)(3) of the Act makes the prohibitions of section 9(a)(2) applicable to a company, any affiliated person of which has been disqualified under the provisions of section 9(a)(2). Section 2(a)(3) of the Act defines ''affiliated person'' to include, among others, any person directly or indirectly controlling, controlled by, or under common control with, the other person. The Injunction would result in a disqualification of CS&Co. from acting in the capacities specified in section 9(a)(2) because CS&Co. would be permanently enjoined by the District Court from engaging in or continuing certain conduct and/or practices in connection with the offer or sale of any security. The Injunction would also result in the disqualification of CSIM under section 9(a)(3) because CS&Co. is an Affiliated Person of CSIM within the meaning of section 2(a)(3) of the Act and would be subject to an injunction described in section 9(a)(2). Other Covered Persons similarly would be disqualified pursuant to section 9(a)(3) were they to act in any of the capacities listed in section 9(a).

2. Section 9(c) of the Act provides that, upon application, the Commission shall by order grant an exemption from the disqualification provisions of

[1] The Fund Servicing Applicants and other Covered Persons may, if the Orders are granted, in the future act in any of the capacities contemplated by section 9(a) of the Act subject to the applicable terms and conditions of the Orders.

section 9(a) of the Act, either unconditionally or on an appropriate temporary or other conditional basis, to any person if that person establishes that: (1) The prohibitions of section 9(a), as applied to the person, are unduly or disproportionately severe; or (2) the conduct of the person has been such as not to make it against the public interest or the protection of investors to grant the exemption. Applicants have filed an application pursuant to section 9(c) seeking a Temporary Order and a Permanent Order exempting the Fund Servicing Applicants and other Covered Persons from the disqualification provisions of section 9(a) of the Act. Applicants and other Covered Persons may, if the relief is granted, in the future act in any of the capacities contemplated by section 9(a) of the Act subject to the applicable terms and conditions of the Orders.

3. Applicants believe they meet the standards for exemption specified in section 9(c). Applicants assert that: (i) The scope of the misconduct was limited and did not involve any of the Fund Servicing Applicants performing Fund Service Activities, or any Fund with respect to which the Fund Servicing Applicants engaged in Fund Servicing Activities or their respective assets; (ii) application of the statutory bar would result in material economic losses, and the operations of the Funds would be disrupted as they sought to engage new underwriters, advisers and/or sub-advisers, as the case may be; (iii) the prohibitions of section 9(a), if applied to the Fund Servicing Applicants and other Covered Persons, would be unduly or disproportionately severe; and (iv) the Conduct did not constitute conduct that would make it against the public interest or protection of investors to grant the exemption from section 9(a).

4. Applicants assert that the Conduct did not implicate any Fund Servicing Activities and did not involve any Fund or the assets of any Fund with respect to which any Applicants provide Fund Servicing Activities. Applicants further note that none of the CS&Co. employees who were directly responsible for determining whether a SAR filing was required for the Advisers had any involvement in Fund Servicing Activities, and that no such person remains in the employ of any of the Fund Servicing Applicants.

5. Applicants assert that neither the protection of investors nor the public interest would be served by permitting the section 9(a) disqualifications to apply to the Fund Servicing Applicants because those disqualifications would deprive the Funds of the advisory or sub-advisory and underwriting services that shareholders expected the Funds would receive when they decided to invest in the Funds. Applicants also assert that the prohibitions of section 9(a) could operate to the financial detriment of the Funds and their shareholders, which would be an unduly and disproportionately severe consequence given that the Conduct did not implicate any of the Fund Servicing Activities. Applicants further assert that the inability of the Fund Servicing Applicants to continue providing investment advisory and underwriting services to Funds would result in the Funds and their shareholders facing other potential hardships, as described in the application.

6. Applicants assert that if the Fund Servicing Applicants were barred under section 9(a) from providing investment advisory and underwriting services to the Funds and were unable to obtain the requested exemption, the effect on their businesses and employees would be severe. Applicants represent that CS&Co. has committed capital and other resources to establish expertise in underwriting the securities of Open-End Funds and to establish distribution arrangements for Open-End Fund shares. Applicants further represent that without relief under section 9(c), CS&Co. would lose the greater part of its business, potentially leading to sales force layoffs and placing CS&Co. at a competitive disadvantage to other distributors who can offer intermediaries a full menu of products. Applicants further represent CSIM has committed substantial capital and other resources to establishing expertise in advising Funds, and that investment advisory services provided to Funds represents more than 94.9% of its assets under management (as of March 31, 2018).

7. Applicants represent that: (1) None of the current or former directors, officers or employees involved in Fund Servicing Activities of the Fund Servicing Applicants had any involvement in the Conduct; (2) none of the CS&Co. employees who were directly responsible for determining whether a SAR filing was required for the Advisers had any involvement in Fund Servicing Activities, and that no such person remains in the employ of any of the Fund Servicing Applicants; and (3) because the Conduct did not involve Fund Servicing Activities, shareholders of Funds were not affected any differently than if those Funds had received services from any other non-affiliated investment adviser or principal underwriter.

8. Applicants represent that CS&Co. has taken substantial remedial actions to address the conduct at issue in the Complaint and Final Judgment. As further detailed in the Application, such remedial actions include improving CS&Co.'s regulatory compliance program with an emphasis on SAR compliance, increasing the number of employees dedicated to anti-money laundering and fraud prevention (including employees with law enforcement backgrounds), and increasing the quantity and quality of internal AML and SAR training.

9. As a result of the foregoing, Applicants submit that granting the exemption as requested in the application is consistent with the public interest and the protection of investors.

10. To provide further assurance that the exemptive relief being requested herein would be consistent with the public interest and the protection of the investors, Applicants agree that they will, as soon as reasonably practical following the entry of the Injunction, distribute to the boards of trustees of the Funds (''Boards'') written materials describing the circumstances that led to the Injunction, as well as any impact on the Funds and the application. The written materials will include an offer to discuss the materials at an in-person meeting with the Boards, including the trustees who are not ''interested persons'' of the Funds as defined in section 2(a)(19) of the Act and their ''independent legal counsel'' as defined in rule 0–1(a)(6) under the Act. Applicants undertake to provide the Boards with all information concerning the Injunction and the application as necessary for those Funds to fulfill their disclosure and other obligations under the U.S. federal securities laws and will provide them a copy of the Final Judgment as entered by the District Court.

11. Applicants state that none of the Applicants nor any of their affiliates have previously applied for orders under section 9(c) of the Act.

**Applicants' Conditions**

Applicants agree that any order granted by the Commission pursuant to the application will be subject to the following conditions:

1. Any temporary exemption granted pursuant to the Application shall be without prejudice to, and shall not limit the Commission's rights in any manner with respect to, any Commission investigation of, or administrative proceedings involving or against, Covered Persons, including, without limitation, the consideration by the Commission of a permanent exemption

from section 9(a) of the Act requested pursuant to the Application or the revocation or removal of any temporary exemptions granted under the Act in connection with the application.

2. Each Applicant and Covered Person will adopt and implement policies and procedures reasonably designed to ensure that it will comply with the terms and conditions of the Orders within 60 days of the date of the Permanent Order.

3. CS&Co. will comply with the terms and conditions of the Consent.

4. The Applicants will provide written notification to the Chief Counsel of the Commission's Division of Investment Management with a copy to the Chief Counsel of the Commission's Division of Enforcement of a material violation of the terms and conditions of the Orders and Consent within 30 days of discovery of the material violation.

**Temporary Order**

The Commission has considered the matter and finds that Applicants have made the necessary showing to justify granting a temporary exemption.

Accordingly,

*It is hereby ordered*, pursuant to section 9(c) of the Act, that the Applicants and any other Covered Persons are granted a temporary exemption from the provisions of section 9(a), effective as of the date of the Injunction, solely with respect to the Injunction, subject to the representations and conditions in the application, until the Commission takes final action on their application for a permanent order.

By the Commission.

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–15078 Filed 7–13–18; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–83616; File No. SR–NYSEARCA–2018–51]**

## Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

July 10, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 2, 2018, 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. 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 modify the NYSE Arca Options Fee Schedule (''Fee Schedule''). The Exchange proposes to implement the fee change effective July 2, 2018. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of this filing is to modify the Fee Schedule, effective July 2, 2018, to provide an incentive for Floor Brokers to bring business to the Trading Floor in the newly listed options on the NYSE FANG+ Index (''NYSE FANG+''), which trades under the symbol FAANG.

The Exchange proposes to introduce rebates for Floor Broker organizations that execute a certain number of FAANG contract sides on the Exchange in a calendar month, based on the highest Tier achieved (the ''Rebate'').

The volume Tiers, and the associated proposed Rebate, are set forth as follows:

FAANG REBATE

| Tier | Floor broker FAANG executions | Rebate |
|---|---|---|
| 1 | From 200 to 999 contract sides | ($1,000) |
| 2 | From 1,000 to 1,999 contract sides | (2,500) |
| 3 | 2,000 to 19,999 contract sides | (5,000) |
| 4 | 20,000 or more contract sides | (10,000) |

The Exchange believes the proposed Rebate would further the Exchange's goal of introducing new products to the marketplace by encouraging trading in this index, in particular by encouraging Floor Brokers to bring business to the Trading Floor, which would in turn, benefit all market participants through increased liquidity and more opportunities to trade.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act, in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes the proposal to introduce a Floor Broker Rebate for executing a certain number of options contract sides on NYSE FANG+ is reasonable, equitable and not unfairly discriminatory for the following reasons. The Exchange believes the proposed rebates, which apply equally to all Floor Broker transactions in NYSE FANG+, regardless of account type, to

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

be reasonable and equitable because business brought to the Trading Floor may be on behalf of any market participant. In addition, such orders benefit all market participants by providing more trading opportunities, which attracts Market Makers, Customers and other participants. An increase in activity, in turn, facilitates tighter spreads, which may result in a corresponding increase in order flow from all market participants.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

In accordance with Section 6(b)(8) of the Act, 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 Exchange believes the proposed rebates for Floor Broker organizations that achieve the proposed Rebate would not place an unfair burden on competition as it would apply to all similarly situated Floor Brokers, and is applicable to business from all account types. The Exchange also believes the proposed Rebate is procompetitive as it would further the Exchange's goal of introducing new products to the marketplace and encouraging Floor Brokers to bring business to the Trading Floor, which would in turn, benefit all market participants. Market participants that do not wish to trade in NYSE FANG+ are not obliged to do so.

The Exchange does not believe that the proposed change will impair the ability of any market participants or competing order execution venues to maintain their competitive standing in the financial markets. Further, the proposed Rebate would be applied to all similarly situated participants (*i.e.,* Floor Brokers), and, as such, the proposed change would not impose a disparate burden on competition either among or between classes of market participants.

*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**

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [4] of the Act and subparagraph (f)(2) of Rule 19b–4 [5] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [6] of the Act to determine whether the proposed rule change should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2018–51 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2018–51. 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 website (*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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2018–51 and should be submitted on or before August 6, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–15082 Filed 7–13–18; 8:45 am]

**BILLING CODE 8011–01–P**

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(2).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–83617; File No. SR–NYSEAMER–2018–36]**

## Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Modify the NYSE American Options Fee Schedule

July 10, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 2, 2018, NYSE American LLC (the ''Exchange'' or ''NYSE American'') 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 modify the NYSE American Options Fee Schedule (''Fee Schedule''). The Exchange proposes to implement the fee change effective July 2, 2018. The proposed change is available on the Exchange's

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

### *A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of this filing is to modify the Fee Schedule, effective July 2, 2018, to provide an incentive for Floor Brokers to bring business to the Trading Floor in the newly listed options on the NYSE FANG+ Index (''NYSE FANG+''), which trades under the symbol FAANG.

The Exchange proposes to introduce rebates for Floor Broker organizations that execute a certain number of FAANG contract sides on the Exchange in a calendar month, based on the highest Tier achieved (the ''Rebate'').

The volume Tiers, and the associated proposed Rebate, are set forth as follows:

FAANG REBATE

| Tier | Floor broker FAANG executions | Rebate |
|---|---|---|
| 1 | From 200 to 999 contract sides | ($1,000) |
| 2 | From 1,000 to 1,999 contract sides | (2,500) |
| 3 | 2,000 to 19,999 contract sides | (5,000) |
| 4 | 20,000 or more contract sides | (10,000) |

The Exchange believes the proposed Rebate would further the Exchange's goal of introducing new products to the marketplace by encouraging trading in this index, in particular by encouraging Floor Brokers to bring business to the Trading Floor, which would in turn, benefit all market participants through increased liquidity and more opportunities to trade.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act, in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes the proposal to introduce a Floor Broker Rebate for executing a certain number of options contract sides on NYSE FANG+ is reasonable, equitable and not unfairly discriminatory for the following reasons. The Exchange believes the proposed rebates, which apply equally to all Floor Broker transactions in NYSE FANG+, regardless of account type, to be reasonable and equitable because business brought to the Trading Floor may be on behalf of any market participant. In addition, such orders benefit all market participants by providing more trading opportunities, which attracts Market Makers, Customers and other participants. An increase in activity, in turn, facilitates tighter spreads, which may result in a corresponding increase in order flow from all market participants.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

In accordance with Section 6(b)(8) of the Act, 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 Exchange believes the proposed rebates for Floor Broker organizations that achieve the proposed Rebate would not place an unfair burden on competition as it would apply to all similarly situated Floor Brokers, and is applicable to business from all account types. The Exchange also believes the proposed Rebate is procompetitive as it would further the Exchange's goal of introducing new products to the marketplace and encouraging Floor Brokers to bring business to the Trading Floor, which would in turn, benefit all market participants. Market participants that do not wish to trade in NYSE FANG+ are not obliged to do so.

The Exchange does not believe that the proposed change will impair the ability of any market participants or competing order execution venues to maintain their competitive standing in the financial markets. Further, the proposed Rebate would be applied to all similarly situated participants (*i.e.,* Floor Brokers), and, as such, the proposed change would not impose a disparate burden on competition either among or between classes of market participants.

### *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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [4] of the Act and subparagraph (f)(2) of Rule 19b–4 [5] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [6] of the Act 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

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(2).

[6] 15 U.S.C. 78s(b)(2)(B).

change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2018–36 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2018–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2018–36 and should be submitted on or before August 6, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–15083 Filed 7–13–18; 8:45 am]

**BILLING CODE 8011–01–P**

[7] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meeting

**TIME AND DATE:** 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 an Open Meeting on July 18, 2018 at 10:00 a.m.

**PLACE:** The meeting will be held in the Auditorium, Room LL–002 at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

**STATUS:** This meeting will begin at 10:00 a.m. (ET) and will be open to the public. Seating will be on a first-come, first-served basis. Visitors will be subject to security checks. The meeting will be webcast on the Commission's website at *http://www.sec.gov.*

**MATTERS TO BE CONSIDERED:** The subject matters of the Open Meeting will be the Commission's consideration of:

1. Whether to adopt an amendment to Securities Act Rule 701(e), as mandated by the Economic Growth, Regulatory Relief, and Consumer Protection Act.

2. Whether to issue a concept release requesting comment on potential revisions to Securities Act Rule 701 and Securities Act Form S–8.

3. Whether to propose amendments to the disclosure requirements in Rule 3–10 and Rule 3–16 of Regulation S–X.

4. Whether to adopt amendments to Rule 3a1–1 and Regulation ATS and new Form ATS–N under the Securities Exchange Act of 1934 related to certain alternative trading systems.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

**CONTACT PERSON FOR MORE INFORMATION:** For further information, please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: July 11, 2018.

**Lynn M. Powalski,**

*Deputy Secretary.*

[FR Doc. 2018–15233 Filed 7–12–18; 4:15 pm]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–83619; File No. SR–MIAX–2018–14]**

### Self-Regulatory Organizations: Notice of Filing of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade on the Exchange Options on the SPIKES™ Index

July 11, 2018.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 28, 2018, Miami International Securities Exchange, LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit 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 list and trade on the Exchange options on the SPIKES™ Index (''SPIKES'' or the ''Index''), a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust. The Exchange also proposes to list and trade short-term, quarterly, and long-term options on SPIKES. Options on SPIKES will be cash-settled and will have European-style exercise provisions.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/,* at MIAX Options' principal office, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange recently adopted generic rules relating to the listing and trading of cash-settled index options on the Exchange.[3] The Exchange now proposes to amend its rules to provide for the listing and trading on the Exchange of options on the Index. The Index measures expected 30-day volatility of the SPDR S&P 500 ETF Trust (commonly known and referred to by its ticker symbol, ''SPY''). Options on the Index will be cash-settled and will have European-style exercise provisions. In addition to regular options, the Exchange proposes to also list short-term, quarterly, and long-term options on the Index. The Index is calculated using published real-time prices and bid/ask quotes of SPY options. The Index represents annualized expected volatility and is quoted in percentage points.

Index Design and Composition

The calculation of the Index is based on the methodology developed by T3i Pty Ltd, a firm that develops proprietary indexes, including derivatives-based indexes and options-enhanced indexes. The Index will be calculated and maintained by the Exchange. The Index measures expected 30-day volatility of SPY, historically the largest and most actively traded ETF in the United States as measured by its assets under management and the value of shares traded.

Like most indices, the Index has a defined rules-based approach to selecting components—a series of options on the SPY—and weighting them to derive a single price for the Index.

Therefore, the formula for expected T-term variance is as follows:

$$\sigma^2 = \frac{1}{T}\left[2e^{RT}\sum_i \frac{\Delta K_i p_i}{K_i^2} - \left(\frac{e^{RT}\,(p_{ATM}^{c} - p_{ATM}^{p})}{K_{ATM}}\right)^2\right]$$

WHERE:

$T$ Time to options expiration (in years, with 1-second precision)[4]

$K_i, p_i$ A list of unique options strikes, ordered from lowest to highest, and corresponding options prices;[5] of a call if $K_i > K_{ATM}$; and of a put if $K_i < K_{ATM}$; if $K_i = K_{ATM}$ then an average between the ATM put and call prices

$\Delta K_i$ Half the difference between the strikes on either side of $K_i$;

$$\Delta K_i = \frac{(K_{i+1} - K_{i-1})}{2}$$

For the last (highest and lowest) selected strikes, $\Delta K_i$ is simply the absolute difference between $K_i$ and the nearest selected option's strike

$R$ Risk-free interest rate to option's expiration

$p_{ATM}^{c}$ Price of the at-the-money (ATM) call option

$p_{ATM}^{p}$ Price of the ATM put option

$K_{ATM}$ Strike closest to the point where linearly interpolated call and put prices intersect.

The Index is calculated using only standard options on SPY that expire on the third Friday of each calendar month. Although weekly options on SPY are available, these are not used in the calculation of the Index.

The calculation linearly interpolates between the variances of two monthly expirations—near-term (the closest expiration more than two full days into the future) and next-term (the monthly expiration following the near-term). This expiration selection method is used to avoid using highly irregular option prices close to the options settlement date. The 30-day point is typically in between these two expirations and the Index is interpolated between the volatilities of these two terms. When the closest

[3] *See* Securities Exchange Act Release No. 81739 (September 27, 2017), 82 FR 46111 (October 3, 2017) (SR–MIAX–2017–39) (Order approving the adoption of rules relating to trading in index options).

[4] Since the SPIKES Index is calculated on a real-time basis, the Exchange uses 1-second precision to measure time in years (which is expressed to at least eight decimal places, by dividing the number of seconds to option expiration by the total number of seconds in a year).

[5] This price is also known as the Reference Price, as defined and discussed in more detail below, in the following subsection 1, Determine Option Prices.

expiration is too close to expiry (less than two full days), rolling to the third-closest expiration occurs. This rolling rule serves to reduce spurious variability in the Index by means of minimizing the period of ''extrapolation'' between the two expirations. The switch from closest to third-closest expiry rarely has any noticeable impact on the actual Index value, as the weight of the switched term is close to zero. The following describes the methodology used to price the Index in greater detail.

1. Determine Option Prices

SPIKES uses a proprietary ''price dragging'' technique to determine the ongoing price for each individual option used in the calculation of the Index (''Reference Price''), to calculate the Index, as follows:

- Initially set all prices to 0;
- If there is a trade, the price of the option is always set to the trade price;
- If there is not yet a trade, on the opening quote, the opening bid is used as the current price;
- For newly-placed ask (bid) quotes, if the ask (bid) is lower (higher) than current Reference Price, the option price is set to ask (bid).

The Exchange believes that this method should materially reduce erratic movements of the Index value as quotations on out-of-the-money (''OTM'') options are rapidly altered during times of low liquidity. The Exchange believes that this method is a material enhancement over existing calculation methodologies, and should result in improved Index stability by smoothing out options price inputs into the Index calculation, especially as options quotes are rapidly changing.

An example of the price dragging technique is given below:

| Time | Market | SPIKES input [6] | Change in SPIKES input | Midpoint input | Change in midpoint input | Difference b/t SPIKES input and midpoint input |
|---|---|---|---|---|---|---|
| 9:30:00 | 0 x 0 | 0.00 | | 0.00 | | 0.00 |
| 9:31:10 | 2.35 x 2.65 | 2.35 | | 2.50 | | 0.15 |
| 9:31:10 | Trade @ 2.38 | 2.38 | | 2.50 | | 0.12 |
| | | | .03 | | | |
| 9:33:01 | 2.31 x 2.65 | 2.38 | | 2.48 | | 0.10 |
| | | | | | .02 | |
| 9:33:48 | 2.31 x 2.39 | 2.38 | | 2.35 | | 0.03 |
| | | | | | .13 | |
| 9:36:41 | Trade @ 2.37 | 2.37 | | 2.35 | | 0.02 |
| | | | .01 | | | |
| 9:38:34 | 2.32 x 2.40 | 2.37 | | 2.36 | | 0.01 |
| | | | | | .01 | |
| 9:38:52 | 2.00 x 6.00 | 2.37 | | 4.00 | | 1.63 |
| | | | | | 1.64 | |
| 9:39:02 | Trade @ 3.10 | 3.10 | | 4.00 | | 0.90 |
| | | | .73 | | | |
| 9:39:20 | 3.05 x 3.50 | 3.10 | | 3.275 | | 0.175 |
| | | | | | 0.725 | |

The example shows a hypothetical market for a specific option used as an input to SPIKES. The results of price dragging are shown in the column ''SPIKES Input,'' and a hypothetical result using an alternative method of calculating the option input price using the midpoint method is shown in the column ''Midpoint Input.'' The difference between the result using the SPIKES Input and the Midpoint Input is shown in the ''Difference b/t SPIKES Input and Midpoint Input Column.'' The shaded cells illustrate changes in the input prices of the two methods after each update to the market. The Exchange believes that the example illustrates that, given the hypothetical market prices, the price dragging technique results in a smoother Index price because it relies primarily on trade prices (which are more indicative of actual value), only using quote prices when a quote bid is higher than the last trade or a quote offer is lower than the last trade. Additionally, the Index performance has been evaluated using alternative calculation methodologies. This evaluation included a comparison of the performance of the Index when calculated using the price dragging technique, versus the performance of the Index when calculated using an alternative midpoint method, and covered periods of both low and high volatility in SPY. The Exchange believes that the price dragging technique consistently outperformed the midpoint method, as measured by the Index's overall stability and smoothness of price changes, resulting from primarily relying on trade prices (which are more indicative of actual value).

The price dragging technique is used to determine the Reference Price for each individual option used in the Index calculation. The Exchange believes that this technique is a material enhancement that may improve Index stability by smoothing out options price inputs into the Index calculation, especially as options quotes are rapidly changing. The price dragging technique is used for intraday calculation of the Index. The Exchange believes that the price dragging technique may be a more accurate and effective way to determine the Index value because the primary factor considered when updating the Reference Price is whether or not a trade has occurred. If a trade occurred, the Reference Price is set to the trade price. This methodology represents a Reference Price which is based on a ''meeting of the minds,'' or the creation of a contract. The Exchange believes that this more accurately represents the fair value at that given time, and thus will benefit investors and market participants trading options on the Index.

A competing volatility index uses an alternative method for calculating its reference price. Specifically, that competing volatility index utilizes the mid-point of the bid and ask and only updates the reference price when there is a change in the bid or ask. The

[6] This value is also referred to as the Reference Price, as defined above.

Exchange believes that this methodology could be less reliable because it creates the potential for skewed reference prices in the event of a wide market. Options are often quoted in bulk by market makers, which in some cases, causes a divergence from the orthodox supply-demand dynamics as quotes are constantly updated across a series of strikes throughout the day. As a result, there can be more notable movements within the bid/ask spread that impact the calculation of an index based on mid-point prices.

Therefore, the Exchange believes that the price dragging technique may create a more accurate and stable Index value and may better represent volatility in the market by emphasizing the actual trade price versus simply the midpoint spread. Furthermore, the Exchange believes that the enhanced feature may provide greater consistency in the marketplace because the price dragging technique results in a Reference Price that is supported by the fair market value at the time versus using the mid-point, which is not necessarily an accurate representation of the fair market value at the time.

2. Select the Options

Another key feature of SPIKES is its exclusion rule (truncation method). The exclusion rule determines how far away from the money to exclude strikes from the volatility calculation. For each of the expirations, the securities to be used in the calculation are selected by removing in-the-money and OTM options, as follows:

- To determine the ATM strike, find the intersection of the put and call linearly interpolated price curves. Select the strike closest to the value of the intersection of the curves—this becomes the ATM strike. If the intersection falls exactly in the middle of two strikes, or if the whole segments overlap (*i.e.,* when four neighboring calls and puts have the same price), use the lower strike. In case of more than one intersection point (in rare cases of highly irregular market prices), use the one closest to the current value of SPY.
- Use all listed puts below the ATM strike and all listed calls above the ATM strike, and both the ATM call and put. When two consecutive option prices of $0.05 or less are encountered when moving away from the ATM, exclude all the strikes beyond that level, from each of the put and call side.

A competing volatility index that uses the midpoint for its option input prices uses a different exclusion rule, which similarly moves away from the ATM, but excludes individual strikes if they have no bid, and excludes all the strikes beyond two consecutive no bid strikes. A comparison of a hypothetical list of put option inputs and the resulting inclusion decision is given below.

| Strike | SPIKES input[7] | SPIKES input included? | Market | VIX input | VIX input included? |
|---|---|---|---|---|---|
| 201 | 0.06 | Include | 0.05 x 0.07 | 0.06 | Include. |
| 200.5 | 0.06 | Include | 0.05 x 0.07 | 0.06 | Include. |
| 200 | 0.05 | Include | 0.05 x 0.07 | 0.06 | Include. |
| 199.5 | 0.04 | Include | 0.04 x 0.06 | 0.05 | Include. |
| 199 | 0.05 | Exclude | 0 x 0.11 | 0.055 | Exclude. |
| 198.5 | 0.03 | Exclude | 0.01 x 0.1 | 0.055 | Include. |
| 198 | 0.04 | Exclude | 0.02 x 0.08 | 0.05 | Include. |
| 197.5 | 0.03 | Exclude | 0.01 x 0.07 | 0.04 | Include. |
| 197 | 0.04 | Exclude | 0.01 x 0.06 | 0.035 | Include. |
| 196.5 | 0.02 | Exclude | 0 x 0.05 | 0.025 | Exclude. |
| 196 | 0.01 | Exclude | 0.01 x 0.06 | 0.035 | Include. |
| 195.5 | 0.01 | Exclude | 0 x 0.05 | 0.025 | Exclude. |

The purpose of the exclusion rule is to remove option inputs from the calculation that could be deemed less reliable and thus potentially negatively impact the calculation outcome. The Exchange believes that its exclusion methodology is a material enhancement over existing methodologies, and should result in a calculation outcome that better reflects the expected measure of volatility.

As discussed previously, the price dragging method reduces the variability of the option inputs. Since the option inputs have reduced variability, and those values are used to determine which strikes make it into the index calculation, the combination of price dragging and exclusion rules work together to, in the Exchange's opinion, create a more reliable Index value.

3. Weight the Options and Estimate Volatility

For each term, the volatility is estimated using the variance swap approximation, with the selected options' prices weighted according to the SPIKES formula:

$$\sigma^2 = \frac{1}{T}\left[2e^{RT}\sum_i \frac{\Delta K_i p_i}{K_i^2} - \left(\frac{e^{RT}\,(p^c_{ATM} - p^p_{ATM})}{K_{ATM}}\right)^2\right]$$

Each eligible option's contribution is proportional to the change in the strike (half the difference between the strike on either side of the option) and the price, and inversely proportional to the square of the option's strike. After calculating for each option, these are summed and multiplied by two times the exponential of the risk free rate times time-to-expiration. The next step is to subtract from this value, the square of, the difference between the ATM call and put prices, times the exponential of the risk free rate times time-to-expiration, divided by the ATM strike. Lastly, divide the result by the time to expiration to arrive at the final value.

4. Calculate the Index

Compute the 30-day weighted average of the near- and next-term variances,

[7] *See supra* note 6.

take the square root, and multiply by 100, as follows:

$$SPIKES = 100 \times \sqrt{\left(\frac{t_1}{t_M}\frac{t_2 - t_M}{t_2 - t_1}\sigma_1^2 + \frac{t_2}{t_M}\frac{t_M - t_1}{t_2 - t_1}\sigma_2^2\right)}$$

$t_1$ Time (in seconds) to near-term expiration
$\sigma_1$ Estimated volatility computed by variance swap approximation, near-term
$t_2$ Time (in seconds) to next-term expiration
$\sigma_2$ Estimated volatility computed by variance swap approximation, next-term
$t_M$ Number of seconds in 30 days (30 × 86,400 = 2,592,000)

Background Information

SPY is the largest and most actively traded ETF in the U.S.[8] According to State Street Global Advisor, the Trustee of SPY, as of May 14, 2018, the net assets under management in SPY was approximately $263 billion; the weighted average market capitalization of the portfolio components was approximately $217 billion; the smallest market capitalization was approximately $3.6 billion (Range Resources Corporation, ticker: RRC), and the largest was approximately $930 billion (Apple, Inc., ticker: AAPL).[9] For the three months ending April 30, 2018, the average daily volume in SPY shares was 119 million, and the average value of shares traded was approximately $31.8 billion.[10] For the same period, the average daily volume in SPY options was approximately 4.2 million contracts.[11] The most recent open interest in SPY options was approximately 23.9 million contracts as of May 14, 2018.[12]

The Exchange believes that, in addition to the other unique and proprietary attributes associated with the Index's calculation and settlement methodology, as well as the Exchange's fully-electronic, transparent, highly-deterministic trading system, using SPY options as the components for a volatility index, in the manner proposed by the Exchange, will offer a number of significant, distinct advantages over other types of volatility indexes. The Exchange believes that the advantages of using SPY options have the potential to result in an extremely liquid volatility product with exceptionally tight spreads, and consequently would not be readily susceptible to fraudulent and manipulative acts. First, SPY options are extremely liquid (they regularly trade 4–5 million contracts a day, and have 20–30 million contracts in open interest). Second, SPY options have consistently tighter bid-ask spreads than SPX options, which are the components for the Cboe Exchange, Inc. (''Cboe'') VIX index. Since SPY options are traded on all 15 option exchanges, it allows market participants to take advantage of arbitrage opportunities across multiple venues. This is in contrast to SPX options which only trade on Cboe, and thus those arbitrage opportunities across venues are not possible. Since SPY options are traded on all 15 option exchanges, at the time of the final settlement of the SPIKES Index on the Exchange,[13] there will be up to 14 other options exchanges open for trading SPY options, thus serving as real-time cross-reference prices for those SPY options included in the Exchange's SPIKES Special Settlement Auction. This is in contrast to SPX options during Cboe's VIX settlement auction, where there are no real-time cross-reference prices for those SPX options included in Cboe's VIX settlement, as SPX options are only traded on one exchange—Cboe. In terms of spreads, SPY spreads are significantly tighter and exhibit much higher consistency with a much narrower range of typical values and far fewer numbers of outliers than SPX. For example, when examining daily closing bid and ask prices of regular monthly options (with time to expiry closest to 30 calendar days) from October 2007 (when SPY options started trading in penny increments) to May 2018, and comparing the following three strike ranges: (A) 1% ATM—at-the-money options within 1% (plus or minus) of the underlying forward price; (B) 1–5% OTM—out-of-the-money options (higher strikes for calls, lower strikes for puts); and (C) 85–95% Puts—far out-of-the-money put options typically included in volatility index calculations, SPY spreads are consistently tighter than SPX spreads, both across strike prices and through time, by a factor of 2 to 4 times (this is after normalizing SPY spreads to SPX spreads, by multiplying SPY spreads by 10). Accordingly, the Exchange believes that these advantages of using SPY options in the manner proposed by the Exchange, when combined with the other features and attributes of the SPIKES Index, have the potential to result in an extremely liquid volatility product with exceptionally tight spreads, and consequently would not be readily susceptible to fraudulent and manipulative acts.

As set forth in Exhibit 3–1, the following are the characteristics of the Index: (i) The initial index value was 13.05 on January 10, 2005; (ii) the index value on May 14, 2018 was 13.44; (iii) the lowest index value since inception was 9.80 and occurred on July 20, 2007; and (iv) the highest index value since inception was 81.85 and occurred on November 20, 2008.

Index Calculation and Maintenance

As noted above, the Index will be maintained and calculated by the Exchange. The level of the Index will reflect the current expected volatility of SPY. The Index will be updated on a real-time basis on each trading day beginning at 9:30 a.m. and ending at 4:15 p.m. (New York time). If the current published value of a component is not available, the last published value will be used in the calculation. Values of the Index will be disseminated to the Options Price Reporting Authority (''OPRA'') at least every 15 seconds during the Exchange's regular trading hours, pursuant to Exchange Rules 1802 and 1803. The Exchange is currently disseminating the cash values of the Index to OPRA under the ticker symbol 'SPIKE' in at least 15 second intervals. In the event the Index ceases to be maintained or calculated, or its values are not disseminated at least every 15 seconds by a widely available source, the Exchange will not list any additional series for trading, and may, for the purpose of maintaining a fair and orderly market and protecting investors, limit transactions in certain options on the Index to closing transactions only.

[8] SPY holds the shares of up to 500 companies listed on U.S. securities exchanges (SPY currently has 506 securities due to multi-share classes for some companies).

[9] *See https://www.spdrs.com/product/fund.seam?ticker=SPY.*

[10] Calculated using data from Thompson Reuters as of May 14, 2018.

[11] Calculated using data from The Options Clearing Corp. as of May 14, 2018.

[12] *Id.*

[13] The final settlement of the SPIKES Index occurs during the SPIKES Special Settlement Auction (defined and discussed below), which commences immediately following the opening of trading on the Exchange.

Exercise and Settlement Value

On the expiration date for expiring SPIKES options, the Exchange will calculate the final settlement value of the Index for expiring SPIKES options. The expiration date for expiring SPIKES options is the same day that the final settlement value of the Index is calculated for those options. This date is the Wednesday that is thirty days prior to the third Friday of the calendar month immediately following the month in which the applicable SPIKES options expire. If that Wednesday or the Friday that is thirty days following that Wednesday is an Exchange holiday, the final settlement value shall be calculated on the business day immediately preceding that Wednesday. The exercise-settlement amount is equal to the difference between the final settlement value of the Index and the exercise price of the option, multiplied by $100. Exercise will result in the delivery of cash on the business day following expiration.

To determine the final settlement value of the Index, the Exchange will perform an Index settlement price calculation which includes all SPY options that expire 30 days after the SPIKES settlement that are included in the settlement (these options are referred to in this rule filing as the ''constituent options''). In order to perform the Index settlement price calculation, each constituent option will be assigned a Settlement Reference Price or ''SRP,'' defined and discussed in more detail below. Each SRP will be determined through a new ''SPIKES Special Settlement Auction,'' which will be conducted once per month, in the constituent options traded on the Exchange, on final settlement day. The SPIKES Special Settlement Auction will utilize the Exchange's standard, existing Opening Process, as defined and fully-described in Exchange Rule 503(f), with a new proposed modification to account for situations where there remains an order imbalance [14] that must be filled at the opening price after the requisite number of iterations of the imbalance process takes place under the Exchange's existing Opening Process (the Exchange's existing Opening Process provides that the Exchange can open with an imbalance after the requisite number of iterations of the imbalance process takes place).[15] This new proposed modification to the Exchange's existing Opening Process to facilitate the execution of this remaining must-fill interest is referred to as the special settlement imbalance process (''SSIP''), which will be governed by new proposed Interpretations and Policies .06 to Exchange Rule 1809, as described more fully below. The Exchange believes that using its fully-electronic and fully-transparent Opening Process functionality, which is accessible to all Members of the Exchange for participation, in highly liquid SPY options (which are simultaneously opening and available for trading on up to 14 other exchanges, thus providing real-time cross-reference prices for the SPY options included in the settlement) to conduct the SPIKES Special Settlement Auction to settle expiring SPIKES options, will offer significant advantages over other types of volatility index auction processes, resulting in a robust Opening Process that presents arbitrage opportunities across multiple venues to drive prices into line and reach equilibrium, and thus consequently would not be readily susceptible to fraudulent and manipulative acts.

The Exchange believes that the SPIKES Special Settlement Auction would not be readily susceptible to fraudulent and manipulative acts for a number of reasons. As discussed more fully below, the Exchange's existing Opening Process runs to completion and precedes the engagement of the new SSIP. The existing Opening Process cannot occur prior to 9:30 a.m. Eastern Time and only begins following the dissemination of a quote or trade in the market for the underlying security.[16] Following the dissemination of a quote or trade in the market for the underlying security, the System will pause for a period of time no longer than one half second to allow the marketplace to absorb this information.[17] When there is an imbalance,[18] the System will broadcast a System Imbalance Message (which includes the symbol, side of the market, quantity of matched contracts, the imbalance quantity, must fill quantity (*i.e.,* the number of contracts that must be filled in order for that option to open on the Exchange at the indicated price), quantity of routable contracts, and price of the affected series) to subscribers of the Exchange's data feeds and begin an Imbalance Timer [19] not to exceed three seconds.[20] Under the existing Opening Process the Exchange may repeat this process up to three times.[21] While the Exchange is conducting its Opening Process, all 14 other option exchanges will also be conducting their opening process for SPY options. As the Exchange works through its process to resolve imbalances under the existing Opening Process, other Exchanges will be open and will serve as real-time cross-reference prices for those SPY options, enabling market participants to send orders to the Exchange if there are pricing anomalies for these SPY options across venues. The longer it takes the Exchange to work through the imbalance, the greater the likelihood that other exchanges will have opened their SPY options market and the natural pressures of a competitive market will help to eliminate any pricing anomalies and aid in eliminating the imbalance on the Exchange. Further, the Exchange's imbalance process is transparent, as every subscriber to the Exchange's data feed receives the imbalance messages, and every Member of the Exchange can participate in the imbalance process.

As previously discussed, on the day the settlement value for the Index is calculated, the Exchange will conduct the SPIKES Special Settlement Auction, using its standard, existing Opening Process for all options on the Exchange, including the constituent options.[22] The following paragraphs provide a high level overview of the Exchange's standard, existing Opening Process, in order to illustrate the complete operation of the SPIKES Special Settlement Auction.

Pursuant to the standard, existing Opening Process, if there are no quotes or orders that lock or cross each other, the System [23] will open by disseminating the Exchange's best bid and offer among quotes and orders that exist in the System at that time. If there are quotes or orders that lock each other, the System will calculate an Expanded Quote Range (''EQR''), as described in Rule 503(f)(2). The EQR represents the limits of the range in which transactions may occur during the Opening Process.[24] The EQR is recalculated any

[14] An ''imbalance'' occurs when there is insufficient liquidity to satisfy all trading interest due an execution at a certain price. *See* Exchange Rule 503(f)(2)(v).

[15] *See* Exchange Rule 503(f)(2)(vii)(B)(5).

[16] *See* Exchange Rule 503(e)(1).

[17] The Exchange notes that the current setting is one half second.

[18] *See supra* note 14.

[19] The Exchange notes that the current Imbalance Timer setting is one second.

[20] *See* Exchange Rule 503(f)(2)(vii).

[21] *See* Exchange Rule 503(f)(2)(vii)(B)(4).

[22] For a complete description of the Exchange's standard, existing Opening Process, refer to Exchange Rule 503, Openings on the Exchange.

[23] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[24] *See* Exchange Rule 503(f)(2)(i). *See also* Exchange Regulatory Circular 2012–02, which sets forth the tables that describe the calculation of the EQR for option classes traded on the Exchange, at *http://www.miaxoptions.com/sites/default/files/*

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time a route timer or Imbalance Timer expires if material conditions of the market (imbalance size, ABBO[25] price and size, liquidity price or size, etc.) have changed during the timer. Once calculated, the EQR represents the limits of the range in which transactions may occur during the Opening Process.[26] The System uses the EQR to determine the highest and lowest price of the opening price range.

To calculate the opening price, the System takes into consideration all valid Exchange quotes and all valid orders, together with other exchanges' markets for the series, and identifies the price at which the maximum number of contracts can trade. If that price is within the EQR and leaves no imbalance, the Exchange will open at that price, executing marketable trading interest as long as the opening price includes only Exchange interest.[27] If the calculated opening price included interest other than solely Exchange interest, the System will broadcast a system imbalance message (which includes the symbol, side of the market, quantity of matched contracts, the imbalance quantity, must fill quantity, quantity of routable contracts, and price of the affected series) to Exchange Members[28] and initiate a ''route timer,'' not to exceed one second.[29]

If all opening and marketable interest cannot be completely executed at or within the EQR without trading at a price inferior to the ABBO, or cannot trade at or within the quality opening market range in the absence of a valid width NBBO,[30] the System will automatically institute an imbalance process.[31] The System will broadcast a system imbalance message (which includes the symbol, side of the market, quantity of matched contracts, the imbalance quantity, must fill quantity, quantity of routable contracts, and price of the affected series) to subscribers of the Exchange's data feeds, and begin an Imbalance Timer, not to exceed three seconds.[32] Market Makers[33] may enter Opening Only (''OPG'') eQuotes,[34] Auction or Cancel (''AOC'') eQuotes,[35] Standard quotes,[36] Opening Orders (''OPG Orders''),[37] AOC Orders[38] and limit orders during the Imbalance Timer. Other Exchange Members may enter OPG Orders, AOC Orders and other order types (except those order types not valid during the Opening Process, as described in Rule 516) during the Imbalance Timer.[39] If, at the conclusion of the timer, quotes and orders submitted during the Imbalance Timer, or other changes to the ABBO, would not allow the entire imbalance amount to trade at the Exchange at or within the EQR without trading at a price inferior to the ABBO, the System will send a new system imbalance message to Exchange Members and initiate a route timer for routable Public Customer orders not to exceed one second. If, during the route timer, interest is received by the System which would allow all interest to trade on the System (*i.e.,* there is no longer an imbalance) at the opening price without trading at a price inferior to other markets, the System will trade and the route timer will end.[40] The System may repeat the imbalance process up to three times (as established by the Exchange).[41] Following completion of the third imbalance process, if there is an opening transaction, any unexecuted contracts from the imbalance not traded or routed will be cancelled back to the entering Member if the price for those contracts crosses the opening price, in effect cancelling that must fill interest.[42] That is the completion of the Exchange's standard, existing Opening Process.

Now, where an imbalance exists in constituent options and the final imbalance process has been conducted as part of the Exchange's standard, existing Opening Process, instead of cancelling that must fill interest back to the entering Member, the Exchange is proposing to conduct the SSIP,[43] where the Exchange will satisfy that must fill interest. The Exchange does not want to cancel any must fill interest, as this liquidity could represent previously hedged interest that must be unwound.

The SSIP is employed to satisfy all liquidity identified as must fill which is creating the imbalance, referred to as the must fill imbalance. The SSIP is an iterative process that is designed to determine a price at which all must fill imbalance interest can be satisfied.[44] In the SPIKES Special Settlement Auction, in addition to any order types that may be regularly accepted by the Exchange, the Exchange will also accept settlement auction only orders (''SAO Orders'') and settlement auction only eQuotes (''SAO eQuotes'') (SAO Orders and SAO eQuotes are collectively referred to as ''SAOs'') at any time after the opening of the Live Order Window (''LOW'')[45] and the Live Quote Window (''LQW''),[46] respectively. SAOs are specific order types that allow a Member to voluntarily tag such order as a SPIKES strategy order, defined below. All orders for participation in the SPIKES Special Settlement Auction that are related to positions in, or a trading strategy involving, SPIKES Index options (''SPIKES strategy orders''), and any change to or cancellation of any such order: (i) Must be received prior to the applicable SPIKES strategy order cut-off time for the constituent option series, as determined by the Exchange, which may be no earlier than the opening of the LOQ or the LQW, and no later than the opening of trading in the series. The Exchange will announce all determinations regarding changes to the applicable SPIKES strategy order cut-off time via Regulatory Circular at least one day prior to implementation (however the Exchange anticipates initially establishing the cut-off time at 9:20 a.m.

*circular-files/MIAX_Opening_Process_and_Pause_Timer.pdf.*

[25] The term ''ABBO'' or ''Away Best Bid or Offer'' means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Rule 1400(f)) and calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

[26] *See* Exchange Rule 503(f)(2)(i).

[27] *See* Exchange Rule 503(f)(2)(iv).

[28] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[29] *See* Exchange Rule 503(f)(2)(iv)(A).

[30] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

[31] *See* Exchange Rule 503(f)(2)(vii).

[32] *See* Exchange Rule 503(f)(2)(vii)(A).

[33] The term ''Market Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[34] An opening only or ''OPG'' eQuote is a quote that can be submitted by a Market Maker only during the Opening as set forth in Rule 503. OPG eQuotes will automatically expire at the end of the Opening Process. *See* Exchange Rule 517(a)(2)(iii).

[35] An Auction or Cancel or ''AOC'' eQuote is a quote submitted by a Market Maker to provide liquidity in a specific Exchange process with a time in force that corresponds with the duration of that event and will automatically expire at the end of that event. *See* Exchange Rule 517(a)(2)(ii).

[36] A Standard quote is a quote submitted by a Market Maker that cancels and replaces the Market Maker's previous Standard quote, if any. *See* Exchange Rule 517(a)(1).

[37] An Opening or ''OPG'' Order is an order that is valid only for the opening process. *See* Exchange Rule 516(h).

[38] An Auction-or-Cancel or ''AOC'' order is a limit order used to provide liquidity during a specific Exchange process with a time in force that corresponds with that event. *See* Exchange Rule 516(b)(4).

[39] *See supra* note 22.

[40] *See* Exchange Rule 503(f)(2)(vii)(B)(2).

[41] *See* Exchange Rule 503(f)(2)(vii)(B)(4).

[42] *See* Exchange Rule 503(f)(2)(vii)(B)(5).

[43] *See* proposed Exchange Rule 503(f)(2)(vii)(B)(5)(a).

[44] *See* proposed Exchange Rule 1809, Interpretations and Policies .06.

[45] The Exchange notes that the current Live Order Window opens at 7:30 a.m.

[46] The Exchange notes that the current Live Quote Window setting opens at 9:25 a.m., however the Exchange plans to open the Live Quote Window for the SPIKES Special Settlement Auction at 8:30 a.m.

Eastern); and (ii) may not be cancelled or modified after the applicable SPIKES strategy order cut-off time, unless the SPIKES strategy order is not executed in the SPIKES Special Settlement Auction and the cancellation or modification is submitted after the SPIKES Special Settlement Auction is concluded (provided that any such SPIKES strategy order may be modified or cancelled after the applicable SPIKES strategy order cut-off time and prior to the applicable non-SPIKES strategy order cut-off time in order to correct a legitimate error, in which case the Member submitting the change or cancellation will prepare and maintain a memorandum setting forth the circumstances that resulted in the change or cancellation and will file a copy of the memorandum with the Exchange no later than the next business day in a form and manner prescribed by the Exchange). In general, the Exchange will consider orders to be SPIKES strategy orders for purposes of Rule 1809 Interpretation and Policy .06, if the orders possess the following three characteristics: (A) Are for options with the expiration that will be used to calculate the exercise or final settlement value of the applicable volatility index option contract; (B) are for options spanning the full range of strike prices for the appropriate expiration for options that will be used to calculate the exercise or final settlement value of the applicable volatility index option contract, but not necessarily every available strike price; and (C) are for put options with strike prices less than the ''at-the-money'' strike price and for call options with strike prices greater than the ''at-the-money'' strike price. They may also be for put and call options with ''at-the-money'' strike prices.

Whether certain orders are SPIKES strategy orders for purposes of Interpretation and Policy .06 depends upon specific facts and circumstances. The Exchange may also deem order types other than those provided above as SPIKES strategy orders if the Exchange determines that to be the case based upon the applicable facts and circumstances.

These requirements are substantially similar to Cboe's requirements for ''strategy orders'' participating in the VIX settlement auction.[47]

The Exchange anticipates that market participants that actively trade SPIKES options may hedge their positions with SPY option series that will also be used to calculate the SPIKES exercise settlement/final settlement value. Market participants holding hedged SPIKES options positions may trade out of their SPY option series on the relevant SPIKES expiration/final settlement date. Specifically, market participants holding short, hedged SPIKES options could liquidate that hedge by selling their SPY options series, while traders holding long, hedged SPIKES options could liquidate their hedge by buying SPY option series. In order to seek convergence with the SPIKE exercise/final settlement value, these market participants may liquidate their hedges by submitting SPIKES strategy orders in the appropriate SPY option series during the SPIKES Special Settlement Auction on the SPIKES expiration/final settlement date.

The SPIKES strategy order cut-off time exists because trades to liquidate hedges can contribute to an order imbalance during the SPIKES Special Settlement Auction in SPY option series on expiration/final settlement dates. For example, traders liquidating hedges could predominantly be on one side of the market and those market participants' orders may create buy or sell order imbalances during the SPIKES Special Settlement Auction in SPY option series on expiration/final settlement dates. As a result of having a SPIKES strategy order cut-off time in place, the Exchange has created a defined window to encourage participation in the SPIKES Special Settlement Auction among market participants who may wish to place off-setting orders against imbalances to which SPIKES strategy orders may have contributed. Additionally, by precluding the modification or cancellation of SPIKES strategy orders from occurring after the cut-off time, the Exchange is ensuring that the order book reflects bona-fide interest for execution, and is a feature designed to prevent manipulation of the final settlement price.

Following is a description of the proposed operation of the SSIP portion of the SPIKES Special Settlement Auction, as set forth in Exchange Rule 1809, proposed Interpretations and Policies .06. To begin the SSIP, the System will broadcast a system imbalance message to all subscribers of the Exchange's relevant data feed and begin an SSIP Imbalance Timer, the duration of which is to be determined by the Exchange, not to exceed ten seconds, and communicated via Regulatory Circular. During the SSIP Imbalance Timer, the System accepts all quote and order types supported during the standard Opening Process. Next, the System will evaluate the must fill imbalance and adjust the EQR by a defined amount by appending to the EQR (adding to offers or subtracting from bids) the EQR value (as previously determined by the Exchange and communicated via Regulatory Circular). During the SSIP, the allowable EQR will be increased .5 times the EQR value upon each iteration of the SSIP. The SSIP will be repeated until a price is reached at which there is no remaining must fill imbalance.

An example of a SPIKES Special Settlement Auction (which utilizes the Exchange's standard, existing Opening Process, as modified by the SSIP), for a constituent option is provided to illustrate the process.

Example

SPY Mar 280 Call—constituent option

The Exchange market for the constituent option is as follows:

| | Bid size | Bid | Offer | Offer size |
|---|---|---|---|---|
| PLMM | 100 | 1.01 | 1.10 | 100 |
| MM1 | 50 | 1.02 | 1.10 | 50 |

The Exchange receives an SAO Order to purchase 500 SPY March 280 contracts with a ''market'' price. Accordingly, there are 150 contracts offered at $1.10 and a market order[48] to buy 500 contracts. This results in the following:

| | |
|---|---|
| Imbalance Quantity | 350 |
| Must Fill Imbalance Quantity | 350 |
| Matched Quantity | 150 |

[47] *See* Cboe Rule 6.2, Hybrid Opening (and Sometimes Closing) System (''HOSS''), Interpretations and Policies .01, Modified Opening Procedure for Series Used to Calculate the Exercise/Final Settlement Values of Volatility Indexes.

[48] A market order is an order to buy or sell a stated number of option contracts at the best price available at the time of execution. *See* Exchange Rule 516(a).

The Exchange's standard Opening Process is used, and because an imbalance exists, the Exchange's Standard Opening Imbalance Process (as defined in Rule 503(f)(2)(vii)) commences. The EQR is expanded by the EQR value of $0.10,[49] becoming $1.02 × $1.20.

After three iterations of the Exchange's Standard Opening Imbalance Process,[50] if the must fill imbalance quantity has not been satisfied, the new SSIP will be employed. (For purposes of this example, assume that all such three iterations have completed and the must fill imbalance quantity still has not been satisfied.)

The SSIP will begin by using an EQR expanded by 1.0 times the EQR value ($0.10). Therefore, the EQR for the first iteration of SSIP is $1.02 × $1.20.

Since no responses have yet been received, a system imbalance message is broadcast to all subscribers of the Exchange's data feeds and the SSIP auction period is started: The following responses are received:

- @20 Milliseconds BD1 response, AOC Order to sell 200 @$1.20 arrives

At the end of the SSIP auction period, the System evaluates the orders and responses to determine if the must fill imbalance quantity can be satisfied at, or within, the EQR.

The Exchange market for the constituent option is as follows:

| | Bid size | Bid | Offer | Offer size |
|---|---|---|---|---|
| PLMM | 100 | 1.01 | 1.10 | 100 |
| MM1 | 50 | 1.02 | 1.10 | 50 |
| BD1 | | | 1.20 | 200 |

The offer of 150 contracts at $1.10 remains and there are now an additional 200 contracts offered at $1.20. This results in the following:

| | |
|---|---|
| Imbalance Quantity | 150 |
| Must Fill Imbalance Quantity | 150 |
| Matched Quantity | 350 |

A must fill imbalance quantity of 150 contracts priced through the EQR remains, as there are a total of 350 contracts offered and a buy order for 500 at the market.

Because an imbalance still exists, a second iteration of the SSIP will begin by expanding the side of the EQR opposite the must fill imbalance quantity quote range, from the original EQR value to the quote range plus 1.5 times the original EQR value ($0.10), becoming $1.25 ($1.10 + $0.15).

A new system imbalance message is broadcast to all subscribers of the Exchange's data feeds and a second SSIP auction period is started:

The following responses are received:

- @500 milliseconds MM2 response, AOC eQuote to sell 1000 @ $1.23 arrives

At the end of the SSIP auction period, the System evaluates the orders and responses to see if the must fill imbalance quantity can be satisfied at, or within, the EQR.

The Exchange market for the constituent option is as follows:

| | Bid size | Bid | Offer | Offer size |
|---|---|---|---|---|
| PLMM | 100 | 1.01 | 1.10 | 100 |
| MM1 | 50 | 1.02 | 1.10 | 50 |
| BD1 | | | 1.20 | 200 |
| MM2 | | | 1.23 | 1000 |

The offer of 150 contracts at $1.10 remains, as well as the 200 contracts offered at $1.20. In addition, there is now an offer to sell 1,000 contracts at $1.23.

In this case, the entire must fill imbalance quantity can be satisfied at $1.23. The SAO Order to purchase 500 contracts at the market price is filled in the following fashion:

- The SAO Order buys 100 from the PLMM @$1.23
- The SAO Order buys 50 from MM1 @ $1.23
- The SAO Order buys 200 from BD1 @ $1.23
- The SAO Order buys 150 from MM2 @$1.23

Once there is no remaining must fill imbalance, SAOs, AOC Orders, AOC eQuotes, OPG Orders, and OPG eQuotes submitted into the SPIKES Special Settlement Auction are cancelled. Any unfilled day limit orders and GTC orders that are priced at the Opening Price are placed on the Book and managed by the System.

As previously discussed, the System will assign an SRP to each constituent option to facilitate the calculation of the final settlement price of the Index. If the System opens the constituent option with a trade, the System assigns the constituent option an SRP equal to the trade price in that option. If there is no locking or crossing interest and the System opens the constituent option without a trade, and the bid-ask spread is at or within a range as defined by the Exchange in an SRP opening width table and communicated via Regulatory Circular, the System assigns the constituent option an SRP equal to the midpoint of the bid and ask prices. If the bid-ask spread is not within a range as defined in the SRP opening width table, the System will conduct an additional process to determine the SRP of the constituent option, as follows.

First, the System will start a settlement reference price timer (''SRPT'') (the duration of which will be defined by the Exchange not to exceed sixty seconds and communicated via Regulatory Circular). If, during the SRPT, there is a trade on the Exchange, the System will set the SRP equal to the trade price. If, during the SRPT, the bid-ask spread changes so that it is within a range defined in the settlement price opening width table, the System will set the SRP equal to the midpoint of the bid and ask price.

[49] The EQR value for options bid $0.00 to $1.00 is $0.05; $1.01 to $2.00 is $0.10; $3.01 to $5.00 is $0.20; $5.01 to $10.00 is $0.30; $10.01 to $20.00 is $0.50; $20.01 to $40.00 is $0.70; and $40.01 and above is $0.90. *See also supra* note 14.

[50] The System may repeat the Standard Opening Imbalance Process up to three times (as established by the Exchange). *See* Exchange Rule 503(f)(2)(vii)(B)(4).

If the SRPT expires, the System will set the SRP equal to the Reference Price (the current price of that option utilizing the cash index calculation formula, described above) of the constituent option if it is equal to or inside the MBBO.[51] If the Reference Price is non-zero and less than the Exchange's bid, then the System will set the SRP equal to the Exchange's bid. If the Reference Price is non-zero and greater than the Exchange's ask, then the System will set the SRP equal to the Exchange's ask. If the Reference Price is zero and if one or both adjacent constituent options have a non-zero SRP, the constituent option will be excluded from the calculation. If the Reference Price is zero and there are multiple adjacent constituent options with a current Reference Price of zero, the System will use the midpoint of the NBBO for the SRP if the NBBO bid-ask spread is at or within a range defined in the settlement price opening width table. If the NBBO bid-ask spread is not within a range defined in the settlement price opening width table, the System will wait for either a trade, or a bid-ask spread that is within a range defined in the settlement price opening width table. Once all constituent options have been assigned an SRP, the System will perform the final settlement price calculation of the Index.

The Exchange believes that this fully-electronic and fully-transparent SPIKES Special Settlement Auction process, which is accessible to all Members of the Exchange for participation, in highly liquid SPY options (which are simultaneously opening and available for trading on 14 other exchanges, thus providing real-time cross-reference prices for the SPY options included in the settlement) to settle expiring SPIKES options, offers significant advantages over other types of volatility auction processes, and will result in a robust opening process that presents arbitrage opportunities across multiple venues to drive prices into line and reach equilibrium, and thus would not be readily susceptible to fraudulent and manipulative acts.

**Contract Specifications**

The contract specifications for options on the Index are set forth in Exhibit 3–2. The Index is a broad-based index, as defined in MIAX Options Rule 1801(k), for the purpose of determining which of the Exchange's rules apply to options on the Index.[52] Options on the Index are European-style and cash-settled. Standard trading hours for index options (9:30 a.m. to 4:15 p.m., New York time) will apply to the Index.[53] The Exchange proposes to apply margin requirements for the purchase and sale of options on the Index that are identical to those applied for other broad-based index options traded on other options exchanges.

The trading of options on the Index will be subject to the trading halt procedures applicable to index options traded on the Exchange.[54] Options on the Index will be quoted and traded in U.S. dollars.[55] Accordingly, all Exchange and Options Clearing Corporation (''OCC'') members shall be able to accommodate trading, clearance and settlement of the Index without alteration. Furthermore, the Exchange believes that OCC will be able to accommodate trading, clearance and settlement of options on the Index without having to obtain any additional approval.

The Exchange proposes that the minimum trading increments for options on the Index shall be $0.05 for series trading below $3, and $0.10 for series trading at or above $3. This is the same pricing convention utilized by Cboe for VIX options. Accordingly, the Exchange is proposing to amend Exchange Rule 404, Series of Option Contracts Open for Trading, by adopting new Interpretations and Policies .11 to specify the minimum trading increments for options on the Index.

The Exchange proposes that there shall be no position or exercise limits for options on the Index. As noted above, the Index will settle using published prices and quotes from its corresponding SPY options. Because the size of SPY options market (as well as the underlying SPY market) is so large, the Exchange believes that there is minimal risk of manipulation by virtue of position size in SPIKES options. The Exchange notes that options on Cboe's VIX are also not subject to any position or exercise limits.[56] Accordingly, the Exchange is proposing to amend Exchange Rule 1804(a) to specify that there will be no position limits and no exercise limits for options on the SPIKES Index.

The Exchange initially proposes to list options on the Index in up to twelve (12) standard monthly expirations. This is the same number of monthly expirations that are permitted for VIX options, pursuant to Cboe Rule 24.9(a).[57] Accordingly, the Exchange is proposing to amend Exchange Rule 1809(a)(3) to permit the listing of up to twelve (12) standard monthly expirations for SPIKES options. The Exchange is also proposing to make changes to Exchange Rule 1809(a)(3), in order to conform the structure of such rule to Cboe's Rule 24.9(a), to allow for the listing of short-term options and quarterly options.

The Exchange proposes to set the minimum strike price interval for options on the Index at $0.50 where the strike price is less than $15, $1 or greater where the strike price is between $15 and $200, and $5 or greater where the strike price is greater than $200. The Exchange believes that $0.50 and $1 strike price intervals will provide investors with greater flexibility by allowing them to establish positions that are better tailored to meet their investment objectives. Further, as proposed, when new series of options on the Index with a new expiration date are opened for trading, or when additional series of options on the Index in an existing expiration date are opened for trading as the current value of the Index moves substantially from the exercise prices of series already opened, the exercise prices of such new or additional series shall be reasonably related to the current value of the Index at the time such series are first opened for trading.[58] The Exchange, however, proposes to eliminate this range limitation that will limit the number of $1 strikes that may be listed in options on the Index. The Exchange's proposal to set minimum strike price intervals without a range limitation is identical to strike price intervals adopted by Cboe for the VIX.[59] Accordingly, the Exchange is proposing to amend Exchange Rule 1809(c), Procedures for Adding and Deleting Strike Prices, to adopt new sub-section (5) to specify the

[51] The term ''MBBO'' means the best bid or offer on the Exchange. *See* Exchange Rule 100.

[52] The proposed rule change relates solely to the Exchange's request to list and trade options on the Index and does not represent a request for the Commission to determine whether the Index is a ''narrow-based index'' as that term is defined under the Act. *See* 15 U.S.C. 78c(a)(55)(B).

[53] *See* Exchange Rule 1808.

[54] *See* Exchange Rule 1808(c).

[55] *See* Exchange Rule 1809(a)(1).

[56] *See* Securities Exchange Act Release No.54019 (June 20, 2006), 71 FR 36569 (June 27, 2006) (SR–CBOE–2006–55). Additionally, the Exchange notes there are currently a number of actively-traded broad-based index options, *i.e.,* DJX, NDX, SPX, that are also not subject to any position or exercise limits.

[57] Cboe Rule 24.9 also permits for the listing of up to six weekly VIX expirations.

[58] *See* Exchange Rule 1809(c)(3). The term ''reasonably related to the current index value of the underlying index'' means that the exercise price is within thirty percent (30%) of the current index value, as defined in MIAX Options 1809(c)(4).

[59] *See* Securities Exchange Act Release No. 63155 (October 21, 2010), 75 FR 66402 (October 28, 2010) (SR–CBOE–2010–096).

minimum strike price intervals for options on the Index.

The trading of options on the Index shall be subject to the same rules that presently govern the trading of Exchange index options, including sales practice rules, margin requirements, and trading rules. In addition, long-term option series having up to sixty months to expiration may be traded.[60] The trading of long-term options on the Index shall also be subject to the same rules that govern the trading of all the Exchange's index options, including sales practice rules, margin requirements, and trading rules. Further, pursuant to Interpretations and Policies .01 of MIAX Options Rule 1809, the Exchange may also list Short Term Option Series and pursuant to Interpretations and Policies .02 of MIAX Options Rule 1809, the Exchange may also list Quarterly Options Series, respectively, on the Index.

Chapter XIII of the Exchange's rules is designed to protect public customer trading and shall apply to trading in options on the Index. Specifically, paragraphs (a) and (b) of MIAX Options Rule 1307 prohibit Members from accepting a customer order to purchase or write an option, including options on the Index, unless such customer's account has been approved in writing by a designated Options Principal of the Member. Additionally, MIAX Options Rule 1309 regarding suitability is designed to ensure that options, including options on the Index, are only sold to customers capable of evaluating and bearing the risks associated with trading in this instrument. Further, MIAX Options Rule 1310 permits Members to exercise discretionary power with respect to trading options, including options on the Index, in a customer's account only if the Member has received prior written authorization from the customer and the account had been accepted in writing by a designated Options Principal. MIAX Options Rule 1310 also requires designated Options Principals or Representatives of a Member to approve and initial each discretionary order, including discretionary orders for options on the Index, on the day the discretionary order is entered. Finally, MIAX Options Rule 1308, Supervision of Accounts, MIAX Options Rule 1311, Confirmation to Customers, and MIAX Options Rule 1315, Delivery of Current Options Disclosure Documents and Prospectus, will also apply to trading in options on the Index.

[60] *See* Exchange Rule 1809(b)(1).

Surveillance and Capacity

The Exchange has an adequate surveillance program in place for options traded on the Index and intends to apply those same program procedures that it applies to the Exchange's other options products. In addition, several new surveillances related to the Index will be added to the MIAX surveillance program. The Exchange has a Regulatory Services Agreement (''RSA'') in place with the Financial Regulatory Authority (''FINRA'') to conduct cross-market surveillances on its behalf and has expanded the RSA to include a new options pattern: Index Expiration for Cash Settled, A.M.-Settled, Index Options. The purpose of this pattern is to determine whether any market participants influenced the settlement price of an a.m. cash-settled index product to benefit their expiring index option position.

In addition to the Index Expiration for Cash Settled report mentioned above, both MIAX Option Regulation and FINRA Options Regulation will manually review options activity during each monthly settlement process. After manually reviewing settlement process activity over the course of months, MIAX Options and FINRA will determine whether additional reports or enhancements to the cash settled report(s) are required.

Further, the Exchange's regulatory department conducts routine surveillance in dozens of discrete areas. Index products and their respective symbols are integrated into the Exchange's existing surveillance system architecture and are thus subject to the relevant surveillance processes. This is true for both surveillance system processing and manual processes that support the Exchange's surveillance program. Additionally, the Exchange is also a member of the Intermarket Surveillance Group (ISG) under the Intermarket Surveillance Group Agreement, dated June 20, 1994. The members of the ISG include all of the U.S. registered stock and options markets.[61] The members of ISG work together to coordinate surveillance and investigative information sharing in the stock and options markets.

The Exchange represents that it has the necessary System capacity to support additional quotations and messages that will result from the listing and trading of options on the Index.

[61] For the current list of members of the ISG, *see https://www.isgportal.org/isgPortal/public/members.htm.*

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of the Act,[62] in general and with Section 6(b)(5) of the Act,[63] 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 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; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed change will permit options trading in the Index pursuant to rules designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade. In particular, the Exchange believes the proposed rule change will further the Exchange's goal of introducing new and innovative products to the marketplace. The Exchange believes that listing options on the Index will provide an opportunity for investors to hedge, or speculate on, the market risk associated with changes in volatility.

The Exchange believes that the enhanced features to the Index may serve to prevent fraudulent and manipulative acts and practices. Specifically, the Exchange believes that its price dragging technique and truncation rule, in combination with the immense liquidity of the underlying options, make the Index less susceptible to market manipulation. The price dragging technique, which is used to determine the ongoing Reference Price for each individual option used in the calculation of the Index, helps prevent market manipulation by utilizing the most recent trade price as the Reference Price. The Exchange believes that this feature may be a more accurate methodology than only using the mid-point of the bid and ask, which is the methodology utilized by a competing volatility index. The Exchange believes the price dragging technique may create a more accurate and stable index value which better represents volatility in the market by emphasizing the actual trade price versus simply the mid-point spread.

Furthermore, the Exchange believes that the enhanced feature may provide

[62] 15 U.S.C. 78a *et seq.*

[63] 15 U.S.C. 78f(b)(5).

greater consistency in the marketplace because the price dragging technique results in a Reference Price that is supported by the fair market value at the time versus using the mid-point, which is not necessarily an accurate representation of the fair market value at the time.

Furthermore, the truncation method, another key enhancement in the Index, determines how far away from the money to exclude strikes from the volatility calculation. This helps to ensure that values are not being included that would skew the resulting Index value by taking into account OTM options which are too far away to be accurately priced into the Index value calculation. By excluding these options from the calculation, the Exchange believes it is able to provide a more reliable Index value. The Exchange believes that its exclusion methodology is a material enhancement over existing methodologies, and should result in a calculation outcome that better reflects the expected measure of volatility.

As discussed previously, the price dragging method reduces the variability of the option inputs (which also referred to herein as the Reference Prices). Since the option inputs have reduced variability, and those values are used to determine which strikes make it into the Index's calculation, the combination of price dragging and exclusion rules work together to, in the Exchange's opinion, create a more reliable Index value. The Exchange believes that a more reliable Index value will benefit investors and market participants trading options on the Index, will promote just and equitable principles of trade, and should serve to prevent fraudulent and manipulative acts and practices.

The Exchange believes that, in addition to the other unique and proprietary attributes associated with the Index's calculation and settlement methodology, as well as the Exchange's fully-electronic, transparent, highly-deterministic trading system, using SPY options as the components for a volatility index, in the manner proposed by the Exchange, will offer a number of significant, distinct advantages over other types of volatility indexes. The Exchange believes that the advantages of using SPY options have the potential to result in an extremely liquid volatility product with exceptionally tight spreads, and consequently would not be readily susceptible to fraudulent and manipulative acts. First, SPY options are extremely liquid (they regularly trade 4–5 million contracts a day, and have 20–30 million contracts in open interest). Second, SPY options have consistently tighter bid-ask spreads than SPX options, which are the components for Cboe's VIX index. Since SPY options are traded on all 15 option exchanges, it allows market participants to take advantage of arbitrage opportunities across multiple venues. This is in contrast to SPX options which only trade on Cboe, and thus those arbitrage opportunities across venues are not possible. Also, at the time of final settlement, there are 14 other options exchanges on which SPY options are traded, and may serve as real-time cross-reference prices for SPY options during the Exchange's SPIKES Special Settlement Auction. This is in contrast to SPX options during Cboe's VIX settlement auction, where there is no such reference market for SPX options open during the time of the VIX settlement, as SPX options are only traded on one exchange—Cboe. In terms of spreads, SPY spreads are significantly tighter and exhibit much higher consistency with a much narrower range of typical values and far fewer numbers of outliers than SPX. SPY spreads are consistently tighter than SPX spreads, both across strike prices and through time, by a factor of 2 to 4 times (this is after normalizing SPY spreads to SPX spreads, by multiplying SPY spreads by 10). Accordingly, the Exchange believes that these advantages of using SPY options in the manner proposed by the Exchange, when combined with the other features and attributes of the SPIKES Index, have the potential to result in an extremely liquid volatility product with exceptionally tight spreads, and consequently would not be readily susceptible to fraudulent and manipulative acts.

The Exchange is currently disseminating the cash values of the Index to OPRA under the ticker symbol 'SPIKE' in at least 15 second intervals. The Exchange believes that disseminating updates in at least 15 second intervals will benefit investors and other market participants, as they will be better able to track the current value of the Index at any given period of time, will promote just and equitable principles of trade, and should prevent fraudulent and manipulative acts and practices.

The Exchange believes that using its fully-electronic and fully-transparent Opening Process functionality, which is accessible to all Members of the Exchange for participation, in highly liquid SPY options (which are simultaneously opening and available for trading on 14 other exchanges, thus providing real-time cross-reference prices for the SPY options included in the settlement) to conduct the SPIKES Special Settlement Auction to settle expiring SPIKES options, will offer significant advantages over other types of volatility auction processes, resulting in a robust opening process that presents arbitrage opportunities across multiple venues to drive prices into line and reach equilibrium, and thus benefiting investors and other market participants, promoting just and equitable principles of trade, and should prevent fraudulent and manipulative acts and practices.

The Exchange believes that having a SPIKES strategy order modification and cancellation cut-off time during the SPIKES Special Settlement Auction in SPY option series on expiration/final settlement date will help to ensure that the order book reflects bona-fide interest for execution, and is a feature designed to prevent manipulation of the final settlement price.

Volatility-focused products have become more prominent over the past several years, and in a number of different formats and types, including ETFs, exchange-traded notes, exchange-traded options, and exchange-traded futures. Such products offer investors the opportunity to manage their volatility risks associated with an underlying asset class. Currently, most of the products focus on underlying equity indexes or equity-based portfolios.

The Exchange proposes to introduce a cash-settled options contract on a new volatility index, which focuses on equity exposure using options on SPY. SPY is the largest and most liquid ETF in the United Sates, and the most actively traded equity option product. The Exchange believes that because the Index is derived from published SPY options prices, and given the immense liquidity found in the individual portfolio components of SPY, the concern that the Index will be subject to market manipulation is greatly reduced. Therefore, the Exchange believes that the proposed rule change to list options on the Index is appropriate.

The Exchange further notes that Exchange Rules that apply to the trading of other index options currently traded on the Exchange would also apply to the trading of options on the Index. Additionally, the trading of options on the Index would be subject to, among others, Exchange Rules governing margin requirements and trading halt procedures.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in options on the Index. The Exchange also represents that it has the necessary systems capacity to support the new options series. Additionally, as stated in

the filing, the Exchange has rules in place designed to protect public customer trading.

*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. . The Exchange notes that the proposed rule change will facilitate the listing and trading of a novel index option product that will enhance competition among market participants, to the benefit of investors and the marketplace.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments were neither solicited nor received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

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. Among other things, the Exchange believes that the use of SPY options in the manner proposed by the Exchange, when combined with the other features and attributes of the SPIKES Index, has the potential to result in an extremely liquid volatility product with exceptionally tight spreads, and consequently would not be readily susceptible to fraudulent and manipulative acts. In particular, the Commission seeks comment on the following:

- Do commenters agree with this overall assertion by the Exchange?
- Do commenters believe any proposed features (*e.g.,* inclusion of relatively illiquid OTM (Out-of-the-Money) put SPY options in SPIKES settlement, SPIKES settlement via a short pre-open auction of SPY options, cash-settlement) of the SPIKES settlement could make options on SPIKES susceptible to manipulation? Why or why not?
- Do commenters believe the definition of ''SPIKES strategy orders'' is sufficiently clear? Why or why not?
- Do commenters believe the proposed SPIKES strategy order cut-off time is adequate to provide sufficient time to work off order imbalances during the SPIKES Special Settlement Auction in SPY option series on final settlement dates? Why or why not?
- Do commenters believe precluding the submission, modification, or cancellation of SPIKES strategy orders after the proposed cut-off time will be effective in reducing the likelihood of manipulation in the calculation of the final settlement value for the SPIKES Index? Why or why not?
- Do commenters believe the proposed exclusion rule/truncation method, which is designed to remove SPY option price inputs deemed less reliable in order to avoid a potential negative impact on the SPIKES calculation outcome, will be effective in reducing the likelihood of manipulation in the calculation of the final settlement value for the SPIKES Index? Why or why not?
- The Exchange discusses the price dragging technique used for intraday calculation of the SPIKES Index value to determine the Reference Price for each of the individual SPY options used in the calculation of the Index value. Do commenters believe that the price dragging technique would improve Index stability by smoothing out options price inputs into the Index calculation, especially as SPY options quotes are rapidly changing? Do commenters agree that the price dragging technique will result in a smoother Index price? What are commenters' views on any potential effect of the price dragging technique, in which the primary factor considered when updating the Reference Price for each of the individual SPY options is whether or not a trade has occurred, on the price efficiency of the SPIKES Index, including whether the price dragging technique may result in stale prices?
- Do commenters believe that the lack of proposed position limits on cash-settled SPIKES Index options could make the options more susceptible to manipulation?[64] Why or why not?

Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2018–14 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2018–14. 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 website (*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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2018–14, and should be submitted on or before August 6, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[65]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–15178 Filed 7–13–18; 8:45 am]

**BILLING CODE 8011–01–P**

[64] *See, e.g.,* Hans R. Dutt & Lawrence E. Harris, *Position Limits for Cash-Settled Derivative Contracts,* 25 J. Futures Mkts. 945 (2005) (arguing that limits on the positions that traders can carry into final settlement can be used to mitigate the susceptibility to manipulation of cash-settled derivative contracts).

[65] 17 CFR 200.30–3(a)(12).

## SURFACE TRANSPORTATION BOARD

**[Docket No. AB 290 (Sub-No. 401X); Docket No. AB 1058X]**

### Tennessee, Alabama & Georgia Railway Company—Discontinuance of Service Exemption—in Walker County, Ga.; Chattooga & Chickamauga Railway Company—Discontinuance of Lease and Trackage Rights Operations—in Walker County, Ga. and Hamilton County, Tenn.

Tennessee, Alabama & Georgia Railway Company (TAG), a wholly owned subsidiary of Norfolk Southern Railway Company, and Chattooga & Chickamauga Railway Company (CCKY) (collectively, TAG and CCKY are referred to as Railroads) have jointly filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* for (1) TAG to discontinue service over approximately 16.8 miles of rail line extending between milepost TA 6.3 (at or near Flintstone, Ga.) and milepost TA 23.l (at or near Hedges, Ga.) in Walker County, Ga.; (2) CCKY to discontinue its lease of approximately 19.20 miles of rail line owned by TAG and the Alabama Great Southern Railroad Company (AGS) extending between milepost TA 3.94 (at Chattanooga, Tenn.) and milepost TA 23.1 in Hamilton County, Tenn., and Walker County, Ga.; and (3) CCKY to discontinue overhead trackage rights it holds over the following connecting lines, all located in Chattanooga, Hamilton County, Tenn.: (a) AGS's line between milepost G–2.66 at a connection with TAG and milepost G–1.02 at the north end of Shipp Yard, a distance of 1.6 miles; (b) Central of Georgia Railroad Company's (COG) line between milepost C–445.4 and its connection with TAG at milepost TA 3.94, a distance of approximately 1.5 miles; and (c) TAG's rail line between milepost TA 3.94 and milepost TA 3.39 (at TAG's connection with AGS), a distance of approximately 0.55 miles (collectively, the ''Line''). The Line traverses United States Postal Zip Codes 30725, 30707, 37407, 37408, 37409, and 37410.

The Railroads have certified that: (1) They have handled no local or overhead common carrier service over the Line for at least two years; (2) overhead traffic, if there were any, could be rerouted over other lines; (3) no formal complaint filed by a user of a rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is pending either with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to these exemptions, any employee adversely affected by the discontinuances of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) [1] to subsidize continued rail service has been received, these exemptions will be effective August 15, 2018, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) [2] must be filed by July 26, 2018.[3] Petitions for reconsideration must be filed by August 6, 2018, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with Board should be sent to the Railroads' representative, William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW, Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our website at: *www.stb.gov.*

Decided: July 11, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

**Marline Simeon,**

*Clearance Clerk.*

[FR Doc. 2018–15142 Filed 7–13–18; 8:45 am]

**BILLING CODE 4915–01–P**

[1] The Board modified its OFA procedures effective July 29, 2017. Among other things, the OFA process now requires potential offerors, in their formal expression of intent, to make a preliminary financial responsibility showing based on a calculation using information contained in the carrier's filing and publicly available information. *See Offers of Financial Assistance,* EP 729 (STB served June 29, 2017); 82 FR 30,997 (July 5, 2017).

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,800. *See Regulations Governing Fees for Servs. Performed in Connection with Licensing & Related Servs.—2017 Update,* EP 542 (Sub-No. 25) (STB served July 28, 2017).

[3] Because these are discontinuance proceedings and not abandonments, trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, these discontinuances do not require environmental review.

## TENNESSEE VALLEY AUTHORITY

### Supplemental Environmental Impact Statement—Natural Resource Plan

**AGENCY:** Tennessee Valley Authority.

**ACTION:** Notice of intent.

**SUMMARY:** The Tennessee Valley Authority (TVA) intends to prepare a supplemental environmental impact statement (EIS) addressing proposed changes to its Natural Resource Plan (NRP). Public comment is invited concerning the scope of the supplemental EIS, including how the plan addresses TVA's management of natural and cultural resources and the environmental issues that should be addressed in the supplemental EIS.

**DATES:** Comments must be received on or before August 20, 2018. To facilitate the scoping process, TVA will hold public scoping meetings in late July and early August 2018; see *https://www.tva.gov/nrp* for the dates and locations of the scoping meetings.

**ADDRESSES:** Written comments should be sent to Matthew Higdon, Tennessee Valley Authority, 400 W Summit Hill Drive #WT11D, Knoxville, Tennessee 37902. Comments may also be emailed to *nrp@tva.gov* or submitted on the TVA website at: *https://www.tva.gov/nrp.*

**FOR FURTHER INFORMATION CONTACT:** For information on the EIS process, contact Matthew Higdon, NEPA Specialist, by email at *mshigdon@tva.gov* or by phone at (865) 632–8051. For information about the NRP, contact Anthony Summitt by email at *adsummitt@tva.gov* or by phone at (423) 467–3811.

**SUPPLEMENTARY INFORMATION:** This notice is provided in accordance with the Council on Environmental Quality's regulations (40 CFR parts 1500 to 1508) and TVA's procedures for implementing the National Environmental Policy Act (NEPA) and Section 106 of the National Historic Preservation Act (NHPA) and its implementing regulations (36 CFR part 800).

### Background

TVA is an executive branch, corporate agency and instrumentality of the United States, established by an act of Congress in 1933, to foster the social and economic welfare of the people of the Tennessee Valley region and to

promote the proper use and conservation of the region's natural resources. Shortly after its creation, TVA began a dam and reservoir construction program that required the purchase of approximately 1.3 million acres of land for the creation of reservoirs within the Tennessee Valley region. Most of these lands are located underneath the water of the reservoir system or have since been sold by TVA or transferred to other state or federal agencies. Today, approximately 293,000 acres of land along TVA reservoirs are managed by TVA for the benefit of the public. Most of these lands remain undeveloped and have been managed by TVA for natural resource conservation, recreation, and the protection of cultural resources.

In 2011, TVA completed its first Natural Resource Plan to guide its stewardship efforts for managing the waters and public lands of the Tennessee River Valley. The NRP represents TVA's high level strategy for managing its natural resources in the near- and long-term. The purpose of the plan is to integrate the goals of resource management programs, provide for the optimum public benefit, and balance sometimes conflicting resource uses. The NRP also guides TVA in achieving the objectives of its Environmental Policy for a more systematic and integrated approach to natural resource stewardship.

When planning for the 2011 NRP, TVA completed an EIS that described the potential resource management programs and activities, alternative approaches to TVA's resource management efforts, and the environmental impacts of the alternatives. In the 2011 EIS, four alternatives were analyzed: The No Action Alternative, Custodial Management, Flagship Management, and Blended Management. In August 2011, the TVA Board of Directors decided that the Blended Management alternative should be implemented as the agency's plan because the alternative aligns best with TVA's Environmental Policy, focuses on key programs that establish a baseline for future enhanced implementation efforts, and provides flexibility for the use of partnerships, volunteers, and other sources of funding to leverage programs to their full potential while working within resource and staff constraints (75 FR 57100, September 15, 2011).

**Proposed Update of the Plan**

In the 2011 NRP, TVA committed to reviewing the NRP every five years and updating the plan to ensure it remains relevant and current. In 2016, in advance of the first update of the NRP, TVA's Natural Resources staff began a holistic review of the NRP and determined that, after extensive discussion and consideration, the plan does not completely fulfill the purposes intended when completed in 2011. The 2011 NRP was not all encompassing of Natural Resources programs and by not being inclusive, the NRP was not comprehensive as desired. TVA concluded that the NRP was not fully serving as the guide for business and budget planning as was first envisioned, and the non-comprehensive program coverage has impacted the plan's usefulness to the Natural Resources group as a management guide.

TVA is proposing to update the NRP to improve its efficacy and is initiating an environmental review of proposed changes. TVA proposes changes to the NRP's structure and to the range of programs it identifies. TVA is seeking the public's input in determining the scope of its environmental review of these changes. The proposed update to the NRP would be consistent with the Blended Management alternative approved by the TVA Board of Directors in August 2011. TVA is considering these changes in a supplement to the 2011 EIS.

TVA proposes to update the NRP so that it is a more useful strategic document that outlines expected benefits and objectives for each of TVA's natural resource management programs. TVA proposes to reorganize the plan and its programs into ten new ''focus areas'' rather than the six resource areas in the 2011 plan. TVA would address additional program efforts in the NRP that were excluded from the current plan, namely: Permitting under Section 26a of the TVA Act and land use agreements; public land protection; nuisance and invasive species management; and ecotourism. TVA has extensive experience in conducting these efforts in the region and proposes to include them in the NRP to ensure that the plan addresses the entire scope of the TVA Natural Resources group's stewardship efforts.

In addition, certain programs described in the 2011 NRP would be regrouped to create focus areas that better reflect the Natural Resources' efforts in order to improve the plan's clarity and usefulness. TVA also proposes to remove some programs from its NRP because these programs are managed better by other entities (*e.g.,* universities, other TVA organizations, non-TVA entities); however, even if a program would be removed from the NRP, TVA may continue to support the management of these programs. Lastly, TVA proposes to add several new programs under the ten focus areas.

TVA proposes to update the NRP by grouping its programs into the following ten focus areas: Land and Habitat Stewardship (Biological Resources in the current NRP); Cultural Resources Management (currently Cultural Resources in the NRP); Water Resources Stewardship (currently Water Resources in the NRP); Public Outreach and Information (currently Public Engagement in the NRP); Reservoir Lands Planning (no change); Recreation (currently Recreation Management in the NRP); Public Land Protection (new); Nuisance and Invasive Species Management (new); Ecotourism (new); and Section 26a and Land Use Agreements (new). More information about the new focus areas and the changes to specific programs can be found at *https://www.tva.gov/nrp.*

Numerous other changes proposed by TVA are administrative or procedural in nature and are unlikely to impact the environment; these changes will be included in the scope of the supplemental EIS to ensure public disclosure of how the NRP would be amended. For example, TVA is proposing to change how its NRP would be updated and how the public would be made aware of its plan implementation. In the revised NRP, TVA would eliminate the provision of the NRP that calls for periodic (5 year) updates to the plan. Alternatively, TVA proposes to inform the public of its activities and progress by publishing an Annual Report on Natural Resources' stewardship efforts and by improving the information available to the public on TVA's stewardship projects on TVA's web page. TVA would provide multiple avenues for continuous public engagement and input, including through the Public Land Information Center, by incorporating a commenting mechanism into the NRP web page and by piloting region specific focus groups that would provide input regarding local needs and trends in the recreation and natural resource fields.

To complement the strategic guidance that the updated NRP would provide, TVA's Natural Resources group would develop a 3–5 Year Action Plan to provide a tactical approach to implement the specific activities associated with each of the ten focus area programs. TVA anticipates that utilizing a short term implementation strategy (3–5 Year Action Plan) that complements the long term strategic guidance document (the updated NRP) would provide the flexibility necessary to achieve the goals and objectives of

the NRP. This approach is intended to ensure that the NRP remains relevant in the long term, since adjustments in the implementation of the NRP (*e.g.,* due to changes such as availability of stewardship funding, new trends in public use and input from the public) would be addressed through the 3–5 Year Action Plan.

TVA would also remove the ''measures of success'' for each program from the 2011 NRP, which experience has shown were too specific. The updated NRP would identify objectives for each focus area to provide high-level, overarching strategic direction for each area. The objectives for the focus areas align with the 2011 NRP resource area goals and would be substantially consistent with TVA's Blended Management approach analyzed in the 2011 EIS. Instead of ''measures of success,'' metrics to measure achievement of focus area objectives would be incorporated into the 3–5 Year Action Plan.

**Scoping Process**

The revised NRP will be considered as an action alternative in the supplemental EIS. TVA invites the public to review the detailed description of its NRP program areas and the revisions to the NRP that is available on the TVA website during the scoping period and to submit comments, questions or suggestions on its proposal. Additional action alternative(s) may be developed based on public input submitted to TVA during the scoping period.

Public scoping is integral to the process for implementing NEPA and ensures that issues are identified early and properly studied; issues of little significance do not consume substantial time and effort; and analysis is thorough and balanced. TVA anticipates that the major environmental resource areas that will be addressed in the supplemental EIS will include water quality, water supply, aquatic and terrestrial ecology, endangered and threatened species, wetlands, prime farmlands, floodplains, recreation, aesthetics including visual resources, land use, historic and archaeological resources and socioeconomic resources.

TVA invites members of the public as well as Federal, state, and local agencies and Native American tribes to comment on the scope of the supplemental EIS. Comments on the scope should be submitted no later than the date given under the **DATES** section of this notice. Pursuant to the regulations of the Advisory Council on Historic Preservation implementing Section 106 of the NHPA, TVA also solicits comments on the potential of the proposed Plan to affect historic properties. This notice also provides an opportunity under Executive Orders 11990 and 11988 for early public review of the potential for TVA's proposal to affect wetlands and floodplains, respectively. Please note that any comments received, including names and addresses, will become part of the administrative record and will be available for public inspection.

After consideration of the public's input and analyzing the environmental consequences of alternatives, TVA will issue a draft EIS for public review and comment. TVA will notify the public of the draft EIS's availability and plans to hold public meetings during the review period. TVA expects to release the draft EIS in mid 2019 and the final EIS and NRP in early 2020.

**Authority:** 40 CFR 1501.7.

**David Bowling,**

*Vice President, Land and River Management.*

[FR Doc. 2018–15161 Filed 7–13–18; 8:45 am]

BILLING CODE 8120–08–P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Environmental Impact Statement: Lake, Cook and McHenry Counties, Illinois

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of intent to prepare an environmental impact statement (EIS).

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed transportation improvement project in Lake, Cook and McHenry Counties in Illinois.

**FOR FURTHER INFORMATION CONTACT:** Catherine A. Batey, Division Administrator, Federal Highway Administration, 3250 Executive Park Drive, Springfield, Illinois 62703, Phone: 217–492–4640. Paul Kovacs, Chief Engineer, Illinois Tollway, 2700 Ogden Avenue, Downers Grove, Illinois 60515, Phone 630–241–6800. Anthony Quigley, Deputy Director of Highways, Region 1 Engineer, Illinois Department of Transportation, 201 West Center Court, Schaumburg, Illinois 60196, Phone: 847–705–4401.

**SUPPLEMENTARY INFORMATION:** The FHWA, in cooperation with the Illinois Tollway and the Illinois Department of Transportation (IDOT), will prepare an environmental impact statement (EIS) for a proposed transportation improvement project in Lake County, northern portions of Cook County, and eastern portions of McHenry County. The FHWA intends to issue a single Final EIS and Record of Decision (ROD) document pursuant to the FAST Act Section 1311 requirements, unless FHWA determines statutory criteria or practicability considerations preclude issuance of a combined document.

Improvements in the project area are proposed to reduce congestion, improve reliability of travel, improve travel options connecting major origins and destinations, and improve local and regional travel efficiency. Alternatives under consideration to address these needs include (1) improvements to the existing roadway network; (2) construction on new alignment; (3) improvements to transit, including rail and bus; (3) improvements to bicycle and pedestrian facilities; (4) transportation system management/transportation demand management strategies; and (5) taking no action.

Federal approvals needed for this project may include permits under Clean Water Act Sections 402 and 404 and Section 401 water quality certification. Section 7 consultation with the US Fish and Wildlife Service may also be required. The project will comply with the Clean Air Act, Title VI of the Civil Rights Act, Section 4(f) of the U.S. Department of Transportation Act of 1966, and Executive Order 12898 ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' and other applicable state and Federal laws.

A Stakeholder Participation Group, consisting of community leaders, technical experts, and interest groups, has been formed as part of early coordination efforts to assist in the development of the purpose and need and to provide input on alternative evaluation. Additionally, all individuals and organizations expressing interest in the project will be able to participate in the process through various public outreach opportunities. These opportunities include, but are not limited to, the project website, public meetings and hearings, speakers' bureau events, and press releases.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Scoping input on the proposed project will be invited during a public informational meeting scheduled for July 25, 2018, and may also be submitted via the project website or in writing to the Illinois Tollway, 2700

Ogden Avenue, Downers Grove, Illinois 60515, attention Pete Foernssler. Comments and questions concerning the proposed action and this notice should be directed to the Illinois Tollway at the address provided above by the close of business on August 24, 2018.

**Authority:** 23 U.S.C. 315; 23 CFR 771.123.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: July 9, 2018.

**Division Administrator,**

*Springfield, Illinois.*

[FR Doc. 2018–15097 Filed 7–13–18; 8:45 am]

**BILLING CODE 4910–22–P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[Docket No. FHWA–2018–0033]**

### Proposed Memorandum of Understanding (MOU) Assigning Certain Federal Environmental Responsibilities to the State of Nebraska, Including National Environmental Policy Act (NEPA) Authority for Certain Categorical Exclusions (CEs)

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of proposed MOU, request for comments.

**SUMMARY:** The FHWA and the State of Nebraska, acting by and through its Department of Transportation (State), propose participation of the State in the Categorical Exclusion Assignment program. This program allows FHWA to assign its authority and responsibility for determining whether certain designated activities within the geographic boundaries of the State, as specified in the proposed Memorandum of Understanding (MOU), are categorically excluded from preparation of an environmental assessment or an environmental impact statement under the National Environmental Policy Act.

**DATES:** Comments must be received on or before August 15, 2018.

**ADDRESSES:** You may submit comments, identified by DOT Document Management System (DMS) Docket Number FHWA–2018–0033, by any of the methods described below. To ensure that you do not duplicate your submissions, please submit them by only one of the means below. Electronic or facsimile comments are preferred because Federal offices experience intermittent mail delays from security screening.

*Federal eRulemaking Portal:* Go to website: *http://www.regulations.gov/.* Follow the instructions for submitting comments on the DOT electronic docket site.

*Facsimile (Fax):* 1–202–493–2251.

*Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590.

*Hand Delivery:* 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Eastern Time, Monday through Friday, except Federal holidays.

For access to the docket to view a complete copy of the proposed MOU, or to read background documents or comments received, go to *http://www.regulations.gov/* at any time, or to 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Eastern Time, Monday through Friday, except Federal holidays.

*Instructions:* You must include the agency name and docket number at the beginning of your comments. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** For FHWA: Melissa Maiefski; by email at *Melissa.Maiefski@dot.gov* or by telephone at 402–742–8473. The Nebraska Division Office's normal business hours are 8 a.m. to 5:00 p.m. (Central Standard Time), Monday through Friday, except Federal holidays. For the State of Nebraska: Brandie Neemann: By email at *Brandie.Neemann@nebraska.gov* or by telephone at 402–479–4795. The Nebraska Department of Transportation's business hours are 8 a.m. to 5 p.m. (Central Standard Time), Monday through Friday, except State and Federal holidays.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Access

Internet users may reach the Office of the Federal Register's home page at: *http://www.archives.gov/* and the Government Publishing Office's database at: *http://www.fdsys.gov/.* An electronic version of the proposed MOU may be downloaded by accessing the DOT DMS docket, as described above, at *http://www.regulations.gov.*

#### Background

Section 326 of Title 23 U.S. Code, creates a program that allows the Secretary of the U.S. Department of Transportation (Secretary), to assign, and a State to assume, responsibility for determining whether certain highway projects are included within classes of action that are categorically excluded (CE) from requirements for environmental assessments or environmental impact statements pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.* (NEPA). In addition, this program allows the assignment of other environmental review requirements applicable to Federal highway projects. The FHWA is authorized to act on behalf of the Secretary with respect to these matters.

The FHWA would execute Nebraska's participation in this program through an MOU. Statewide decision making responsibility would be assigned for all activities within the categories listed in 23 CFR 771.117(c) and those listed as examples in 23 CFR 771.111(d), and any activities added through FHWA rulemaking to those listed in 23 CFR 771.117(c) or example activities listed in 23 CFR 771.117(d) after the date of the execution of this MOU. In addition to the NEPA CE determination responsibilities, the MOU would assign to the State the responsibility for conducting Federal environmental review, consultation, and other related activities for projects that are subject to the MOU with respect to the following Federal laws and Executive Orders:

- Clean Air Act (CAA), 42 U.S.C. 7401–7671q. *Including determinations for project-level conformity if required for the project*
- Noise Control Act of 1972, 42 U.S.C. 4901–4918
- Compliance with the noise regulations in 23 CFR part 772 (except approval of the State noise policy in accordance with 23 CFR 772.7)
- Section 7 of the Endangered Species Act of 1973, 16 U.S.C. 1531–1544, and 1536
- Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d
- Migratory Bird Treaty Act, 16 U.S.C. 703–712
- Bald and Golden Eagle Treaty Act, as amended, 16 U.S.C. 668–668c
- Section 106 of the National Historic Preservation Act of 1966, as amended, 54 U.S.C. 306108
- Archeological Resources Protection Act of 1979, 16 U.S.C. 470aa–mm
- Title 54, Chapter 3125—Preservation of Historical and Archeological Data, 54 U.S.C. 312501–312508
- Native American Grave Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3001–3013; 18 U.S.C. 1170
- Section 4(f) of the Department of Transportation Act of 1966, 23 U.S.C.

138 and 49 U.S.C. 303; 23 CFR part 774
- American Indian Religious Freedom Act, 42 U.S.C. 1996
- Farmland Protection Policy Act (FPPA), 7 U.S.C. 4201–4209
- Clean Water Act, 33 U.S.C. 1251–1377, Sections 401, 404, and 319
- Rivers and Harbors Act of 1899, 33 U.S.C. 403
- Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287
- Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931
- Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(3)
- FHWA wetland and natural habitat mitigation regulations, 23 CFR part 777
- Flood Disaster Protection Act, 42 U.S.C. 4001–4128
- Safe Drinking Water Act (SDWA), 42 U.S.C. 300f–300j–6
- Section 4(f) of the Department of Transportation Act of 1966, 23 U.S.C. 138 and 49 U.S.C. 303; and 23 CFR part 774
- Land and Water Conservation Fund (LWCF), Public Law 88–578, 78 Stat. 897 (known as Section 6(f))
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601–9675
- Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9671–9675
- Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901–6992k
- Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319
- E.O. 11990, Protection of Wetlands
- E.O. 11988, Floodplain Management (except approving design standards and determinations that a significant encroachment is the only practicable alternative under 23 CFR 650.113 and 650.115)
- E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations
- E.O. 11593, Protection and Enhancement of Cultural Resources
- E.O. 13007, Indian Sacred Sites
- E.O. 13175 Consultation and Coordination with Indian Tribal Governments
- E.O. 13122 and E.O. 13751, Invasive Species
- Planning and Environmental Linkages, 23 U.S.C. 168, except for those FHWA responsibilities associated with 23 U.S.C. 134 and 135
- Programmatic Mitigation Plans, 23 U.S.C. 169 except for those FHWA responsibilities associated with 23 U.S.C. 134 and 135

The MOU allows the State to act in the place of FHWA in carrying out the functions described above, except with respect to government-to-government consultations with federally recognized Indian Tribes. The FHWA will retain responsibility for conducting formal government-to-government consultation with federally recognized Indian Tribes, which is required under some of the above-listed laws and Executive Orders. The State may also assist FHWA with formal consultations, with consent of a tribe, but FHWA remains responsible for the consultation.

This assignment includes transfer to the State of Nebraska the obligation to fulfill the assigned environmental responsibilities on any proposed projects meeting the criteria in Stipulation 1(B) of the MOU that were determined to be CEs prior to the effective date of the proposed MOU but that have not been completed as of the effective date of the MOU.

The FHWA will consider the comments submitted on the proposed MOU when making its decision on whether to execute this MOU. The FHWA will make the final, executed MOU publicly available.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

**Authority:** 23 U.S.C. 326; 42 U.S.C. 4331, 4332; 23 CFR 771.117; 40 CFR 1507.3, 1508.4.

**Joseph A. Werning,**

*Division Administrator, Federal Highway Administration.*

[FR Doc. 2018–15099 Filed 7–13–18; 8:45 am]

BILLING CODE 4910–22–P

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## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2015–0149]**

### Withdrawal of Proposed Enhancements to the Safety Measurement System

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice.

**SUMMARY:** On June 29, 2015 and October 5, 2016, FMCSA proposed enhancements to the Agency's Safety Measurement System (SMS) and published a preview version of the changes. However, the Fixing America's Surface Transportation Act (FAST Act) required the National Research Council of the National Academy of Sciences (NAS) to conduct a study of FMCSA's Compliance, Safety, Accountability (CSA) program and the Safety Measurement System (SMS). NAS published their report titled, ''Improving Motor Carrier Safety Measurement'' on June 27, 2017. This notice announces that FMCSA will not complete the enhancements previously proposed and the preview is removed from the SMS website.

**FOR FURTHER INFORMATION CONTACT:** Ms. Barbara Baker, Compliance Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Telephone (202) 366–3397 or by email at *Barbara.Baker@dot.gov*. Office hours are from 8:00 a.m. to 5:00 p.m., ET, 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:**

### Background

#### June 2015 Notice

On June 29, 2015 (80 FR 37037), FMCSA proposed the SMS enhancements and requested initial comments in advance of providing motor carriers with a preview of how their safety performance data would be presented on the SMS website. The proposed changes included:

1. Changing some of the SMS Intervention Thresholds to better reflect the Behavior Analysis and Safety Improvement Categories' (BASICs) correlation to crash risk.
2. Two changes to the Hazardous Materials (HM) Compliance BASIC:
   a. Segmenting the HM Compliance BASIC by Cargo Tank (CT) and non-CT carriers; and
   b. Releasing motor carrier percentile rankings under the HM Compliance BASIC to the public.
3. Reclassifying violations for operating while Out of Service (OOS) under the Unsafe Driving BASIC rather than the BASIC of the underlying OOS violation.
4. Increasing the maximum Vehicle Miles Traveled used in the Utilization Factor to more accurately reflect the operations of high-utilization carriers.

The Agency's analysis and explanations were provided in the June 29, 2015, notice. Stakeholders had 30 days to submit comments. The comment period ended on July 29, 2015.

#### October 2016 Notice

The October 5, 2016, **Federal Register** notice (81 FR 69185) announced a

preview of proposed enhancements to the SMS website, responded to comments to the June 2015 **Federal Register** notice, and advised of additional enhancements.

As a result, the preview reflected six potential changes to the SMS methodology for calculating percentiles.

1. SMS Intervention Thresholds were adjusted to better reflect correlation to crash risk.
2. Changes to the HM Compliance BASIC to segment by CT and non-CT carriers and to post motor carrier percentile rankings under the HM Compliance BASIC to the public.
3. Reclassifying violations for operating while OOS under the Unsafe Driving BASIC rather than the BASIC of the underlying OOS violation.
4. Increasing the maximum vehicle miles traveled used in the Utilization Factor to more accurately reflect the operations of high-utilization carriers.
5. Increasing the minimum number of crashes in the Crash Indicator BASIC from two to three.
6. Assigning BASIC percentiles only to carriers that have had an inspection with a violation in the past year.

Only 25 comments were received on the preview from 11 individuals, five trucking or bus companies, nine associations and one safety consultant. Eight commenters posted comments regarding determining the preventability of crashes; therefore, these comments were outside of the scope of the notice. Four other commenters made broad comments about the Agency that were not applicable to this notice. In addition, the Insurance Institute of Highway Safety provided a copy of their report titled ''Crash Risk Factors for Interstate Large Trucks in North Carolina'' as support for the Agency's correlation of vehicle maintenance to crashes.

### FAST Act Correlation Study

Section 5221 of the FAST Act, titled ''Correlation Study,'' required FMCSA to commission the National Research Council of the National Academies to conduct a study of FMCSA's CSA program and SMS.

On June 27, 2017, NAS published the report titled ''Improving Motor Carrier Safety Measurement.'' The report is available at *https://www.nap.edu/catalog/24818/improving-motor-carrier-safety-measurement*. In preparing the report, NAS collected and analyzed all the quantitative data available to FMCSA in its databases, which contain information on the safety of commercial motor carriers and drivers subject to the Federal Motor Carrier Safety Regulations and the HM Regulations. In addition, NAS held three public meetings to engage stakeholders from the truck and bus industry, safety advocates, researchers, and other government organizations. The meeting agendas are included in an appendix to the report. FMCSA accepted the NAS report's recommendations, including the recommendation to develop a new statistical model to support the SMS, and is working to implement the recommended changes. The NAS cautioned the Agency against making changes to the algorithm based on ad hoc analysis and instead to rely on the Item Response Theory model.

### SMS Preview Site

As a result of the ongoing implementation of the NAS recommendations, FMCSA removed the preview from the SMS website and will not be proceeding with the proposed changes at this time.

Issued on: July 10, 2018.

**Raymond P. Martinez,**

*Administrator.*

[FR Doc. 2018–15109 Filed 7–13–18; 8:45 am]

BILLING CODE 4910–EX–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2018–0189]**

## Agency Information Collection Activities; New Information Collection: Truck and Bus Maintenance Requirements and Their Impact on Safety

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. This new request titled ''Truck and Bus Maintenance Requirements and Their Impact on Safety'' will allow for a study that focuses on vehicle maintenance and aims to determine the impact of vehicle maintenance requirements on overall motor carrier safety. This information collection supports the DOT Strategic Goal of Safety.

**DATES:** We must receive your comments on or before September 14, 2018.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA–2018–0189 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

*Instructions:* All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. 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.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* and follow the online instructions for accessing the dockets, or go to the street address listed above.

*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,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

*Public Participation:* The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the ''help'' section of the Federal eRulemaking Portal website. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

**FOR FURTHER INFORMATION CONTACT:** Quon Y. Kwan, Program Manager, Technology Division, Department of Transportation, OA, West Building 6th

Floor, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–385–2389; email *quon.kwan@dot.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background:* FMCSA's core mission is to reduce crashes, injuries, and fatalities involving large trucks and buses. To aid in accomplishing this, the Agency uses the Compliance, Safety, Accountability (CSA) enforcement program to prioritize and target interventions of those motor carriers who are most likely to be involved in a future crash. As part of the CSA program, the Agency deploys the Safety Measurement System (SMS). SMS uses inspection, crash, and investigation data captured in the Motor Carrier Management Information System (MCMIS) to calculate a percentile for each motor carrier. A motor carrier's SMS percentile is based on its past compliance with a complete range of safety-based regulations (such as driver safety, hours of service, driver fitness, and vehicle maintenance, among others). The survey described in this notice focuses on the vehicle maintenance component of those safety regulations. The study goal is to determine what improvements, ranging from better compliance interventions to better vehicle maintenance requirements, would enhance motor carrier safety.

In 2014, the John A. Volpe National Transportation Systems Center (Volpe) conducted a study to assess the effectiveness of SMS in identifying the highest risk motor carriers to be targeted for interventions. One finding from the study was that motor carriers targeted for intervention due to ''vehicle maintenance'' issues (*i.e.,* violations) had a 65 percent higher crash rate compared to the national average. These violations are based on Federal and state inspections of components critical to the safe operation of the vehicle. It is important to recognize that proper and regular preventative maintenance (*i.e.,* systematic maintenance programs) among carriers—rather than Federal and state inspections, which are by nature limited to the most visible or obvious safety-related components—should be the primary activity applied to ensure safe equipment operation.

While these initial findings are important, they raise additional questions. One such question is prompted by the stipulation in 49 CFR 396.3(a), which states that every carrier must have a program to ''systematically inspect, repair, and maintain, or cause to be systematically inspected, repaired, and maintained, all motor vehicles and intermodal equipment subject to its control.'' Though this regulation provides some direction, there is no supporting definition of the word ''systematic,'' and because this term is subjective, it is likely to vary from one carrier to another. The lack of specificity regarding standard intervals for preventative maintenance makes it difficult for federal and state personnel to evaluate the effectiveness of and compliance with a carrier's maintenance program. Furthermore, the lack of specificity may make it difficult for carriers to ascertain and therefore comply with the regulation's intent.

The current research effort, augmented by the proposed survey, is necessary to improve FMCSA's understanding of the safety impact of preventative vehicle maintenance and to clarify the requirements of section 396.3(a). The study objectives are as follows:

1. Develop an operational definition of ''systematic maintenance.''

2. Evaluate whether current regulations and the intervention process could be modified to improve compliance with vehicle maintenance requirements. Examples of such requirements are as follows: (i) Preventative maintenance intervals, (ii) preventative maintenance inspections with adequately trained/equipped mechanics, and (iii) adequacy of motor carriers' maintenance facilities. [However, the results of the survey will be used only to explore what areas of rulemaking and/or other areas, such as policy guidance and training, might be useful in the future; the results of the survey will not be used for rulemaking, per se.]

3. Gather information to assist in establishing minimum standards for inspection intervals, mechanic qualifications and training, and certification of maintenance facilities.

FMCSA is authorized to conduct this research under 49 U.S.C. 31108, Motor Carrier Research and Technology Programs. Under section 31108(a)(3)(C), FMCSA may fund research, development, and technology projects that improve the safety and efficiency of commercial motor vehicle operations through technological innovation and improvement. This information collection supports the U.S. Department of Transportation (USDOT) strategic goal of Safety.

Under contract to FMCSA, the Virginia Tech Transportation Institute (VTTI) at the Virginia Polytechnic Institute and State University (VT) will use online surveys to obtain the data required to address the study objectives. The information collection will be administered in two phases:

Phase I: Online Recruitment Survey. This voluntary, seven-question survey will screen carriers and verify their eligibility for Phase II participation. To be eligible for Phase II participation, carriers must fall into one of two groups: (a) The Recommended Practices (RP) Group, which includes carriers with the lowest Vehicle Maintenance and Crash Indicator Behavior Analysis and Safety Improvement Categories (BASIC) percentiles (*i.e.,* less than or equal to the 33rd percentile); or (b) the Intervention Effects (IE) Group, which includes carriers that have experienced Federal or State interventions in the last 24 months due to vehicle maintenance violations. The BASICs are Unsafe Driving, Crash Indicator, Hours-of-Service (HOS) compliance, Vehicle Maintenance, Controlled Substances/Alcohol, Hazardous Materials (HM) Compliance, and Driver Fitness. More information on the SMS methodology can be found at *https://csa.fmcsa.dot.gov/Documents/SMSMethodology.pdf.*

Phase II: Carrier Maintenance Management Survey. This voluntary, 106-question survey will include questions about demographics; maintenance practices, intervals, personnel, and facilities; and State and Federal inspections, among other things. The Phase II survey will employ branch logic; as such, carriers will be prompted to complete different sections based on their survey group (and for one section, carrier size). Consequently, no participating carrier will be asked to complete all 106 questions.

In the Phase II survey, carriers (of all sizes) in the RP Group will be asked to provide additional information about maintenance personnel and facilities (*e.g.,* mechanic training levels, tools required for adequate inspection, and certification of facilities) and vehicle maintenance issues that may impact safety. Information from the RP Group will seek to address Objective 1, relating to development of an operational definition of ''systematic maintenance,'' Objective 2, and Objective 3, relating to establishment of minimum standards for inspection intervals, mechanic qualifications and training, and certification of maintenance facilities.

Carriers in the IE Group will be asked to complete the section on intervention effects, which includes questions about the status of active interventions or investigations; results of closed interventions or investigations; interactions with State versus Federal agencies; intervention activities experienced; the accuracy of violations leading to interventions; actions taken in response to interventions; changes in

carrier vehicle maintenance practices as a result of an intervention; significant benefits of interventions; and ways the intervention process could be improved. Information provided by the IE Group will address the portion of Objective 2 regarding sufficiency of regulations and where interventions need to be improved to facilitate complying with these regulations.

Survey responses will be summarized and reported using plots, tables, content analysis, and calculated summary statistics. Plots and tables will provide a visual comparison of multiple choice and checkbox survey responses for successful carriers (*i.e.,* carriers in the RP Group) and those receiving interventions in the last 24 months (*i.e.,* carriers in the IE Group). These methods will also allow researchers to summarize responses by carrier operation type (*i.e.,* truck or bus) and size. Bar charts will be used to plot responses to many survey questions. Some survey responses may be summarized with tables with rows for each of the carrier operation types (truck or bus) and each carrier-size subgroup. To explore and summarize responses to open-ended survey questions, researchers will use content analysis methods. An illustration of an open-ended question in the survey is ''List examples of critical safety-related maintenance activities for trailer vehicle milestones.'' The goal of content analysis of open-ended questions will be to identify common answers.

The results of this information collection will be documented in a technical report to be delivered to and published by FMCSA. In addition, the results will be used to create a ''recommended best practices'' report that will outline minimum standards for inspection intervals, mechanic qualifications and training, and certification of maintenance facilities. Finally, VTTI is required under the contract with FMCSA to compile and analyze the collected information and develop a public-use data set.

This ICR is for a one-time data collection. If this data collection does not take place, the truck and bus industry would continue to operate with the uncertainty of what a ''systematic maintenance'' program, as currently worded in section 396.3(a), consists of. This term's ambiguous definition makes it difficult for federal and state inspectors to evaluate the effectiveness of a carrier's maintenance program or its compliance with this provision. Furthermore, this uncertainty may make it difficult for carriers to ascertain and therefore comply with the regulation's intent.

*Title:* Truck and Bus Maintenance Requirements and Their Impact on Safety.

*OMB Control Number:* 2126–XXXX.

*Type of Request:* New information collection.

*Respondents:* Freight motor carriers and passenger carriers.

*Estimated Number of Respondents:* 578 respondents [578 respondents will complete the Online Recruitment Survey. Of those 578 respondents, 289 will also complete the Carrier Maintenance Manager Survey].

*Estimated Time per Response:* Varies [Online Recruitment Survey: 5 minutes. Carrier Maintenance Manager Survey: 45 minutes].

*Expiration Date:* 3 years after approval.

*Frequency of Response:* Once.

*Estimated Total Annual Burden:* 265 hours [Online Recruitment Survey: 578 respondents × (5 minutes ÷ 60 minutes) = 48 hours; Carrier Maintenance Manager Survey: 289 respondents × (45 minutes ÷ 60 minutes) = 217 hours].

*Public Comments Invited:* You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Issued under the authority of 49 CFR 1.87 on: July 10, 2018.

**Kelly Regal,**

*Associate Administrator for Office of Research and Information Technology.*

[FR Doc. 2018–15151 Filed 7–13–18; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF VETERANS AFFAIRS

### Notice of Intent To Prepare a Programmatic Environmental Impact Statement of the Department of Veterans Affairs Housing Loan Program

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice of intent.

**SUMMARY:** Under the authority of the National Environmental Policy Act (NEPA) and its implementing regulations, VA intends to prepare a Programmatic Environmental Impact Statement (PEIS) to evaluate the potential direct, indirect, and cumulative environmental consequences of continued operation and administration of VA's Housing Loan Program (HLP). VA's reference to the HLP includes federal assistance, administered by the Veterans Benefits Administration (VBA), in the form of loans made, insured, or guaranteed by VA. It also includes housing benefits that can be used in conjunction with the HLP (*e.g.,* the Specially Adapted Housing program). Under the HLP, VBA is also responsible for the management, marketing, and disposition of real estate owned (REO) properties that VA acquires following the foreclosure of certain VA-guaranteed loans and loans held in VA's portfolio. This notice opens the public scoping phase and invites interested parties to identify potential issues, concerns, and reasonable alternatives that should be considered in the PEIS. Following the scoping meeting referenced below, a Draft PEIS will be prepared and circulated for public comment.

**DATES:** All written comments should be submitted by August 15, 2018.

VA invites federal, state, tribal, and local entities; non-profit organizations; businesses; interested parties; and the general public to comment on the proposed scope and content of the PEIS. VA will consider all scoping comments in developing the PEIS. VA will conduct a public scoping meeting on Thursday, August 2, 2018, from 6:00 to 8:00 p.m. at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, Rockville, Maryland 20852. The scoping meeting will afford the public an opportunity to learn more about the project and provide input on the environmental analysis process. During the meeting, VA will provide an overview of the project, as well as details regarding the PEIS scope, purpose, and need. VA will also outline the overall NEPA process. Additionally, VA will post a scoping presentation on a publicly available website during the 30-day scoping period. Such presentation will be available at *http://www.benefits.va.gov/homeloans/environmental_impact.asp.*

Proposed Actions and Alternatives: VA's Proposed Action is to continue administering the HLP and incorporating programmatic changes as necessitated by amendments to program authorities, Veteran need, market conditions, and factors not foreseen at the time of this publication.

VA's No Action Alternative refers to a scenario wherein VA operates the HLP in a manner consistent with policies

and procedures as of fiscal year 2017 (October 1, 2016 through September 30, 2017). The No Action Alternative is being presented as a snapshot in time to provide a baseline from which to compare the Proposed Action. Nevertheless, the No Action Alternative is likely unrealistic, as it assumes that HLP policies and requirements are frozen, and thereby does not account for subsequent programmatic improvements, legislation, Executive Branch directives, or other requirements.

**ADDRESSES:** Written comments may be submitted through *http://www.regulations.gov;* by mail or hand delivery to the Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1063B, Washington DC 20420; or by fax to 202–273–9026. Comments should indicate that they are submitted in response to ''Notice of Intent to Prepare a Programmatic Environmental Impact Statement of the Department of Veterans Affairs Housing Loan Program''. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1063B, Washington, DC 20420, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except Federal holidays). Please call (202) 461–4902 (this is not a toll-free number) for an appointment. During the comment period, comments may also be viewed online through the Federal Docket Management System at *www.regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** Elysium Drumm, VA Housing Loan Program, at 202–632–8790 or *VAHLPNEPA.VBAVACO@va.gov*.

**SUPPLEMENTARY INFORMATION:** The most significant element of the HLP is the provision of housing benefits that assist eligible Veterans in financing the purchase, construction, repair, or improvement of a home for their personal occupancy. See 38 U.S.C. 3701 *et seq.* VBA administers these and other housing benefits, such as assistance to Veterans who want to adapt their homes, to assist Veterans in readjusting to civilian life. The HLP provides what can be, for some Veterans, their sole opportunity to obtain crucial housing loans and adaptations.

Through this PEIS, VA is using the NEPA process to evaluate the potential physical, environmental, cultural, and socioeconomic effects of the HLP; to invite public participation; and to assist with and inform future agency planning and decision making related to the HLP. The PEIS will also evaluate the HLP, which assists hundreds of thousands of Veterans each year across the United States and its territories, to ensure that VA appropriately considers the human environmental elements and effects specified in 40 CFR 1508.8 (*i.e.,* ecological, aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative) in carrying out the various elements and aspects of the program. This PEIS is unique in that it addresses an existing program, and VA has no specific or immediate need to change its operational structure or procedures to address environmental impacts. Furthermore, the making of loan guaranties, direct loans, and grants do not typically, in and of themselves, result in direct environmental impacts. Environmental impacts, if they occur, would be the result of private citizen actions (*e.g.,* construction of a house funded by VA-guaranteed loan financing) related to a specific property. In this case, the primary environmental impacts of concern for VA would be the potential indirect impacts from homeowner actions and the potentially significant cumulative impacts of small incremental actions on local and regional resources.

As part of the scoping process, VA encourages federal, state, tribal, and local entities; non-profit organizations; businesses; interested parties; and the general public to provide input on any areas of environmental concern relevant to the HLP, and suggestions regarding potential environmental impacts that should be evaluated. VA will consult with such parties during VA's preparation of the PEIS.

## 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. Jacquelyn Hayes-Byrd, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on July 10, 2018, for publication.

Dated: July 10, 2018.

**Jeffrey M. Martin,**

*Impact Analyst, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

[FR Doc. 2018–15073 Filed 7–13–18; 8:45 am]

BILLING CODE 8320–01–P

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0609]**

## Agency Information Collection Activity: Survey of Veteran Enrollees' Health and Use of Health Care

**AGENCY:** Veterans Health Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** Veterans Health Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each renewal of a currently approved collection, and allow 60 days for public comment in response to the notice.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before September 14, 2018.

**ADDRESSES:** Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Brian McCarthy, Office of Regulatory and Administrative Affairs (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Brian.McCarthy4@va.gov.* Please refer to ''OMB Control No. 2900–0609'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

**FOR FURTHER INFORMATION CONTACT:** Brian McCarthy at (202) 615–9241.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, 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.

*Authority:* N/A.

*Title:* Survey of Veteran Enrollees' Health and Use of Health Care.

*OMB Control Number:* 2900–0609.

*Type of Review:* Renewal currently approved collection.

*Abstract:* The VA Survey of Enrollees gathers information from Veterans enrolled in the VA Health Care System about factors which influence their health care utilization choices. Data collected are used to gain insights into Veteran preferences and to provide VA and Veterans Health Administration (VHA) management guidance in preparing for future Veteran needs. In addition to factors influencing health care choices, the data collected include enrollees' perceived health status and need for assistance, available insurances, self-reported utilization of VA services versus other health care services, reasons for using VA, barriers to seeking care, ability and comfort level with accessing virtual care, as well as general demographics and family characteristics that may influence utilization but cannot be accessed elsewhere.

*Affected Public:* Individuals and households.

*Estimated Annual Burden:* 14,000 hours.

*Estimated Average Burden per Respondent:* 20 minutes.

*Frequency of Response:* Annually.

*Estimated Number of Respondents:* 42,000.

By direction of the Secretary.

**Cynthia D. Harvey-Pryor,**

*Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018–15085 Filed 7–13–18; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0128]**

## Agency Information Collection Activity: Notice of Lapse, Notice of Past Due Payment

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** Veterans Benefits Administrations, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed from veterans to reinstate a lapsed life insurance policy. The information requested is authorized by law, 38 CFR Section 8.11.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before September 14, 2018.

**ADDRESSES:** Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administrations (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0128'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Harvey-Pryor at (202) 461–5870.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

**Authority:** Public Law 104–13; 44 U.S.C. 3501–3521.

*Title:* Notice of Lapse, Notice of Past Due Payment—VA Form 29–389 and 29–389–1

*OMB Control Number:* 2900–0128.

*Type of Review: Extension* of a previously approved collection.

*Abstract:* These forms are used by the policyholder to reinstate a lapsed life insurance policy. The information requested is authorized by law, 38 CFR Section 8.11.

*Affected Public:* Individuals and households.

*Estimated Annual Burden:* 4,281 hours.

*Estimated Average Burden per Respondent:* 11 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 23,352.

By direction of the Secretary.

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.*

[FR Doc. 2018–15084 Filed 7–13–18; 8:45 am]

**BILLING CODE 8320–01–P**

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Part II

## Department of Homeland Security

Federal Emergency Management Agency

44 CFR Parts 59, 61, and 62

National Flood Insurance Program (NFIP): Conforming Changes To Reflect the Biggert-Waters Flood Insurance Reform Act of 2012 (BW–12) and the Homeowners Flood Insurance Affordability Act of 2014 (HFIAA), and Additional Clarifications for Plain Language; Proposed Rules

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Parts 59, 61, and 62**

**[Docket ID FEMA–2018–0026]**

**RIN 1660–AA95**

# National Flood Insurance Program (NFIP): Conforming Changes To Reflect the Biggert-Waters Flood Insurance Reform Act of 2012 (BW–12) and the Homeowners Flood Insurance Affordability Act of 2014 (HFIAA), and Additional Clarifications for Plain Language

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The National Flood Insurance Program (NFIP), established pursuant to the National Flood Insurance Act of 1968, as amended, is a voluntary program in which participating communities adopt and enforce a set of minimum floodplain management requirements to reduce future flood damages. This proposed rule would revise the NFIP's implementing regulations to codify certain provisions of the Biggert-Waters Flood Insurance Reform Act of 2012 and the Homeowner Flood Insurance Affordability Act of 2014 that FEMA has already implemented and to clarify certain existing NFIP rules relating to NFIP operations and the Standard Flood Insurance Policy.

**DATES:** Submit comments on or before September 14, 2018.

**ADDRESSES:** You may submit comments, identified by Docket ID: FEMA–2018–0026, by one of the following methods:

*Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

*Mail/Hand Delivery/Courier:* Regulatory Affairs Division, Office of Chief Counsel, Federal Emergency Management Agency, Room 8NE, 500 C Street SW, Washington, DC 20472–3100.

To avoid duplication, please use only one of these methods. FEMA will post all comments received without change to *http://www.regulations.gov,* including any personal information provided. For instructions on submitting comments, see the Public Participation portion of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Kelly Bronowicz, Director, Policyholder Services Division, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 557–9488.

**SUPPLEMENTARY INFORMATION:**

## I. Public Participation

The Federal Emergency Management Agency encourages the public to participate in this rulemaking by submitting comments and related materials. The Agency will consider all comments and material received during the comment period.

When submitting a comment, identify the agency name and the docket ID for this rulemaking, indicate the specific section of this document to which each comment applies and give the reason for each comment. The public may submit comments and materials by electronic means, mail, or delivery to the address under the **ADDRESSES** section. Please submit comments and material by only one means.

Regardless of the method used for submitting comments or material, all submissions will be posted without change to the Federal e-Rulemaking Portal at *http://www.regulations.gov* and will include any personal information the commenter provides. Therefore, submitting this information makes it public. Those considering commenting may wish to read the Privacy and Security notice that is available via a link on the homepage of *http://www.regulations.gov.*

*Viewing comments and documents:* For access to the docket to read background documents or comments received, go to the Federal e-Rulemaking Portal at *http://www.regulations.gov.* Background documents and submitted comments may also be inspected at FEMA, Office of Chief Counsel, Room 8NE, 500 C Street SW, Washington, DC 20472–3100.

*Public Meeting:* We do not plan to hold a public meeting, but you may submit a request for one at the address under the **ADDRESSSES** section explaining why one would be beneficial. If FEMA determines that a public meeting would aid this rulemaking, it will hold one at a time and place announced by a notice in the **Federal Register**.

## II. Background and Authorities

### *A. National Flood Insurance Program*

Congress created the National Flood Insurance Program (NFIP) through enactment of the National Flood Insurance Act of 1968 (NFIA) (Title XIII of Pub. L. 90–448, 82 Stat. 476), found at 42 U.S.C. 4001 *et seq.* The NFIP is a Federal program enabling property owners in participating communities to purchase insurance as a protection against flood losses in exchange for State and community floodplain management requirements that reduce the risk of future flood damages. Communities participate in the NFIP based on an agreement between the community and FEMA. If a community adopts and enforces a floodplain management ordinance to reduce future flood risk to new construction in floodplains, FEMA will make flood insurance available within the community as a financial protection against flood losses. Accordingly, the NFIP is comprised of three key activities: Flood insurance, floodplain management, and flood hazard mapping.

1. Flood Insurance

The NFIP makes flood insurance available to property owners or lessees in communities that participate in the NFIP through the adoption and enforcement of community-wide floodplain management requirements. If a community adopts and enforces a floodplain management ordinance that meets certain minimum floodplain management requirements to reduce future flood risks within an area known as the Special Flood Hazard Area (SFHA) the Federal Government will make flood insurance available to property owners in that community. NFIP flood insurance indemnifies property owners from flood losses, reducing the need for Federal disaster assistance. NFIP floodplain management requirements reduce future flood damages, thus further reducing the need for Federal disaster assistance. In addition to providing flood insurance and reducing flood damages through floodplain management, the NFIP identifies and maps the nation's floodplains. FEMA disseminates maps depicting flood hazard information to create broad-based awareness of flood hazards, to provide data for rating flood insurance policies, and to apply the appropriate minimum floodplain management requirements for flood-prone areas.

Prior to enactment of the Biggert-Waters Flood Insurance Reform Act of 2012 (BW–12), the NFIA made federally subsidized flood insurance available to property owners or lessees of buildings in NFIP-participating communities.[1] Subsidized flood insurance rates were available for policies covering existing buildings or buildings built prior to the community's adoption of its initial Flood Insurance Rate Maps (FIRMs),

[1] Flood insurance is also available to cover the contents owned by tenants in a rental property.

generally referred to as ''pre-FIRM buildings.'' Subject to certain short-term statutory exceptions, FEMA offers only actuarial rates to all buildings constructed, or substantially damaged or improved, on or after the effective date of the initial FIRM for the community or after December 31, 1974, whichever is later, generally referred to as ''post-FIRM buildings.'' *See* 42 U.S.C. 4014(a)(1), 4015(b). In addition, building owners must purchase flood insurance as a condition of receiving federally-backed or federally-regulated loans and Federal assistance in SFHAs of participating communities. *See* Flood Disaster Protection Act of 1973, sec. 103 (Pub. L. 93–234, 87 Stat. 975 (codified as amended at 42 U.S.C. 4001 *et seq.*)).

As discussed in more detail below, with the passage of BW–12, Congress mandated that FEMA phase out subsidies for certain pre-FIRM properties. These pre-FIRM properties include non-primary residences, business properties, severe repetitive loss properties, substantially damaged properties, substantially improved properties, and properties for which the cumulative claims payments exceed the fair market value of the property.

The Homeowner Flood Insurance Affordability Act of 2014 (Pub. L. 113–89, 128 Stat. 1020) (HFIAA) requires a phase-out of subsidies on all pre-FIRM properties at a rate of no less than 5 percent and no more than 15 percent premium increases per year, subject to certain exceptions established by statute (such as the BW–12 provisions) requiring a quicker phase-out for certain types of pre-FIRM properties. Accordingly, FEMA will likely phase out subsidies on all pre-FIRM properties within the next 12 to 17 years.

A prospective policyholder may purchase an NFIP flood insurance policy either: (1) Directly from the Federal Government through a direct servicing agent (referred to as ''NFIP Direct''), or (2) from a participating private insurance company through the Write Your Own (WYO) Program. The Standard Flood Insurance Policy (SFIP) sets out the terms and conditions of insurance. *See* 44 CFR part 61, Appendix A. FEMA establishes terms, rate structures, and premium costs of SFIPs. The terms, coverage limits, and flood insurance premiums are the same whether purchased from the NFIP Direct or the WYO Program. *See* 44 CFR 62.23(a).

The SFIP is a single-peril (flood) policy that pays for direct physical damage to insured property. There are three forms of the SFIP: The Dwelling Form, the General Property Form, and the Residential Condominium Building Association Policy (RCBAP) Form. The Dwelling Form insures a one to four family residential building or a single-family dwelling unit in a condominium building. *See* 44 CFR part 61, Appendix A(1). Policies under the Dwelling Form offer coverage for building property, up to $250,000, and personal property up to $100,000. The General Property Form insures a five or more family residential building or a non-residential building. *See* 44 CFR part 61, Appendix A(2). The General Property Form offers coverage for building and contents up to $500,000 each. The RCBAP Form insures residential condominium association buildings and offers building coverage up to $250,000 multiplied by the number of units and contents coverage up to $100,000 per building. *See* 44 CFR part 61, Appendix A(3). RCBAP contents coverage insures property owned by the insured condominium association. Individual unit owners must purchase their own Dwelling Form policy in order to insure their own contents.

In addition to coverage for building or contents losses, most NFIP policies also include Increased Cost of Compliance (ICC) coverage. ICC coverage applies when flood damages are so severe that the local government declares the building ''substantially damaged,'' thus requiring the building owner to bring the building up to current community standards. If a community has a repetitive loss ordinance, ICC coverage will also cover compliance requirements for a repetitive loss structure. ICC coverage provides up to $30,000 of the cost to elevate, demolish, floodproof, or relocate an insured building or any combination thereof.

FEMA publishes a Flood Insurance Manual with detailed explanations of the terms and conditions of the SFIP and relevant program policies and procedures. The Flood Insurance Manual is primarily used by insurers and agents selling and servicing Federal flood insurance. FEMA normally publishes the Flood Insurance Manual twice a year and 6 months prior to a new manual version becoming effective. The current version became effective on October 1, 2017. The current flood insurance manual, as well as previous versions, is available at *https://www.fema.gov/flood-insurance-manual.* Page numbering restarts for each section of the Flood Insurance Manual, so FEMA cites to both the section and page number. For the purposes of this notice, all citations to the Flood Insurance Manual are to the version that became effective on October 1, 2017, which is available at *https://www.fema.gov/media-library/assets/documents/133846.*

Additionally, FEMA publishes policy statements and underwriting bulletins to further explain and clarify the coverage under the SFIP. These are available at *www.fema.gov/library* and *www.nfipservice.com.*

2. Floodplain Management

A local community with land use authority may elect to participate in the NFIP. Communities participate under a voluntary agreement with FEMA. In order to participate in the NFIP, a community must adopt and enforce floodplain management requirements that incorporate the NFIP minimum floodplain management requirements. *See* 44 CFR 59.2(b), 59.22(a)(3), 60.1(d). The intent of these standards is to reduce flood risk and prevent loss of life and property. Communities incorporate these requirements into their zoning codes, subdivision ordinances, and building codes, or they adopt special purpose floodplain management ordinances. These NFIP requirements apply to areas mapped as SFHAs. The community ordinances must also include effective enforcement provisions. 44 CFR 59.2(b). The NFIP will suspend a participating community from theNFIP if the community fails to adopt the minimum NFIP floodplain management requirements within 6 months from the date the NFIP provides the flood map. 44 CFR 59.24(a), 60.13. Moreover, the NFIP may suspend or put on probation any participating community that does not adequately enforce its floodplain management ordinance. 44 CFR 59.24(b)–(c).

3. Flood Hazard Mapping

Through its Flood Hazard Mapping Program, FEMA identifies flood hazards, assesses flood risks, and collaborates with States and communities to provide accurate flood hazard and risk data to guide them to mitigation actions. Congress requires FEMA to identify flood-prone areas and then subdivide them into flood risk zones. 42 U.S.C. 4101(a). FEMA then uses this data to support community floodplain management requirements and rate flood insurance policies. Mapping of flood hazards also promotes public awareness of the degree of hazard within such areas and provides for the expeditious identification and dissemination of flood hazard information. FEMA maintains and updates data through FIRMs and Flood Insurance Studies (FISs).

*B. Recent Legislative Changes*

1. Biggert-Waters Flood Insurance Reform Act of 2012

Congress enacted BW–12 (Title II, Subtitle A of Pub. L. 112–141, 126 Stat. 405) to extend the NFIP's authorities through September 30, 2017, and to adopt significant program reform. The law requires changes to all major components of the program, including flood insurance, flood hazard mapping, and the management of floodplains.

The provisions of BW–12 relevant to this rulemaking include the following. First, BW–12 requires FEMA to increase the maximum coverage amount for multi-family properties to the same amount as that allowed for commercial properties. Second, BW–12 establishes a minimum deductible amount for NFIP polices. Third, BW–12 prohibits FEMA from denying payment to policyholders for damage or loss to a condominium unit under the Dwelling Form based solely on the fact that the condominium association has inadequate flood insurance coverage on the entire condominium. Fourth, BW–12 requires FEMA to review, among other things, the processes and procedures for making flood in progress determinations. *See* SFIP Article V.B. FEMA implemented these requirements by updating the Flood Insurance Manual after BW–12's enactment. The NFIP described these program changes in WYO Bulletin W–13070 (Dec. 16, 2013). FEMA also issued WYO Bulletin W–12045 (July 10, 2012), which implemented BW–12 section 100241's waiver of the standard 30-day waiting period for coverage of flood damage due to flood on Federal land caused, or exacerbated, by post-wildfire conditions. FEMA now proposes to codify these changes in the NFIP regulations.

2. Homeowner Flood Insurance Affordability Act of 2014

Congress enacted HFIAA to address flood insurance affordability concerns related to BW–12. Accordingly, HFIAA repealed some provisions of BW–12, mostly related to establishing premium rates. HFIAA also made a number of new program changes. The provisions of HFIAA relevant to this rulemaking include a requirement in Section 8 of HFIAA that FEMA offer a high deductible option of $10,000, which FEMA discusses below.

**III. Discussion of Proposed Rule**

FEMA proposes to amend parts 59, 61, and 62 of 44 CFR. These parts contain regulations implementing the NFIP. In addition, FEMA proposes to amend Appendices A(1)–A(3) of part 61, containing the three forms of the SFIP: The Dwelling Policy Form, the General Property Form, and the Residential Condominium Building Association Form. These forms are used in NFIP polices.

FEMA proposes this rulemaking for three purposes. First, it intends to make several non-substantive changes designed to improve the readability, uniformity, and clarity of the NFIP regulations. Second, FEMA proposes to make several non-substantive updates to regulations to align with the requirements of BW–12 and HFIAA. Third, FEMA proposes two substantive, albeit miniminally so, changes to its regulations codifying the requirements of BW–12 and HFIAA.

*A. Part 59: General Provisions*

1. Part 59 Authority Citation

FEMA proposes to update the authority citation for Part 59 to reflect changes to FEMA's source of authority. Currently, the authority citation is 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR 1979 Comp., p. 376. FEMA proposes to replace the citations to Reorganization Plan No. 3 and Executive Order 12127 with a citation to the current codification of the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.* The authority citation would therefore read, ''42 U.S.C. 4001 *et seq.;* 6 U.S.C. 101 *et seq.*'' FEMA proposes this change because Reorganization Plan No. 3 and Executive Order 12127 originally created FEMA as an executive agency and provided the legal basis for FEMA's existence until the passage of the Post-Katrina Emergency Management Reform Act of 2006, Public Law 109–295, 120 Stat. 1394 (PKEMRA). PKEMRA amended the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, to establish FEMA in statute and define the Agency's authorities and responsibilities. A citation to the codification of the Homeland Security Act after the citation to the NFIA is therefore more appropriate.

2. Section 59.1 Definitions

44 CFR part 59 contains general provisions applicable to the NFIP's regulations. Section 59.1 contains a list of definitions generally applicable throughout the NFIP regulations. FEMA proposes to add 13 new definitions and modify three definitions in this section to make this section consistent with its proposed rule changes to parts 61 and 62.

First, FEMA proposes to revise the definition of ''act.'' Currently, the regulation defines ''act'' to mean ''statutes authorizing the National Flood Insurance Program that are incorporated in 42 U.S.C. 4001–4128.'' However, the NFIA now extends to section 4131. Rather than revise the citation to ''42 U.S.C. 4001–4131,'' FEMA proposes to change the citation to ''42 U.S.C. 4001 *et seq.*'' As the NFIA is amended often, it makes more sense to use ''*et seq.*'' so that the citation stays current and FEMA will not have to revise it every time sections are added.

Second, FEMA proposes to revise the definition of ''deductible.'' Currently, ''deductible'' is defined as ''the fixed amount or percentage of any loss covered by insurance which is borne by the insured prior to the insurer's liability.'' FEMA proposes to revise the definition of ''deductible'' to mean ''the amount of an insured loss that is the responsibility of the insured and that is incurred before any amounts are paid for the insured loss under the insurance policy.'' While there is no substantive difference between the two definitions, FEMA believes the proposed definition is clearer and more consistent with the language in Article VI.A of the SFIP, as well as the language in proposed section 61.5, which would provide guidance on deductibles available for NFIP policies (discussed in further detail below).

Third, FEMA proposes to revise the definition of ''Emergency Flood Insurance Program or emergency program.'' Currently, ''Emergency Flood Insurance Program or emergency program'' is defined as ''the Program as implemented on an emergency basis in accordance with section 1336 of the Act. It is intended as a program to provide a first layer amount of insurance on all insurable structures before the effective date of the initial FIRM.'' FEMA proposes to remove ''Emergency Flood Insurance Program'' so the term only reads ''Emergency Program,'' and revise the definition to mean ''the initial phase of a community's participation in the National Flood Insurance Program, as prescribed by Section 1306 of the Act.'' FEMA proposes this change because although the new definition is substantively the same as the current definition, it is clearer and more consistent with the definition of this term in the SFIP.

FEMA also proposes to add definitions for several terms. These terms are: ''condominium building,'' ''mixed use building,'' ''multifamily building,'' ''non-residential building,'' ''non-residential property,'' ''other residential building,'' ''other residential property'' ''residential building,''

''residential property,'' ''single family dwelling,'' and ''two to four family building.'' The NFIP already uses these terms when describing the program to the public because they align with the terminology used in the private insurance industry and addresses important nuances not adequately addressed in statute and regulation. FEMA proposes defining these terms in regulation because they support the consistent interpretation and application of the NFIA and its regulations. Accordingly, codifying them in regulation will support greater uniformity and clarity for the public. FEMA provides further explanation of these definitions elsewhere in this preamble, under discussion of the relevant sections where these terms appear.

*B. Part 61: Insurance Coverage and Rates*

1. Part 61 Authority Citation

The current authority citation for part 61 is 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376. FEMA proposes to replace the citations to Reorganization Plan No. 3 and Executive Order 12127 with a citation to the current codification of the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.* The authority citation would therefore read 42 U.S.C. 4001 *et seq.;* 6 U.S.C. 101 *et seq.* FEMA proposes this change because while Reorganization Plan No. 3 and Executive Order 12127 originally created FEMA as an executive agency, PKEMRA amended the Homeland Security Act of 2002, Public Law 107–296, by establishing the Agency in statute and defining the Agency's authorities and responsibilities. Accordingly, a citation to the codification of the Homeland Security Act is more appropriate.

2. Section 61.1 Purpose of Part

Section 61.1 describes the overall purpose of part 61. It states that part 61 describes the types of properties eligible for flood insurance coverage under the NFIP, the limits of such coverage, and the premium rates actually to be paid by insureds. It states that the specific communities eligible for coverage are designated by the Federal Insurance Administrator from time to time as applications are approved under the Emergency Program and as ratemaking studies of communities are completed prior to the regular program. Finally, it states that lists of such communities are periodically published under part 64 of this subchapter. FEMA proposes to remove the last two sentences of Section 61.1 addressing the specific communities eligible for coverage and publication of the list of communities because they provide information relevant to part 64, not part 61. Removing these sentences would therefore avoid possible confusion regarding the subjects covered in part 61.

3. Section 61.3 Types of Coverage

Section 61.3 states that insurance coverage under the NFIP is available for structures and their contents, and that coverage for each may be purchased separately.

FEMA proposes to change the title of this section from ''Types of coverage'' to ''Coverage and benefits provided under the Standard Flood Insurance Policy'' because this new title provides a more accurate description of the proposed revisions to this section.

FEMA proposes to replace ''structure'' with ''building'' because in current practice the program uses the term ''building'' rather than ''structure'' throughout its guidance documents and other communications. The term ''building'' is a more precise and accurate term, because the SFIP insures buildings, not structures. While the term ''structure'' encompasses the term ''building,'' it also includes things that are not buildings, such as carports and gas or liquid storage tanks, and thus not insurable under the terms and conditions of the SFIP. Consistent use of this terminology will improve the overall clarity and accuracy of the regulation when viewed within the larger context of FEMA's communications and guidance documents regarding the NFIP, as ''building'' rather than ''structure'' is more commonly used outside of the CFR.

FEMA proposes to add two new provisions to this section to provide a more accurate depiction of the coverages and benefits available under the SFIP and to improve the Section's overall clarity. First, FEMA proposes to add paragraph (b) stating that in addition to building and contents coverage, each form of the SFIP provides coverage for other flood-related expenses. The Dwelling Form of the SFIP covers debris removal, loss avoidance measures, and condominium loss assessments. The General Property Form of the SFIP covers debris removal, loss avoidance measures, and pollution damage. The Residential Condominium Policy Form of the SFIP covers debris removal and loss avoidance measures. Second, FEMA proposes to add paragraph (c) stating that with the purchase of building coverage, the SFIP also covers costs associated with bringing the building into compliance with local floodplain ordinances. FEMA believes this information may be useful to a reader of the CFR.

4. Section 61.4 Limitations on Coverage

Section 61.4 provides that coverage obtained through the NFIP is subject to the NFIA, relevant regulations, the SFIP, and each individual policy's declaration page, and the maximum limits of coverage. FEMA proposes to remove this section because it duplicates the provisions of current section 61.5(e), which provide that the SFIP ''is authorized only under terms and conditions established by Federal statute, the program's regulations, the Administrator's interpretations and the express terms of the policy itself.'' As section 61.5(e) conveys the same information as section 61.4, FEMA finds that section 61.4 is not necessary. (Note that FEMA proposes to move 61.5(e) to proposed 61.13, discussed below.)

5. Section 61.5 Special Terms and Conditions

Paragraph (a) of section 61.5 states that no new flood insurance or renewal of flood insurance policies shall be written for properties declared by a duly constituted State or local zoning or other authority to be in violation of any flood plain, mudslide (*i.e.,* mudflow), or flood-related erosion area management or control law, regulation, or ordinance. FEMA proposes to change ''shall'' to ''will'' to avoid ambiguity.

Paragraph (b) of section 61.5 states that to reduce the administrative costs of the NFIP, of which the Federal Government pays a major share, payment of the full policyholder premium must be made at the time of application. FEMA proposes to reword ''payment of the full policyholder premium'' to state ''applicants must pay the full policy premium'' because premiums are associated with policies, not policyholders. No substantive change is intended.

FEMA proposes to retain the substance of paragraphs (a) and (b), but proposes to move them to their own section (proposed 61.4) but retaining the current title of the section (''Special terms and conditions'').

Paragraph (c) of section 61.5 states that because of the seasonal nature of flooding, refunds of premiums upon cancellation of coverage by the insured are permitted only if the insurer ceases to have an ownership interest in the

covered property at the location described in the policy. It further states that refunds of premiums for any other reason are subject to the conditions set forth in 62.5 of this subchapter. FEMA proposes to remove paragraph (c) and add the substance of it to paragraph (b) of proposed 62.5 (the proposed changes to which are discussed more fully later in this preamble). Section 62.5 addresses policy cancellations and nullifications, and thus the substance of current section 61.5(c) is more appropriate for section 62.5.

Similar to current section 61.4, paragraph (e) of section 61.5 states that the SFIP is authorized only under terms and conditions established by Federal statute, the program's regulations, the Administrator's interpretations and the express terms of the policy itself. Section 61.5 also states that representations regarding the extent and scope of coverage which are not consistent with the NFIA or with NFIP regulations are void, and the duly licensed property or casualty agent acts for the insured and does not act as agent for the Federal Government, the Federal Emergency Management Agency, or the servicing agent. As noted above, FEMA proposes to move 61.5(e) to proposed 61.13. The provisions appear in proposed paragraph (e) of section 61.13 (''Authorized only under terms and conditions established by the Act and Regulation'') and paragraph (f) (''Agent acts only for policyholder''). These provisions are more appropriate for proposed section 61.13 because the section contains general provisions about the SFIP, and 61.5(e) also constitutes general provisions concerning the SFIP. These changes would improve the overall organization and cohesiveness of part 61. FEMA does not intend any substantive changes with these proposed revisions.

6. Proposed Section 61.5 Deductibles (Formerly Paragraph (d) of Current Section 61.5)

Current paragraph (d) of section 61.5 states that optional deductibles are available in all zones for four categories of properties, and presents those categories as four tables. The Category One table lists some of the deductible options for one to four family building and contents coverage policies. The Category Two table lists some of the deductible options for one to four family building coverage only or contents coverage only policies. The Category Three table lists some of the deductible options for ''other residential'' (residential buildings with five or more units) and nonresidential policies. The Category Four table lists some of the deductible options for residential condominium building policies. A note to these tables indicates that policyholders may submit any other deductible combination for rating to the NFIP. This note allows FEMA to offer deductibles listed in the deductible tables in the Rating Section of Flood Insurance Manual, pages 17–18.

FEMA proposes several revisions to paragraph (d). First, FEMA proposes to remove the number for the paragraph because, as noted above, paragraphs (a) and (b) would be moved to a new section 61.4 and paragraph (c) would be incorporated into section 62.5. As a result, paragraph (d) would be the only paragraph in the section, thus making the paragraph number unnecessary.

FEMA proposes to replace the current contents of paragraph (d) (proposed unnumbered paragraph) with a requirement that FEMA must provide policyholders with deductible options in various amounts, up to and including $10,000, subject to certain minimum deductibles. FEMA proposes this change because the current regulation's listing of deductible options may give readers the impression that the list is exhaustive even though the note following the Category Four table allows for FEMA to offer deductible options not listed in the table. The proposed text would make clear that FEMA may offer various options, subject to other restrictions.

The proposed text would require FEMA to offer deductible options up to and including $10,000 to comply with the requirements of Section 1306(d) of the NFIA, as amended by section 12 of HFIAA (42 U.S.C. 4013(d)), which requires FEMA to offer deductibles up to $10,000 for residential properties. As previously explained, current regulations allow policyholders to request deductible amounts not currently listed in regulation (including the $10,000 deductible option required under HFIAA). Thus, this proposed change would clarify the regulatory text consistent with statutory requirements, but not expand or contract the deductible options offered by the NFIP under current regulations.

FEMA also proposes to limit deductible options in accordance with section 1312(b) of the NFIA, as added by section 100210 of BW–12 (42 U.S.C. 4019(b)). Per this provision, FEMA proposes to establish minimum deductibles as follows: (1) $1,500 for policies covering pre-FIRM buildings charged less than full-risk rates with building coverage amounts less than or equal to $100,000; (2) $2,000 for policies covering pre-FIRM buildings charged less than full risk rates with building coverage amounts greater than $100,000; (3) $1,000 for policies covering post-FIRM buildings and pre-FIRM buildings charged full risk rates with building coverage amounts equal to or less than $100,000; and (4) $1,250 for policies covering post-FIRM buildings and pre-FIRM buildings charged full risk rates with building coverage amounts greater than $100,000.

Overall, the proposed deductible section would provide readers with a clear understanding of available deductible options, including minimum deductibles required under Section 1312(b) of the NFIA, as added by Section 100210 of BW–12 (42 U.S.C. 4019(b)) and the $10,000 deductible option required by Section 1306(d) of the NFIA, as amended by Section 12 of HFIAA (42 U.S.C. 4013(d)). However, it would not expand or contract the deductibles available to policyholders under current law.

FEMA also proposes to rename the section heading of 61.5 to ''Deductibles'' because section 61.5 would only address deductible amounts.

7. Section 61.6 Maximum Amounts of Coverage Available

Current section 61.6 details the maximum amounts of coverage available under the NFIA. *See* 42 U.S.C. 4013(b). The current table shows varying coverage amounts available, depending on whether a policy is under the Emergency Program or the Regular Program, the use and occupancy of the building, and the building's location. As provided under the NFIA, for residential occupancies, the table lists coverage limits of $250,000 for buildings and $100,000 for contents. *See id.* For nonresidential occupancies, the table lists coverage limits of $500,000 for buildings and $500,000 for contents. *See id.* FEMA proposes to revise the table to more closely conform it to the one currently in the Rating Section of the Flood Insurance Manual, page 1. The Manual more clearly describes the different coverage limits based on occupancy by using terminology that more accurately conveys relevant statutory requirements. In comparison, the current table in the CFR includes terminology and distinctions that are no longer programmatically relevant.

i. Title of Table

The current table does not have a title. FEMA proposes to entitle the table ''Maximum Amounts of Coverage Available.'' While the Flood Insurance Manual uses the title ''Amount of insurance available,'' FEMA proposes to use ''coverage'' instead of ''insurance'' to conform to the current section title of

section 61.6. There is no substantive difference between the two titles in this context.

ii. Vertical Axis of Maximum Coverage Table

The current table has one vertical axis that lists the different categories of occupancy applicable to both building and contents coverages. These categories are, in order: ''Single Family Residential,'' ''Other Residential,'' ''Nonresidential,'' and ''Contents.'' Although the table provides a ''contents'' heading on this axis, there is no corresponding label for the building coverages. FEMA proposes to add ''Building Coverage'' to the vertical axis to distinguish between ''building coverage'' and ''contents coverage.'' This ''Building Coverage'' category would encompass ''Single Family Residential,'' ''Other Residential,'' and ''Nonresidential.'' FEMA believes this change would prevent confusion by improving the table's overall clarity and internal consistency.

As noted above, the current table lists the different categories of occupancy applicable to each coverage—''Single Family Residential,'' ''Other Residential,'' and ''Nonresidential.'' The current table further divides the ''Single Family Residential'' and ''Other Residential'' categories by whether or not a subject property is located within Hawaii, Alaska, Guam, or the U.S. Virgin Islands. It divides the ''Nonresidential'' category into either ''Small business'' or ''Churches and other properties.'' Similarly, the ''Contents'' coverage category only distinguishes between ''Residential,'' Small business,'' and ''Churches, other properties.'' The proposed table would make several changes to the categorization to use standardized terminology, improve the overall design and readability of the table, and use occupancy categories that more accurately reflect statutory and program differences in available coverages.

FEMA proposes to substitute the current use of ''Single Family Residential'' with ''Single Family Dwelling'' to describe a property. FEMA proposes this change because although the two terms (''dwelling'' and ''residential'') are interchangeable within the NFIP, ''Single Family Dwelling'' is the term used most often in the NFIP, as reflected in the Rating section of the Flood Insurance Manual. The Flood Insurance Manual has used this term for many years. *See* Flood Insurance Manual (May 1, 2005).[2]

Because ''single family dwelling'' is not currently defined, FEMA proposes to define ''single family dwelling'' in section 59.1 to mean ''either (a) a residential single-family building in which the total floor area devoted to non-residential uses is less than 50 percent of the building's total floor area, or (b) a single-family residential unit within a two to four family building, other residential building, business, or non-residential building, in which commercial uses within the unit are limited to less than 50 percent of the unit's total floor area.'' FEMA adopted this definition in the Flood Insurance Manual as early as 1978 to align with common industry practices in non-flood property insurance policies and it is the same definition found in the Definitions Section of the Flood Insurance Manual. This proposed definition reflects current NFIP practice and will not result in any substantive changes to the program.

FEMA proposes to add a new occupancy category, ''two to four family building.'' (The table would list the same maximum coverage amounts as those for a Single Family Dwelling, $35,000 for Emergency Program and $250,000 for the Regular Program.) FEMA proposes to include this category because it would be clearer to provide the public with a complete spectrum of occupancy categories so that the coverage limits for all occupancy types are more transparent. This does not reflect a substantive change to the program.

Because ''two to four family building'' is not currently defined, FEMA proposes to define it in section 59.1 to mean ''a residential building, including an apartment building, containing two to four residential spaces and in which commercial uses are limited to less than 25 percent of the building's total floor area.'' FEMA proposes to define ''two to four family building'' in this manner because it is the same definition used in the Flood Insurance Manual. This definition supports the NFIA's distinctions between residential and non-residential properties.

While FEMA proposes to maintain the ''Other Residential'' occupancy category that is in the current table, FEMA proposes to revise the category to read, ''Other Residential Building (including Multifamily Building).'' FEMA proposes to do this to make clear to the reader that ''Other Residential Building'' encompasses ''Multifamily Buildings,'' a term used in section 1305 of the NFIA, as added by section 100204 of BW–12 (42 U.S.C 4012(d)).

Because neither ''other residential building'' nor ''multifamily building'' is defined, FEMA proposes to define these in section 59.1. It proposes to define ''other residential building'' to mean ''a residential building that is designed for use as a residential space for 5 or more families or a mixed use building in which the total floor area devoted to non-residential uses is less than 25 percent of the total floor area within the building.'' It proposes to define ''multifamily building'' to mean ''an Other Residential Building that is not a condominium building.'' FEMA proposes to define these terms in this manner because the program currently defines them as such; these definitions appear in the Definitions Section of the Flood Insurance Manual. FEMA believes this definition of ''Other Residential Building'' fairly distinguishes the term from the ''single family dwelling'' and ''two to four family building'' occupancy categories, in terms of either residential spaces or square-footage. Defining ''multifamily building'' this way enables easier reference to condominium-building specific policies that will be discussed below.

FEMA proposes to add the ''Condominium Building'' occupancy category to the table (with maximum coverage amounts of ''$250,000 times the number of units in the building'' under the Regular Program, and nothing available under the Emergency Program). FEMA proposes this addition to integrate into the table information contained in current section 61.6(b). Section 61.6(b) states that ''[i]n the insuring of a residential condominium building in a regular program community, the maximum limit of building coverage is $250,000 times the number of units in the building (not to exceed the building's replacement cost).'' By adding the ''Condominium Building'' occupancy category to the table, FEMA plans to incorporate all the information in section 61.6(b) except the language in parentheses, ''not to exceed the building's replacement cost.'' FEMA proposes to omit this language because Article V of the RCBAP form (44 CFR 61, Appendix A(3)) already provides that FEMA will not pay beyond the replacement cost of the building.

While FEMA proposes to maintain the ''Nonresidential'' occupancy category, FEMA proposes to revise the category to read ''Non-Residential Building.'' This category would continue to have building limits of $100,000 in the Emergency Program and $500,000 in the Regular Program.

In order to provide greater clarity, FEMA proposes to incorporate the existing definition of ''non-residential building'' into regulation. Current regulations and statute do not define the

[2] *http://www.fema.gov/txt/nfip/manual200505.txt.*

extent of the term ''nonresidential'' used in maximum coverage limits found at NFIA 1306(b)(4) (42 U.S.C. 4013(b)(4)) and 44 CFR 61.6(a). However, 42 U.S.C. 4013(b)(3) does make clear that ''nonresidential building'' includes churches. Accordingly, FEMA has previously defined the term ''non-residential building'' as ''a commercial or mixed-use building where the primary use is commercial or non-habitational.'' Definitions Section of Flood Insurance Manual, page 7. FEMA proposes to incorporate this definition into regulation because it aligns with the common understanding of the term and encompasses churches and other houses of worship.

FEMA proposes to adjust the occupancy categories under the ''Contents Coverage'' portion of the coverage limits table. Currently, the table at section 61.6(a) divides the contents coverage portion amongst three categories: ''Residential,'' ''Small business,'' and ''Churches, other properties.'' FEMA proposes to remove the distinction between ''Small business'' and ''Churches, and other properties,'' and divide contents coverage into just two categories: ''Residential Property'' and ''Non-Residential Property.'' FEMA proposes this change to reflect the current practice of the program. Although NFIA section 1306(b)(1)(B) (42 U.S.C. 4013(b)(1)) provides a specific method for determining the maximum coverage available to small businesses, FEMA has opted to provide all other non-residential properties with the same coverage limits available to small businesses. Accordingly, while the statute may still distinguish small businesses from all other properties, current NFIP practice does not.

In addition to the adjustments to the categories of occupancy described above, FEMA proposes two changes to the footnotes. In the current table, there are two footnotes. Footnote 1 appends ''Emergency program'' in ''Emergency Program first layer'' and provides that ''[o]nly [the] first layer [is] available under the emergency program.'' Footnote 2 appends the ''Contents'' label and reads, ''Per unit.''

FEMA proposes to revise footnote 1 by appending it to the title of the table, ''Maximum Amount of Coverage Available,'' to describe the table generally. It would read, ''This Table provides the maximum coverage amounts available under the Emergency Program and the Regular Program, and the columns cannot be aggregated to exceed the limits in the Regular Program, which are established by statute. The aggregate limits for building coverage are the maximum coverage amounts allowed by statute for each building included in the relevant Occupancy Category.'' FEMA proposes this revision because, as described in greater detail below in subsection iv., *Horizontal Axis of Maximum Coverage Table,* the current footnote 1 is associated with the ''layer'' language FEMA proposes to remove, and the revised footnote's language more accurately reflects the NFIP's intent.

FEMA proposes to leave footnote 2 in the same place (after ''Contents Coverage''—the term replacing ''Contents'' in the current table), but expand it from ''Per unit'' to instead read, ''The policy limits for contents coverage are not per building. Although a single insured may not have more than one policy covering contents in a building, several insureds may have separate policies of up to the policy limits.'' FEMA proposes this revision to footnote 2 to more clearly reflect the restriction that the current footnote 2 attempts to convey, which is that the coverage limits apply to each unit of the building.

For instance, the tenants of a building with two independent living units may obtain separate contents policies for each unit. Each policy could have limits up to $100,000 and a contents claim for one unit would not affect the contents claim of the other unit. However, the existing NFIP rule—not reflected in the current footnote—is that the owner of the building cannot obtain two separate contents policies themselves. Instead, they could only obtain one contents policy with coverage up to $100,000. FEMA's proposed language in footnote 2 seeks to more clearly explain NFIP statutory authority that even though the contents coverage limits are per unit rather than per building, an insured cannot have more than one policy in a building.

FEMA proposes to append a new footnote—footnote 3—to the ''Residential Property'' occupancy category under ''Contents Coverage.'' Footnote 3 would explain that ''[t]he Residential Property occupancy category includes the Single Family Dwelling, Two to Four Family Building, Other Residential Building, and Condominium Building occupancies categories.'' FEMA proposes appending this new footnote to help improve the overall clarity of the table by linking the building coverage occupancy categories with the contents coverage occupancy categories.

iii. Special Provisions for Property in Hawaii, Alaska, Guam, and the U.S. Virgin Islands

The current maximum coverage table in section 61.6(a) lists separate increased limits in the Emergency Program within the ''Single Family Residential'' and ''Other Residential'' occupancy categories for residential structures located in Hawaii, Alaska, Guam, and the U.S. Virgin Islands. This is because the NFIP provides increased building coverage to these structures pursuant to 42 U.S.C. 4013(b)(1)(A)(iii). FEMA proposes to remove these lines referencing Hawaii, Alaska, Guam, and the U.S. Virgin Islands and place them instead in asterisked footnotes. FEMA does not intend any substantive change in these limits, but believes this design will improve the overall readability of the table.

iv. Horizontal Axis of Maximum Coverage Table

FEMA also proposes to make several clarifying, nonsubstantive changes to the horizontal axis of the table in section 61.6(a). The current table's horizontal axis is one label, ''Regular program.'' Under that label are three sub-labels: ''Emergency program first layer,'' ''Second layer,'' and ''Total amount available.'' As noted above, ''Emergency program first layer'' has a footnote (footnote 1) that reads, ''Only first layer available under emergency program.''

FEMA's proposed replacement table would dispense with the ''layer'' language and use only two columns, ''Emergency Program'' and ''Regular Program.'' Each column would list the applicable coverage limit for each occupancy type under each type of program. (The values under ''Emergency Program'' and ''Regular Program'' would be independent of each other and not subject to aggregation).

FEMA proposes these simpler horizontal axis labels for two reasons. The first reason is to improve overall clarity, as the ''layer'' language is unclear and inaccessible to the reader. The second reason is to more accurately reflect the NFIP's intent. This is because the current table reflects a previous approach for describing the NFIP's coverage limits. The idea was that the NFIP divided the Regular Program's coverage limits into two layers. The first layer was available for all NFIP policies, whether under the Emergency Program or the Regular Program. The NFIP only made the second layer of coverage available through the Regular Program. The current table attempts to capture this by placing the ''Emergency program

first layer'' and ''Second layer'' under the ''Regular program'' label. However, the table also combines the two layers under the ''Total amount available'' column, which is also under the ''Regular program'' label. A person could read this formulation as indicating that the three sub-headings combined provided the maximum amount of coverage under the ''Regular program.'' This is not FEMA's intent. The proposed replacement table conveys the same limits described in the current table, but it in a much clearer and concise way.

Moreover, it is for this reason that FEMA proposes to revise footnote 1, as described above, to clarify that the maximum coverage amounts listed for the Emergency Program and the Regular Program are not cumulative. Rather, the maximum amounts listed under the Regular Program are the maximum amounts authorized under the NFIA and include the amounts for the Emergency Program. (In other words, the amounts for the Emergency Program are not in addition to the amounts for the Regular Program).

v. Paragraph (b): Application of Limits to Additional Coverages

As noted above, current paragraph (b) is being removed and its contents are being incorporated into the proposed table. FEMA proposes to add a new paragraph (b) that would state, ''[c]overage and benefits payable under the SFIP pursuant to sections 61.3(b) and 61.3(c) are included in, not in addition to, the coverage limits provided by the Act or stated in paragraph (a) of this section.'' The purpose of this new paragraph is to explain that the coverage limits described in the table in section 61.6(a) apply to all coverages payable under the SFIP, including mitigation, and debris removal coverage described in proposed section 61.3(b) and ICC coverage described in proposed section 61.3(c).

This revision would not make any substantive change to NFIP policy, but rather would provide a clarifying link to the coverage and benefits listed in proposed section 61.3 and how coverage limits relate to those coverages and benefits.

Overall, FEMA intends for the proposed changes to section 61.6 to improve the clarity of the Section and ensure that it uses terminology consistent with that currently used by the NFIP. The Agency does not intend for the proposed changes to 61.6 to modify the substance of the NFIP flood insurance policies or the maximum coverage limits available for buildings and contents covered under such policies.

8. Section 61.10 Requirements for Issuance or Renewal of Flood Insurance Coverage

FEMA proposes to add a new section, 61.10, entitled ''Requirements for Issuance or Renewal of Flood Insurance Coverage.'' The proposed section would state that FEMA will not issue or renew flood insurance unless FEMA receives: (1) The full amount due (including applicable premiums, surcharges, and fees); and (2) a complete application, including the information necessary to establish a premium rate for the policy, or submission of corrected or additional information necessary to calculate the premium for the renewal of the policy. FEMA proposes this new section because these requirements are already implicitly indicated in current sections 61.5(b) and 61.11(b), but are nowhere explicitly stated. Pursuant to section 61.5(b), ''payment of the full policyholder premium must be made at the time of application.'' Section 61.11(b) provides that coverage is effective at the time of loan closing, ''provided the written request for the coverage is received by the NFIP and flood insurance policy is applied for and the presentment of payment of premium is made at or prior to the loan closing.'' Further, the statutory 30-day waiting period begins on the ''date that all obligations for [flood insurance] coverage (including completion of the application and payment of any initial premiums owed) are satisfactorily completed.'' NFIA 1306(c)(1) (42 U.S.C. 4013(c)(1)). FEMA believes that explicitly stating the requirements for issuance or renewal of a policy will provide policyholders with clearer descriptions of these requirements.

9. Section 61.11 Effective Date and Time of Coverage Under the Standard Flood Insurance Policy—New Business Applications and Endorsements

Section 61.11 describes the methods for calculating the effective dates of new policies. In general, under current paragraph (c), the effective date and time of any new policy or added coverage is ''12:01 a.m. (local time) on the 30th calendar day after the application date and the presentment of payment of premium.'' Current paragraphs (a) and (b) provide two exceptions to this 30-day waiting period. Section 61.11(a) provides for an effective date of 12:01 a.m. on the first calendar day after application and payment for the initial purchase of flood insurance pursuant to a revision or update of floodplain areas or flood risk zones under section 1360(f) of the NFIA, if such purchase took place within 1 year of the notice of such revision or updating under section 1360(h). *See also* 42 U.S.C. 4013(c)(2). Section 61.11(b) provides that for the initial purchase of flood insurance in connection with the making, increasing, extension, or renewal of a loan, coverage is effective as of the date of the loan closing as long as application and payment were made prior to that. *See also* 42 U.S.C. 4013(c)(2)(A). FEMA does not propose any changes to these exceptions in current paragraphs (a) and (b), as neither BW–12 nor HFIAA made any changes to these exceptions.

FEMA proposes to add a third exception to the 30-day waiting period relating to flooding linked to post-wildfire conditions in proposed paragraph (c), and proposes to redesignate current paragraph (c) as paragraph (d). The proposed provision would allow for a next-day effective date where (1) the FEMA Administrator determines that the property was affected by flooding on Federal land as a ''result of, or is exacerbated by, post-wildfire conditions,'' and (2) that coverage was purchased no later than 60 calendar days after the fire containment date of the wildfire relating to the post-wildfire conditions described in clause (1). FEMA proposes adding this exception pursuant to BW–12. *See* NFIA section 1306 (42 U.S.C. 4013), as amended by BW–12 section 100241. FEMA has already implemented this provision, *see* the General Rules Section of the Flood Insurance Manual, and now proposes to codify the exception into regulation to provide a comprehensive list of effective date exceptions.

As stated above, FEMA proposes to redesignate current paragraph (c) as paragraph (d). FEMA also proposes to make two minor changes to current paragraph (c). First, FEMA proposes to add a reference to new paragraph (c) to indicate that in addition to paragraphs (a) and (b), paragraph (c) is one of the exceptions to the 30-day waiting period. Second, FEMA proposes to change ''shall'' to ''will.'' FEMA proposes this change to incorporate plainer language. This change would not change the substantive meaning of the provision.

Current paragraph (d) allows policyholders to add new coverage or increase the amount of coverage in force during the term of any policy. FEMA proposes to redesignate current paragraph (d) as paragraph (e), and proposes to add the language ''subject to any applicable waiting periods.'' FEMA proposes adding this language to make it clear that unless the policy change qualifies under one of the exceptions in

sections 61.11(a)–(c), such changes would be subject to the 30-day waiting period. This ensures that policyholders cannot suddenly expand their coverage immediately before needing it, for instance before a hurricane strikes. This requirement is already stated in current 61.11(c) (proposed 61.11(d)), but its inclusion in proposed 61.11(e) would add additional clarity to this provision and ensure that 61.11(e) will not be mistakenly read without the limitations imposed by proposed 61.11(d). FEMA also proposes to change ''shall'' to ''will.'' FEMA proposes this change to incorporate plainer language.

Current paragraph (e) states that with respect to any submission of an application in connection with new business, the payment of the premium by an insured to an agent or the issuance of premium payment by the agent does not constitute payment to the NFIP. It further states that it is important that an application for flood insurance and its premium be mailed to the NFIP promptly to have the effective date of coverage based on the application date plus the waiting period.

It states that if the application and the appropriate premium payment are received at the office of the NFIP within ten (10) calendar days from the date of application, the waiting period will be calculated from the date of application. FEMA proposes to revise this paragraph slightly to state that it is important that an application for flood insurance and the ''full amount due'' be mailed to the NFIP promptly. FEMA proposes to change ''premium'' to ''full amount due'' in the sentence following it as well. Making this change would make clear that the policyholder must pay the full amount due at that time (including any surcharges and fees), not just a portion thereof.

FEMA proposes to redesignate current paragraph (e) as paragraph (f). Current paragraph (f) describes the method for determining the effective date when a WYO company receives a proper application, but decides to refer the application to the NFIP's Direct Servicing Agent rather than write the policy itself. FEMA proposes to remove this paragraph because it describes the business model of a WYO company that is no longer participating in the WYO Program. FEMA is not aware of any other WYO company that is using this model, and therefore the provision is unnecessary. Any new companies entering the WYO Program would need to conform their practices to the resulting regulation. Accordingly, FEMA proposes to remove these provisions to avoid confusion. Because FEMA proposes to remove this paragraph, FEMA also proposes to remove the last two clauses of the first sentence of current paragraph (e) (proposed paragraph (f)) that addresses the application of applicable waiting periods for this model, as it too would no longer be necessary. Finally, FEMA proposes to make minor revisions to current paragraph (g) to reflect the removal of current paragraph (f).

10. Section 61.13 Standard Flood Insurance Policy

Section 61.13 describes the applicable sources of terms and conditions associated with polices issued through the NFIP, including the SFIP forms, endorsements, and applications.

FEMA proposes to add new paragraphs (e) and (f), and redesignate current paragraphs (e) and (f) as (g) and (h). FEMA's proposed new paragraph (e) would explain that flood insurance policies issued through the NFIP are subject to the NFIA, its regulations, and the terms and conditions of the SFIP. As discussed previously, similar language is in current sections 61.4(a) and (b), which FEMA proposes to remove. Moving this language into section 61.13 provides a more logical organization. Further, FEMA proposes to add additional language that any representations not consistent with these sources are void. While implicit in the current regulations, this explicit language would make clear the sources of law applicable to NFIP policies.

FEMA's proposed new paragraph (f) would specify that the property or casualty agent acts on the behalf of the policyholder and never on behalf of the Federal Government, FEMA, or the WYO company. This language is similar to that which FEMA proposes to remove from 61.5(e), but would cover WYO companies as well. FEMA intends that the proposed provision would ensure that policyholders know that the representations of agents involved in the program do not bind the NFIP. Also, while current 61.5(e) uses the word ''insured,'' FEMA proposes to substitute the word with ''policyholder'' in proposed section 61.13(f). ''Policyholder'' refers specifically to the individual or business named in the policy itself, whereas the word ''insured'' can refer to the policyholder as well as anyone who submits payment on behalf of the policyholder and/or who has the right to a claim payment under the policy (*e.g.,* the mortgagee). ''Policyholder'' is the more appropriate term in this context because FEMA is only referring to an agent's relationship with the policyholder specifically, not any other party who may be submitting payment on behalf of the policyholder and/or who has a right to claims payments under the policy.

Current paragraph (f) (proposed paragraph (h)), provides that private sector WYO property insurance companies may issue SFIPs. FEMA proposes to revise proposed paragraph (h) to provide that WYO companies will issue NFIP policies in their own name, rather than the current language providing that WYO companies may issue NFIP policies in their own name. This change would conform to the current FEMA–WYO company relationship described in Article I of Appendix A of 44 CFR part 62. Further, FEMA proposes to add language at the end of the paragraph stating that the risk of loss is borne by the NFIP, rather than the WYO company. This language would further clarify the existing relationship between FEMA and WYO companies.

Overall, the proposed changes to 61.13 would provide greater clarity to the public regarding the existing relationship between FEMA, policyholders, and WYO companies.

*C. Appendix A(1) to Part 61: Standard Flood Insurance Policy Dwelling Form*

Appendix A(1) to part 61 contains the Dwelling Form of the SFIP. This form, as well as the other two SFIP policy forms (the General Property Form and the RCBAP), defines the relationship between FEMA or the WYO company, as the insurers, and the insured.

Throughout Appendix A(1), FEMA proposes to replace the word ''covered'' with the word ''insured'' because ''covered'' is a generic and undefined term that does not conform to common industry or Agency usage. The use of ''insured'' better conveys the application of the SFIP to property.

1. Prefatory Paragraph and Article I ''Agreement''

The prefatory paragraph states that the policy insures (1) a non-condominium residential building designed for principal use as a dwelling place of one to four families, or (2) a single-family dwelling unit in a condominium building. FEMA proposes to revise (1) to read ''a one to four family residential building, not under a condominium form of ownership'' because this language is clearer and more consistent with the wording used in the Definitions section for condominium buildings. FEMA proposes to add (3) ''personal property in a building'' to clarify that personal property is also insured under this policy. FEMA has always insured personal property under this policy, but

proposes to make this fact more explicit in this initial coverage statement.

In the current policy, Article I ''Agreement'' begins after the prefatory paragraph. It states in the first paragraph that FEMA provides flood insurance under the terms of the NFIA, its amendments, and 44 CFR. It states in the second paragraph that FEMA will pay for direct physical loss by or from flood to the insured property if the insured has paid the correct premium, complied with all terms and conditions of the policy, and furnished accurate information and statements. It states in the last paragraph that FEMA has the right to review the information provided by the insured at any time and to revise the policy based on this review.

FEMA proposes to begin Article I before the prefatory paragraph, and to relabel the prefatory paragraph as Section A, current Article I's first paragraph as Section B, the second paragraph as Section C, and the third paragraph as Section D. This is to clarify that the prefatory paragraph, which is actually an initial coverage statement, is part of the policy and not just an introduction to the policy.

FEMA also proposes to modify proposed Section C (currently the second paragraph in Article I) and add three new sections to Article I (proposed sections E, F, and G) to clarify existing rules and limitations under the SFIP.

i. Proposed Section C

As previously described, FEMA proposes to renumber the second paragraph in Article I as Section C of Article I. This provision currently states that FEMA will pay for direct physical loss by or from flood to the insured property if (1) the insured has paid the correct premium; (2) complied with all terms and conditions of the policy; (3) and furnished accurate information and statements. FEMA proposes to modify the first prong of this statement by stating that coverage is contigent on the policyholder paying the ''full amount due (including applicable premiums, surcharges, and fees)'' instead of ''the correct premium.'' FEMA proposes this change to make clear that policyholders must pay any applicable surcharges, such as the one required under 42 U.S.C 4015a, in addition to applicable premiums.

ii. Proposed Section E

Proposed Section E would state that the policy insures only one building. If the insured owns more than one building, coverage will apply to the single building specifically described in the Flood Insurance Application. While the SFIP's limitation on coverage to one dwelling is already implied by current Article III.A, FEMA proposes to clarify this limitation here to allow policyholders to better understand the extent of coverage, particularly where an insured may own more than one building on the same land.

iii. Proposed Section F

Proposed Section F would state that multiple policies with building coverage cannot be issued to insure a single building to one insured or to different insureds, even if separate policies were issued through different NFIP insurers. It would also state that payment for damages may only be made under a single policy for building damages under Coverage A—Building Property. This proposed section would incorporate current Article VII.U's general language stating that there may not be more than one NFIP policy on a property. Proposed section F would be subject to the exception in proposed Section G involving condominiums, which provides that a condominium unit may be covered by an RCBAP policy and a dwelling policy.

FEMA proposes this clarification because there have been several instances where multiple persons have taken out multiple, overlapping building policies. This in turn may leave policyholders to believe they have more coverage than is allowed by the NFIA. This is most common in instances where both a building owner and a tenant obtain building policies. As described in WYO Bulletin W–15001 (Jan. 13, 2015),[3] FEMA has taken steps to identify such instances and inform policyholders as needed. FEMA believes that the language in proposed Section F would help avoid such situations.

iv. Proposed Section G

FEMA proposes to add Section G, which would define the relationship between a Dwelling Form policy and an RCBAP policy that insures the same condominium unit. Section G would state that a Dwelling Form policy with building coverage may be issued to a unit owner in a condominium building that is also insured under an RCBAP. However, no more than $250,000 may be paid in combined benefits for a single unit under the Dwelling Form policy and the RCBAP. This would explicitly state FEMA's application of the statutory maximum coverage limits for one to four family residential buildings, found at 42 U.S.C. 4013(b)(2), as applied to condominium units.

FEMA proposes this section to clarify instances where a condominium unit is covered by both a Dwelling Form policy and an RCBAP policy, and to codify its current practice (pursuant to BW–12) of waiving the requirement found in current regulation to limit payments to affected policyholders. Current Article VII (''Coinsurance'') of the RCBAP policy (Appendix A(3) to Part 61) restricts payments for damage to condominium associations that insure less than 80 percent of the full replacement cost of the RCBAP insured condominium building, or less than the maximum amount of insurance available. In turn, current Article III.C.3.b.4 of the Dwelling Form policy precludes payment for a loss assessment if the reason for the shortage is application of the RCBAP's coinsurance penalty provision. Current Article VII.C.2 of the Dwelling Form policy provides that where a condominium unit is covered by both the Dwelling Form policy and an RCBAP (or other flood insurance coverage purchased by the condominium association), the Dwelling Form policy will be in excess over the RCBAP (or other insurance).

Since 2007, FEMA has issued individual waivers of these provisions' requirements to limit payments to affected policyholders. Section 100214 of BW–12 (42 U.S.C. 4019(c)) validated this policy by prohibiting FEMA from limiting payments pursuant to Article III.C.3.b.4. FEMA implemented this prohibition through a general waiver. *See* WYO Bulletin W–16024 (April 7, 2016).[4] Accordingly, FEMA now seeks to codify this change in the SFIP by adding Section G.

Proposed Section G would also state that FEMA will only pay for damage once, and items of damage paid for under an RCBAP cannot also be claimed under the Dwelling Form policy. FEMA proposes to add this language to clarify the existing rule under current Article VII.C.2 that if a single property is insured by both policies forms, the Dwelling Form will only pay what is not covered under the RCBAP policy.

2. Article II Definitions

i. General Changes

FEMA proposes to remove the last sentence of the second paragraph in Article II.A which states, ''The precise definitions are intended to protect you.'' FEMA proposes removal of this sentence because it is an incorrect statement of the purpose of providing the definitions. The definitions are to provide clarity to the language of the

[3] Available at *http://bsa.nfipstat.fema.gov/wyobull/2015/w-15001.pdf.*

[4] Available at *https://bsa.nfipstat.fema.gov/wyobull/2016/w-16024.pdf.*

Dwelling Form policy so that both FEMA and the policyholder will know the terms and conditions under which payments will be made under the policy.

FEMA also proposes to move the definition of ''flood,'' which is currently in the third paragraph of Article II.A, to a separate Section B. Accordingly, FEMA also proposes to redesignate current Section B as Section C.

ii. Proposed Removal of Definition

FEMA proposes to remove one definition, ''expense constant,'' from the Dwelling Form. The term describes a flat charge assessed on all policies to defray expenses to the Federal Government related to flood insurance. FEMA proposes to remove this definition because FEMA no longer charges an expense constant and FEMA does not use this term in the Dwelling Form.

iii. Proposed Addition of Definitions

FEMA proposes to add a definition of ''condominium building'' to mean a type of building for which the form of ownership is one in which each unit owner has an undivided interest in common elements of the building. FEMA intends for this addition to conform with the addition of the definition to 44 CFR 59.1. FEMA proposes to add this definition because it is used throughout the Dwelling Form.

FEMA also proposes to define the term ''deductible'' as ''the fixed amount of an insured loss that is your responsibility and that is incurred by you before any amounts are paid for the insured loss under this policy.'' This definition aligns with the definition of ''deductible'' currently proposed for 44 CFR 59.1. FEMA proposes to include this definition in the SFIP to support related provisions in Article VI.

iv. Proposed Changes to Existing Definitions

FEMA proposes to modify several definitions currently in the Dwelling Form. First, FEMA proposes to revise the definition of ''application'' by striking the last sentence. FEMA proposes this change because the last sentence is not a definition, but rather a separate requirement. Further, the sentence does not align with proposed Article I.C, which states that policyholders must submit ''the full amount due'' which includes applicable premiums, surcharges, and fees.

FEMA proposes to revise the definition of the term ''basement.'' Currently, ''basement'' is defined as ''any area of the building, including any sunken room or sunken portion of a room, having its floor below ground level (subgrade) on all sides.'' FEMA proposes to replace the word ''the'' before the word ''building'' with the word ''a'' to correct a grammar error in the current Dwelling Form SFIP. FEMA also proposes to remove the word ''subgrade'' because, due to the many and varying definitions of this word, its use is causing confusion. Removal of the term ''subgrade'' is not intended to have any substantive effect.

FEMA proposes to revise the term ''condominium.'' Currently, ''condominium'' is defined as ''that form of ownership of real property in which each unit owner has an undivided interest in common elements.'' FEMA proposes to replace the term ''real property'' with the phrase ''one or more buildings'' because FEMA believes that this nonsubstantive change uses plainer language that the public can more easily understand.

Similarly, FEMA proposes to adjust the definition of ''condominium association.'' Currently, this term is defined as the entity made up of the unit owners responsible for the maintenance and operation of (a) common elements owned in undivided shares by unit owners; and (b) other real property in which the unit owners have use rights; where membership in the entity is a required condition of unit ownership. FEMA proposes to replace the term ''real property'' with ''buildings'' because FEMA believes that this change uses plainer language that the public can more easily understand while maintaining the substantive meaning of the definition.

FEMA proposes to revise the definition of ''dwelling.'' Currently, ''dwelling'' is defined as ''a building designed for use as a residence for no more than four families or a single-family unit in a building under a condominium form of ownership.'' FEMA proposes to replace the phrase ''building under a condominium form of ownership'' with ''condominium building'' to integrate the defined term ''condominium building'' while maintaining the substance of the current definition.

FEMA proposes to revise the definition of ''emergency program.'' Currently, ''emergency program'' is defined as the initial phase of a community's participation in the National Flood Insurance Program. The definition also states that during this phase, only limited amounts of insurance are available under the NFIA. FEMA proposes to retain this definition but add at the end the phrase ''and the regulations prescribed pursuant to the Act.'' FEMA proposes to add this phrase to align the SFIP definition of this term with its definition at 44 CFR 59.1.

FEMA proposes minor revisions to the definition of ''improvements.'' Currently, this term is defined as ''fixtures, alterations, installations, or additions comprising a part of the insured dwelling or the apartment in which you reside.'' FEMA proposes to remove the word ''insured'' because it is not necessary. It proposes to remove the word ''the'' from before the word ''apartment'' for readability.

FEMA proposes to move the definition of ''principal residence'' from Art. VII.V.1.a.1 (''Loss Settlement'') of the Dwelling Form to the Definitions Section (Article II). Currently, under Article VII.V.1 a principal residence means the single-family dwelling where the policyholder or the policyholder's spouse has lived for at least 80 percent of (a) the 365 days immediately preceding the time of loss; or (b) the period of ownership, if either the policyholder or policyholder's spouse owned the dwelling for less than 365 days immediately preceding the time of loss. FEMA proposes to move the substantively unchanged definition to the Definitions Section of Article II because that is the more appropriate place to define terms used in the Dwelling Form.

FEMA proposes to revise the definition for ''probation premium'' by replacing the defined term ''probation premium'' with the term ''probation surcharge.'' ''Probation surcharge'' would retain the same definition as the current definition for ''probation premium,'' which is a flat charge the policyholder must pay on each new or renewal policy issued covering property in a community the NFIP has placed on probation under the provisions of 44 CFR 59.24. FEMA proposes this revision because there is no such thing as a ''probation premium;'' this incorrect term was intended to reference the probation surcharge that is applied to policies in NFIP communities that have been placed on suspension from the NFIP.

FEMA proposes to amend the definition of ''regular program.'' Currently, ''regular program'' is defined as the final phase of a community's participation in the National Flood Insurance Program. In this phase, a Flood Insurance Rate Map is in effect and full limits of coverage are available under the NFIA. FEMA proposes to add the phrase ''and the regulations prescribed pursuant to the Act'' at the end to clarify, without changing the substance of the definition, that the coverage amounts for NFIP policies are

subject to the rules established in both statute and regulation, not just statute.

FEMA also proposes to modify the definition of ''Special Flood Hazard Area'' to include the appropriate acronym, ''SFHA.''

FEMA proposes to revise the term ''unit.'' Currently, ''unit'' is defined as ''a single-family unit you own in a condominium building.'' FEMA proposes to replace the word ''unit'' with ''residential space'' so that the word ''unit'' would not be used to define itself.

3. Article III Property Covered

Article III of the Dwelling Form (''Property Covered'') is divided into four sections, each addressing different types of property: Section A, ''Coverage A—Building Property,'' Section B, ''Coverage B—Personal Property,'' Section C, ''Coverage C—Other Coverages,'' and Section D, ''Coverage D—Increased Cost of Compliance.''

i. Coverage A—Building Property

Article III.A.5.b.2 describes the zones above which the lowest floor of a non-walled or roofed building under construction, alteration, or repair must be to be covered. FEMA proposes to replace ''levels are'' with ''level is'' to improve readability. FEMA also proposes to replace ''and'' with ''or,'' also to improve readability. No substantive changes are intended.

In Article III.A.6, FEMA proposes to replace the reference to ''II.B.6.b and II.B.6.c'' with a reference to ''II.C.6'' to reflect the renumbering proposed for Article II.

Article III.A.7 provides a list of items of property covered under Coverage A only. FEMA proposes to replace ''covered'' with ''insured'' because ''covered'' is a generic and undefined term that does not conform to common industry or Agency usage. The use of ''insured'' better conveys the application of the SFIP to property.

Article III.A.8 limits coverage on items of property in a building enclosure below the lowest elevated floor of an elevated post-FIRM building in specified zones. FEMA proposes to remove the phrase ''in a building enclosure'' to clarify that the section only insures items of property that are below the lowest elevated floor, not the building enclosure itself. This has always been the case, but removing this language would make this clearer. Removing the language would also clarify that FEMA insures any property identified in Article III.A.8 that is below the lowest elevated floor within the footprint of the building, regardless of whether such property is located in a building enclosure.

ii. Coverage B—Personal Property

Article III.B.1 describes the conditions under which the policy covers personal property inside a building. Current Article III.B.1.b contains two unnumbered paragraphs. FEMA proposes to number these two unnumbered paragraphs as ''1.'' and ''2.'' respectively, and to renumber subsequent paragraphs accordingly, to improve readability and organization.

Article III.B.3 (renumbered B.5.in the proposed text) limits coverage for items of property in a building enclosure below the lowest elevated floor of an elevated post-FIRM building located in specified zones or a basement. FEMA proposes to remove the phrase ''in a building enclosure'' to clarify that the section only insures items of property that are below the lowest elevated floor, not the building enclosure itself. While FEMA has always interpreted this provision this way, removing this language would make this clearer to policyholders. In addition, this proposed change would also clarify that FEMA insures certain property identified in Article III.B.3 (proposed B.5) that is below the lowest elevated floor within the footprint of the building, regardless of whether such property is located in a building enclosure.

iii. Coverage C—Other Coverages

Article III.C describes other coverages under the SFIP, including for debris removal, property relocation, and condominium loss assessments. In III.C.2.b, FEMA proposes to number the currently unnumbered paragraphs immedietly following III.C.2.b.2 as III.C.2.b.3 and III.C.2.b.4, respectively, to improve organization and readability.

Article III.C.3.a describes the terms of coverage for condominium loss assessments. FEMA proposes to revise the first sentence of Article III.C.3.a to add the phrase ''Subject to III.C.3.b below'' to the beginning of the sentence to clarify that the general statement in III.C.3.a that FEMA would pay for condominium loss assessments would be limited by the restrictions established in III.C.3.b. FEMA also proposes to add ''condominium'' before ''unit'' in that sentence, for the sake of clarity. The second sentence in Article III.C.3.a states that the assessment must be made as a result of direct physical loss by or from flood during the policy term, to the building's common elements. FEMA proposes to replace ''as a result of'' with ''because of'' and ''to the building's common elements'' with ''to the unit or to the common elements of the NFIP insured condominium building in which this unit is located.'' FEMA proposes to revise this language for greater clarity and consistency with the ''condominium building'' definition added in Article II.

Article III.C.3.b describes scenarios where FEMA will not pay any loss assessment charged against the policyholder. Article III.C.3.b.1 provides that FEMA will not pay any loss assessment charged against the policyholder ''and the condominium association by any governmental body.'' FEMA proposes to relocate the phrase ''charged against you'' from III.C.3.b to III.C.3.b.1 to improve the sentence structure of the provision.

Article III.C.3.b.4 states that the NFIP would not insure any loss assessments on units in a condominium building that were underinsured as described in this paragraph. FEMA proposes to remove this paragraph, as these restrictions were superseded by section 100214 of BW–12, which prohibits FEMA from denying coverage for a condominium unit under a Dwelling Form policy based solely, or in part, on the flood insurance coverage of the condominium association or others on the overall property insured by the condominium association. Accordingly, to implement this requirement, FEMA proposes to remove Article III.C.3.b.4 as it prevents unit owners from recovering under the Dwelling Form policy for loss assessments charged against them because the condominium building in which the unit is located is underinsured. FEMA has waived this provision in current practice for affected individual policies. The proposed change would conform the language of the Dwelling Form to FEMA's current practice and allow FEMA to discontinue use of the individual waiver process.

Current Article III.C.3.b.5 provides that FEMA will not pay for loss assessments to the extent that payment under this policy for a condominium loss, in combination with payments under any other NFIP policies for the same building loss, exceeds the maximum amount of insurance permitted under the NFIA for that kind of building. Similarly, current section III.C.3.b.6 provides that FEMA will not pay for loss assessments to the extent that payment under this policy, in combination with any recovery available to the tenant in common under any NFIP condominium association policies for the same building loss, exceeds the amount of insurance permitted under the NFIA for a single family dwelling. FEMA proposes to renumber these subsections as (4) and

(5) respectively due to FEMA's proposed removal of current subsection (4). In addition, FEMA proposes to revise current subsection (5) (proposed subsection (4)) to state ''[i]n which the total payment combined under all policies exceeds the maximum amount of coverage available under the Act for a single unit in a condominium building where the unit is insured under both a Dwelling Policy and a RCBAP.'' FEMA also proposes to revise current subsection (6) (proposed subsection (5)) to state ''[o]n any item of damage that has already been paid under a RCBAP where a single unit in a condominium building is insured by both a Dwelling Policy and a RCBAP.'' FEMA proposes this revised language to streamline these provisions and to make the same points more clearly.

The last sentence of current III.C.3.b.6 states that ''[l]oss assessment coverage does not increase the Coverage A Limit of Liability.'' FEMA proposes to renumber this sentence as III.C.3.c. FEMA also proposes to revise the language so that it reads ''Condominium Loss Assessment coverage does not increase the Coverage A Limit of Liability and is subject to the maximum coverage limits available for a single family dwelling under the Act, payable between all policies issued and covering the unit, under the Act.'' This would clarify that the combined payments under the Dwelling Form and the RCBAP, or any other payment issued under the Dwelling Form to a unit owner where there is also an RCBAP that covers the property, are subject to the $250,000 coverage limit on the combined payments under both policies. Congress only authorized a maximum coverage of $250,000 on a single dwelling, and both the RCBAP and Dwelling Forms rely upon that single authority for establishing the available policy limits. As such, the unit owner and the condominium association each filing separate claims under their separate policies cannot circumvent the limit imposed by Congress. FEMA proposes to add this language to emphasize the point that even though a condominium unit may be insured by both a Dwelling Form policy and an RCBAP, this fact does not alter the statutory coverage limits.

iv. Coverage D—Increased Cost of Compliance

Article III.D (''Increased Cost of Compliance'') describes the terms of coverage for costs associated with complying with State or local floodplain management laws or ordinances affecting repair or reconstruction of a structure suffering flood damage. FEMA proposes to revise the language in this section so that the word ''structure'' is replaced by the word ''building'' throughout the section. The reason for this change is the NFIP insures SFIP defined ''buildings,'' not structures. FEMA also proposes to replace the phrase ''this coverage'' with the phrase ''Coverage D in III.D.3.d and III.D.3.e'' to clarify that the coverage referred to in these provisions is Coverage D.

4. Article V Exclusions

Article V of the Dwelling Form (''Exclusions'') provides the terms and conditions of the SFIP relating to what losses are excluded from coverage under the SFIP. Article V.B excludes coverage for losses resulting from a flood that began prior to the effective date of a policy; this is referred to as the ''flood in progress'' exclusion. If the SFIP covered losses for policies obtained after a flood became imminent, people could avoid paying for insurance during the times they did not need to make a claim. FEMA would then have to increase rates to compensate for the lost premiums and higher losses. This would in turn drive more people out of the program, which would require higher rates.

Currently, the exclusion specifies that FEMA will not pay for a loss that was ''directly or indirectly caused by a flood that is already in progress'' prior to the effective date of the policy. FEMA is proposing changes to Article V because the current language does not describe how a policyholder could determine when a flood was in progress. This ambiguous provision has historically caused significant confusion among the public. As a result, FEMA made several attempts to clarify the provision and apply it to the specific attributes of certain floods. *See* WYO Bulletin W–11030 (May 17, 2011); WYO Bulletin W–11034 (June 6, 2011); WYO Bulletin W–11045 (June 30, 2011); Definitions Section of the Flood Insurance Manual, page 4.

While these clarifications provided workable guidance on the issue, BW–12 directed the FEMA Administrator to review ''the processes and procedures for determining that a flood event has commenced or is in progress for purposes of flood insurance coverage made available under the National Flood Insurance Program.'' BW–12 section 10227(a)(1)(A) (42 U.S.C. 4011 note). Accordingly, FEMA now proposes to modify the Flood in Progress Exclusion to maintain its practical impact, but to provide clearer terms for its application.

FEMA proposes to revise the language of Article V.B to allow for two separate exclusions for floods in progress, depending on how the policyholder applied for the policy. If the policy became effective at the time of a loan closing, as provided by 44 CFR 61.11(b), then FEMA would not pay for losses caused by a flood that is a continuation of a flood that existed prior to coverage becoming effective. In all other circumstances, FEMA would not pay for a loss caused by a flood that is a continuation of a flood that existed on or before the day the policyholder submitted the application for coverage and paid the full amount due. This exclusion would apply to new policies subject to the 30-day waiting period, as well as those for which the overnight waiting period is applied, as provided by 42 U.S.C. 4013(c)(2)(b).

FEMA believes the proposed formulation provides a more thorough understanding of what constitutes a flood in progress, providing greater clarity to policyholders, without altering the actual effect of the provision because the proposed language captures the principles underlying the previous agency guidance. FEMA also believes the proposed language would successfully prevent a policyholder from waiting until flooding becomes imminent to apply for coverage, as well as prevent a person facing imminent flooding from obtaining a small mortgage to avoid the otherwise 30-day effective date waiting period required by 42 U.S.C. 4013(c)(1).

In article V.C.6, regarding gradual erosion, FEMA proposes to replace ''insured'' with ''covered'' because ''covered'' is a generic and undefined term that does not conform to common industry or Agency usage. The use of ''insured'' better conveys the application of the SFIP to property. Also in article V.C.6, FEMA proposes to update the reference to the definition of flood to articles II.B.1.c and II.B.2.

5. Article VII General Conditions

Article VII (''General Conditions'') provides the general terms and conditions of the Dwelling Form SFIP, such as provisions related to other insurance; amendments, waivers, and assignments; policy reformation; policy renewal; requirements if there is a loss; and loss payments.

i. Section B—Concealment or Fraud and Policy Avoidance

Article VII.B (''Concealment or Fraud and Policy Avoidance'') provides the general terms and conditions of the Dwelling Form SFIP related to concealment or fraud and policy avoidance. FEMA proposes to move Article VII.B to a new Article VIII.A (''Policy Nullification for Fraud,

Misrepresentation, or Making False Statements'') and make some revisions, which are explained in the discussion of new Article VIII below.

ii. Section C—Other Insurance

Article VII.C (''Other Insurance'') discusses terms related to instances where property is covered by more than one insurance policy with flood coverage. FEMA proposes to redesignate Article VII.C as Article VII.B due to FEMA's proposed removal of VII.B. Current Article VII.C.2 (proposed VII.B.2) states that where there is other insurance in the name of the policyholder's condominium association covering the same property covered by this policy, then this policy will be in excess over the other insurance. FEMA proposes to replace the word ''covered'' with ''insured.'' FEMA proposes to replace the word ''covered'' with the word ''insured'' because ''covered'' is a generic and undefined term that does not conform to common industry or Agency usage. The use of ''insured'' better conveys the application of the SFIP to property. FEMA also proposes to add the phrase ''issued under the Act'' directly following the phrase ''other insurance'' to clarify that the language referring to other insurance is referring to other NFIP insurance, not other non-NFIP insurance.

FEMA proposes to add language to Article VII.C.2 (proposed VII.B.2) to provide that the section does not apply where a condominium loss assessment to the unit owner results from a loss sustained by the condominium association that was not reimbursed under an RCBAP because the building was not insured for an amount equal to the lesser of: (a) 80 percent or more of its full replacement cost; or (b) the maximum amount of insurance permitted under the NFIA. FEMA proposes to add this exception to codify the existing implemention of section 100214 of BW–12. Under the terms and conditions of the Dwelling Form policy and the RCBAP, the RCBAP is primary, and the Dwelling Form policy acts as an excess flood insurance policy. In order to allow the Dwelling Form to respond as if the RCBAP coverage has in fact been exhausted, FEMA must revise Article VII.C.2 (proposed VII.B.2) so that it does not apply in those situations in which the coinsurance provision of the RCBAP has been triggered.

FEMA also proposes to add language to proposed Article VII.B.2 clarifying that even when a condominium unit is insured by two policies, the maximum statutory coverage limit available under the NFIA of $250,000 still applies. FEMA proposes to add this language to emphasize that the fact that a condominium unit is insured by both a Dwelling Form policy and an RCBAP does not alter or permit payments to exceed the statutory coverage limits.

iii. Section D—Amendments, Waivers, Assignment

Article VII.D ('' Amendments, Waivers, Assignment'') provides that any amendments or waivers to the policy require express written consent of the Federal Insurance Administrator. It allows a policyholder to assign this policy when transferring title of his or her property except when the policy (1) covers only personal property, or (2) covers a structure during the course of construction. FEMA proposes to redesignate Article VII.D as Article VII.C due to the proposed removal of VII.B and subsequent renumbering discussed above. FEMA proposes to replace the phrase ''structure during the course of construction'' with ''building under construction'' both to correspond with the replacement of the word ''structure'' with ''building'' throughout Article V of the policy, and also because ''building under construction'' is the proper term of art, as used in Article III.A.5.a and Article VI.A. Also, FEMA proposes to replace ''covers'' with ''insures'' because ''covered'' is a generic and undefined term that does not conform to common industry or Agency usage. The use of ''insured'' better conveys the application of the SFIP to property.

iv. Section E—Cancellation of the Policy by You

Article VII.E (''Cancellation of the Policy by You'') authorizes a policyholder to cancel the policy in accordance with the applicable rules and regulations of the NFIP and provides that a policyholder who cancels may be entitled to a full or partial refund of premium. FEMA proposes to move Article VII.E to a new Article VIII discussing policy nullifications, cancellations, and non-renewals. The new Article VIII is discussed below.

v. Section F—Non-Renewal of the Policy by Us

Article VII.F (''Non-Renewal of the Policy by Us'') states that a policy will not be renewed if the community where the covered property is located stops participating in the NFIP, or the building has been declared ineligible under section 1316 of the NFIA. FEMA proposes to move Article VII.F to a new Article VIII discussing policy nullifications, cancellations, and non-renewals. The new Article VIII is discussed below.

vi. Section G—Reduction and Reformation of Coverage

Article VII.G (''Reduction and Reformation of Coverage'') describes the terms and conditions of the policy related to situations in which it is discovered that the premium paid on an annual policy, or the information used to rate the policy, is insufficient. Specifically, this section details how coverage under the policy would be reformed in such situations and the policyholder's options upon reformation.

FEMA proposes to redesignate Article VII.G as Article VII.D to conform to the relocation and redesignation of preceding sections described above. FEMA proposes to change the title of the section from ''Reduction and Reformation of Coverage'' to ''Insufficient Premium or Rating Information.'' FEMA proposes this change to the title because it is clearer than the current section title. Additionally, FEMA proposes to add the term ''insufficient'' before ''rating information'' to make it clear that this provision applies to both cases: Where the information needed to rate the policy is incomplete and where it is incorrect. With respect to the premium, the term ''insufficient'' applies to situations in which the premium paid is incorrect. With respect to the rating information, the term ''insufficient'' applies to situations in which the rating information provided for determining the premium rate is incomplete, such as when an elevation certificate is not provided or is incorrect. FEMA proposes to make corresponding language changes throughout this section to ensure that the provisions of this section are applied in both of these situations.

FEMA proposes to add a new Article VII.D.1, entitled ''Applicability.'' The proposed Article would state that the provisions in proposed Article VII.D, Insufficient Premium or Rating Information, apply to all instances where the premium paid on a policy is insufficient or where the rating information is insufficient, such as where an Elevation Certificate is not provided. This change reflects FEMA's current policies and would not substatively impact the NFIP.

Current Article VII.G.1 provides that if the premium received was not enough to buy the kind and amount of coverage requested, FEMA will provide only the amount of coverage that can be purchased for the premium payment received. FEMA proposes to redesignate

this section as Article VII.D.2 to correspond to the redesignations described above, and add a title, ''Reforming the Policy with Reduced Coverage,'' for improved clarity. FEMA proposes to add the phrase ''Except as otherwise provided in VII.D.1'' at the beginning of the paragraph. FEMA proposes this change to correspond to the exception established in the new proposed language at VII.D.1. FEMA also proposes to replace the phrase ''not enough'' with the phrase ''not sufficient,'' the word ''amount'' to ''amounts,'' and replace ''only the amount of coverage'' with ''only the kinds and amounts of coverage.'' FEMA believes that these non-substative changes would improve readability.

FEMA proposes to add three paragraphs to this section. Proposed paragraph D.2.a clarifies that, for determining whether the premium is sufficient to buy the kinds and amounts of coverage requested, FEMA will first deduct all applicable fees and surcharges. Proposed paragraph D.2.b clarifies that if the amount paid, after deducting the costs of all applicable fees and surcharges, is not sufficient to buy any amount of coverage, the Program will refund the policyholder's payment and there will be no coverage under the policy. FEMA proposes to add these clarifications because they are not explicitly stated in the current regulations, although FEMA has previously interpreted regulations to require this. Thus this is not a substantive change but merely reflects existing practice. Proposed paragraph D.2.c states that ''[c]overage limits on the reformed policy will be based upon the amount of premium submitted per type of coverage, but will not exceed the amount originally requested.'' FEMA proposes this paragraph to codify its current practice. When FEMA calculates the total policy cost, it knows how much of the total cost will be allocated to premium, surcharges, fees, etc. Under FEMA's current practice, it tries to preserve the ratio of building coverage to contents coverage, regardless of how much premium the policyholder intended to allocate to each type of coverage. For example, if a policyholder originally requested $200,000 in building coverage and $100,000 in contents, FEMA would try to preserve the 2 to 1 ratio when reducing the coverage through reformation. The proposed rule seeks to clarify that FEMA's practice is to reflect the policyholder's intent by considering the amount of premium the policyholder intended to allocate to each type of coverage. Using the example above, therefore, if the policyholder paid a total of $600 premium, wishing to allocate $500 for the $200,000 in building coverage and $100 for the $100,000 in contents, FEMA would provide the amount of building coverage that $500 would purchase under the reformed rate, and the amount of contents coverage that $100 would purchase under the reformed rate.

Current Article VII.G.2 discusses how a policy can be reformed to increase the amount of coverage where insufficient premium or incomplete rating information is discovered before a loss (current paragraph (a)), and where insufficient premium or incomplete rating information is discovered after a loss (current paragraph (b)). FEMA proposes to redesignate current Article VII.G.2 as VII.D.3 and to restructure it to improve organization and readability. Specifically, FEMA proposes to combine the provisions on discovery of insufficient premium or rating information before a loss and discovery of insufficient premium or rating information after a loss. To that end, the Agency proposes to title proposed Article VII.D.3 as ''Discovery of Insufficient Premium or Rating Information.'' The proposed subsection would state that if the Program discovers that the premium or rating information is insufficient, the Program would reform the policy as described in proposed Article VII.D.2. The proposed subsection also gives policyholders the option of increasing the amount of coverage resulting from the reformation to the amount he or she requests in accordance with the rest of the section. This does not constitute a substantive change from the current regulations and procedure; rather, it is a streamlining of the current regulations without altering the substance.

Proposed Article VII.D.3.a would be entitled ''Insufficient Premium'' and would address situations where FEMA discovers that the premium is insufficient. This section would retain the first sentence in current VII.G.2.a.1 providing that where FEMA discovers the policyholder has not paid enough premium, the policyholder, and any mortgagee or trustee of which the insurer has written notice, will be sent a bill for the required additional premium for the current policy term (or that portion of the current policy term following any endorsement changing the amount of coverage). From the current language, FEMA proposes to replace ''enough'' with ''sufficient'' to align with current program usage and proposes to add commas after ''you'' and ''us'' to improve readability.

The last sentence in current VII.G.2.a.1 provides that where the policyholder pays the additional premium within 30 days from the date the bill is sent, the Program will reform the policy to the originally requested amount of coverage. FEMA proposes to relocate this last sentence to its own separate subsection (proposed VII.D.3.a.1) and replace it with language stating that if it is discovered that the initial amount charged for any fees or surcharges is incorrect, the difference will be added or deducted, as applicable, to the total amount in this bill. FEMA proposes this sentence because in addition to the premium, policyholders must pay additional fees and surcharges, which can vary based on the characteristics of the property and its use; this language reflects its existing practice that FEMA adjusts the total bill for overpayment or underpayment of fees and surcharges.

As mentioned above, FEMA proposes to relocate the last sentence in current Article VII.G.2.a.1 to its own separate subsection (proposed VII.D.3.a.1). Because this language only addresses what happens if the policyholder pays the additional premium within 30 days from the date the bill is sent, FEMA proposes to add additional language (proposed VII.D.3.a.2) clarifying that if the policyholder does not pay the premium within 30 days from the date of the bill, the Program would settle any flood insurance claim based on the reduced amount of coverage (as reduced pursuant to Article VII.D.2). This is already implicitly in the current regulation and FEMA's current practice, but FEMA proposes to add it to improve the clarity of the regulation.

FEMA proposes to add a third subsection (proposed VII.D.3.a.3) allowing the policyholder the option of paying all or part of the amount due out of a claim payment based on the originally requested amount of coverage. Though not explicitly anticipated in the SFIP, FEMA currently provides this option to policyholders through coordination of disbursement of claim proceeds and additional premium collections with the insurer. FEMA proposes to incorporate this option into the SFIP to provide policyholders with a comprehensive understanding of their options after FEMA discovers a misrating after a loss.

Proposed Article VII.D.3.b would be entitled ''Insufficient Rating Information'' and would address situations where it is discovered that the rating information is insufficient. This section would retain the substance of the first sentence in VII.G.2.a. stating that if it is determined that the rating

information for the policy is insufficient and prevents the insurer from calculating the additional premium, the policyholder would be required to provide this information within 60 days of a request by the insurer. The last sentence in current VII.G.2.a.2 provides that once the amount of additional premium for the current policy term is determined, the procedures outlined in G.2.a.1 will be followed. FEMA proposes to relocate this sentence to its own subsection (proposed VII.D.3.b.1) and revise it to state that where information is received within 60 days, the amount of additional premium for the current policy term would be determined and the procedures in VII.D.3.a would be followed.

Current VII.G.2.a.3 and G.2.b.3 address situations where the additional premium or information is not received by the date it is due. FEMA proposes to replace these sections with proposed VII.D.3.b.2 to state that where information is not received within 60 days of the request, no claims would be paid until the requested information is provided. Coverage would be limited to the amount of coverage that could be purchased for the payments received, as determined when the requested information is provided. The proposed provision reflects FEMA's existing interpretation of the SFIP, as reflected in the General Rules Section of the Flood Insurance Manual, page 13. FEMA proposes this provision to clearly reflect FEMA's policy.

FEMA proposes to add a new Article VII.D.4, entitled ''Coverage Increases,'' which would incorporate the language in current Articles VII.G.2.a.3 and VII.G.2.b.3. The proposed language states that if the policyholder does not submit the amounts requested in Article VII.D.3.a or the additional information requested in Article VII.D.3.b by the date it is due, the amount of coverage could only be increased by endorsement subject to the appropriate waiting period. However, no coverage increases would be allowed until the information requested in Article VII.D.3.b is provided. FEMA proposes this additional language to explicitly state the currently implied consequence of not providing the necessary payment or information.

Finally, FEMA proposes to redesignate current Article VII.G.3 as Article VII.D.5, which would be entitled ''Falsifying Information.'' Currently, this paragraph states that if the policyholder or their agent intentionally did not tell FEMA about, or falsified, any important fact or circumstance or did anything fraudulent relating to this insurance, the provisions allowing policy cancellations for fraud will apply. FEMA proposes to update the references to other policy provisions to align with the citations as revised under this proposed rule.

In section J (proposed section G) (''Requirements in Case of Loss''), section L (proposed section I) (''No Benefit to Bailee''), and section T (propsed section Q) (''Continious Lake Flooding''), FEMA proposes to replace ''covers'' with ''insures'' because ''covered'' is a generic and undefined term that does not conform to common industry or Agency usage. The use of ''insured'' better conveys the application of the SFIP to property.

As a consequence of the changes proposed above, FEMA also proposes to renumber sections H through T as sections E through Q. No other changes were made to these sections other than conforming cross-references.

vii. Section U—Duplicate Policies Not Allowed

Article VII.U (''Duplicate Policies Not Allowed'') currently describes restrictions on insuring property with more than one NFIP policy. FEMA proposes to remove the Section and incorporate the language into the new language at Articles I.F and VIII.D (discussed in III.C.1.ii and III.C.6.iv of this document, respectively). FEMA further proposes to redesignate all subsequent sections in Article VII, starting with section ''VII.V'' as ''VII.R.''

viii. Section V—Loss Settlement

Current Article VII.V (''Loss Settlement'') (proposed VII.R) describes the three methods for settling losses under the SFIP: Replacement cost loss settlement, special loss settlement, and actual cash value loss settlement. Article VII.V.1.a.1 (proposed VII.R.1.a.1) provides that replacement cost loss settlement applies to a single-family dwelling provided that it is the policyholder's principal residence within the meaning described further in the paragraph. As discussed in III.C.2, FEMA proposes to remove the definition of ''principal residence'' currently embedded in this provision and move it to the Definitions article of the SFIP. This change would improve readability of the provision without substantive impact.

Throughout proposed section VII.R, FEMA proposes to update internal references to this section (*i.e.,* replacing ''V'' with ''R'').

ix. Internal Citation Updates Within Article VII

FEMA proposes to redesignate the letter identifiers for the following sections due to the resdesignation of earlier sections of Article VII. The changes are as follows: Current Article VII.J (proposed VII.G), Requirements in Case of Loss; current Article VII.M (proposed VII.J), Loss Payment; current Article VII.T (proposed VII.Q), Continuous Lake Flooding; and current Article VII.V (proposed VII.R), Loss Settlement.

6. Article VIII Policy Nullification, Cancellation, and Non-Renewal

As discussed above, FEMA proposes to add a new Article VIII (''Policy Nullification, Cancellation, and Non-Renewal''), which would address in one place all the current reasons for which a policy may be nullified, cancelled, or non-renewed. This would consolidate the policy nullification, cancellation, and non-renewal reasons currently in the Dwelling Form at Article VII.B (''Concealment or Fraud and Policy Voidance''), VII.E (''Cancellation of the Policy by You''), and VII.F (''Non-Renewal of the Policy by Us''), and VII.U (''Duplicate Policies Not Allowed''). It would also incorporate the reasons that are being codified into regulation at 44 CFR 62.5 (discussed below). This consolidation would improve the organization and structure of the document. This new article would also improve transparency to the policyholder regarding the reasons for which a policy may be nullified, cancelled, or non-renewed.

i. Section A—Policy Nullification for Fraud, Misrepresentation, or Making False Statements

Current Article VII.B.1–3 provides that a policy is void, has no legal force or effect, cannot be renewed, and cannot be replaced by a new NFIP policy if the policyholder (or another insured or agent) has intentionally concealed or misrepresented any material fact or circumstance, engaged in fraudulent conduct, or made false statements related to this or any other NFIP policy. It also provides that the policy would be void as of the date the wrongful acts were committed, and that fines, civil penalties, and imprisonment may also apply. FEMA proposes to move these sections to Article VIII.A, rename it ''Policy Nullification for Fraud, Misrepresentation, or Making False Statements,'' and reorganize it without substantive change for greater clarity.

ii. Section B—Policy Nullification for Reasons Other Than Fraud

Current Article VII.B.4 provides that the policy is void and has no legal force where the property is located in a community not participating in the NFIP on the policy's inception date and

did not join or reenter the program during the policy term and before the loss occurred, or if the property is not otherwise eligible for NFIP coverage. FEMA proposes to establish a new Article VIII.B, entitled ''Policy Nullification for Reasons Other Than Fraud'' which would incorporate the provisions of current VII.B.4 but add additional reasons that a policy may be void. These are: (1) The applicant or policyholder never had an insurable interest (proposed VIII.B.1.c); (2) the policyholder provided an agent with an application and payment, but the payment did not clear (proposed VIII.B.1.d); and (3) the insurer received notice from the policyholder, prior to the policy effective date, that the policyholder has decided not to take the policy and the policyholder is not subject to a requirement to obtain and maintain flood insurance pursuant to any statute, regulation, or contract. These added reasons for policy voidance reflect current agency interpretations and practices, as reflected in the Cancellation/Nullification Section of the Flood Insurance Manual.

FEMA proposes to add Article VIII.B to state that the applicant or policyholder would be entitled to a full refund of all premium, fees, and surcharges received, but if a claim was paid for a policy that is void, the claim payment must be returned to FEMA or offset from the premiums to be refunded before the refund will be processed. This reflects current agency interpretations and procedures, as reflected in the Cancellation/Nullification Section of the Flood Insurance Manual.

iii. Section C—Cancellation of the Policy by You

Current Article VII.E (''Cancellation of the Policy by You'') provides that a policyholder may cancel the policy in accordance with the NFIP's rules and regulations, in which event they may be entitled to a full or partial refund of premium under those same rules and regulations. FEMA proposes to incorporate the provisions of current Article VII.E into a new Article VIII.C, entitled ''Cancellation of the Policy by You.'' The proposed section C would retain the same language except for two changes. First, instead of stating ''in accordance with the applicable rules and regulations of the NFIP,'' it would state ''in accordance with the terms and conditions of this policy and the applicable rules and regulations of the NFIP.'' Second, it would replace the phrase ''premium also under the applicable rules and regulations of the NFIP'' with ''premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.'' No substantive change is intended.

iv. Section D—Cancellation of the Policy by Us

FEMA proposes to establish a new Article VIII.D, entitled ''Cancellation of the Policy by Us,'' which would state four reasons for which a policy may be cancelled by the insurer: 1. Cancellation for underpayment of amounts owed on the policy, 2. cancellation due to lack of an insurable interest, 3. cancellation of duplicate policies, and 4. cancellation due to physical alteration of property.

The first reason for which the insurer may cancel a policy is in proposed Article VIII.D.1, entitled ''Cancellation for Underpayment of Amounts Owed on Policy.'' This provision would state that the insurer may cancel the policy if, pursuant to VII.D.2, it is determined that the amounts paid by the policyholder were not sufficient to buy any amount of coverage, and the policyholder did not pay the additional amount of premium owed to increase the coverage to the originally requested amount within the required time period. FEMA proposes to add this cancellation reason to align with current practice, as reflected in proposed VII.D.2, that FEMA will cancel a policy where the policyholder has paid a premium that is insufficient to buy a policy with the lowest available coverage limits.

FEMA proposes to add the second reason for which the insurer may cancel a policy in proposed Article VIII.D.2, entitled ''Cancellation Due to Lack of an Insurable Interest.'' Proposed Article VIII.D.2.a would state that if the policyholder no longer has an insurable interest in the insured property, the insurer will cancel the policy, and that the policyholder would cease to have an insurable interest if (1) for building coverage, the building was sold, destroyed, or removed, and (2) for contents coverage, the contents were sold or transferred ownership, or the contents were completely removed from the described location. Proposed Article III.D.2.b would state that if a policy is cancelled for these reasons, the policyholder may be entitled to a partial refund of premium under the applicable rules and regulations of the NFIP. This reflects FEMA's current practice and interpretations, as shown in the Cancellation/Nullification section of the Flood Insurance Manual, pages 1–2 (''1. Building Sold or Removed, Destroyed or Physically Altered to no Longer Meet the Definition of an Eligible Building'').

FEMA proposes to add the third reason for which the insurer may cancel a policy in proposed Article VIII.D.3, entitled ''Cancellation of Duplicate Policies.'' Article VIII.D.3 would have three subsections. Subsection (a) would state that except as allowed under Article I.G (*i.e.,* for a Dwelling Form policy on a condominium unit that is also insured by an RCBAP policy), property may not be insured by more than one NFIP policy. This would incorporate the language in the current Article VII.U, stating that duplicate policies are not allowed under the NFIP, as well as the exception to that rule created in Article I.G. FEMA also proposes to add that payment for damages will only be made under one policy. This would align with current Article VII.U, which prevents coverage under more than one NFIP policy and VII.U.2, which states which one policy will pay for a loss in the case of duplicate policies. This proposed language would improve the clarity of the policy by explicitly stating what is currently strongly implied in the SFIP.

Subsection (b) would state that except as allowed under Article I.G, if the property is insured by more than one NFIP policy, all but one of the policies will be cancelled, and that the policy, or policies, will be selected for cancellation in accordance with 44 CFR 62.5 and the applicable rules and guidance of the NFIP. FEMA proposes to add this provision in conjunction with its proposed revisions to the cancellation provisions at 44 CFR 62.5 (discussed below).

Subsection (c) would state that if a policy is cancelled pursuant to VIII.D.4.b, the policyholder may be entitled to a full or partial refund of premium, surcharges, or fees. FEMA proposes to add the third subsection in conjunction with the refund rules proposed at 44 CFR 62.5.

FEMA proposes to add the fourth reason for which the insurer may cancel a policy in proposed Article VIII.D.4, entitled ''Cancellation Due to Physical Alteration of Property.'' The proposed provision states that the insurer may cancel the policy if the insured building has been physically altered in such a manner that it is no longer eligible for flood insurance coverage, and that if the policy is cancelled for this reason, the policyholder may be entitled to a partial refund of premium under the terms and conditions of the policy and the applicable regulations of the NFIP. This reflects current agency practice and interpretations, as shown in the Cancellation/Nullification section of the Flood Insurance Manual, pages 1–2.

v. Section E—Non-Renewal of the Policy by Us

Current Article VII.F (''Non-Renewal of the Policy by Us'') provides that a policy will not be renewed if the community where the covered property is located stops participating in the NFIP, or if the building has been declared ineligible under the section 1316 of the NFIA. FEMA proposes to incorporate these provisions into proposed Article VIII.E, entitled ''Non-Renewal of the Policy by Us.'' FEMA proposes to retain both provisions stating that the property is located in a suspended or non-participating community and the building is ineligible for NFIP coverage, but proposes to move the words ''if'' from the beginning of each subsection and instead put the word ''if'' directly after the phrase ''will not be renewed''; to replace the word ''covered'' with ''insured,'' and replace the phrase ''has been declared'' with the phrase ''is otherwise.'' FEMA proposes these revisions to improve the language.

FEMA also proposes to add a new provision stating that the policy will not be renewed if the policyholder has not provided the information necessary to rate the policy within the required deadline. FEMA proposes to add this third reason for which a policy will not be renewed to clarify that a policyholder has an obligation to provide the information needed to rate the policy and that failure to provide this information within the required deadline will result in that policy not being renewed. This is implicit in the language of Article I of the SFIP and reflects FEMA's current practices, but the proposed language is a more explicit statement needed to increase the transparency and clarity of the policy.

FEMA further proposes to renumber current Articles VIII and IX as IX and X, respectively, due to the renumbering of prior articles.

7. Article IX What Law Governs

Current Article IX (''What Law Governs'') describes which law applies to the SFIP. FEMA proposes to redesignate current Article IX as Article X and to add ''the insurer's policy issuance'' and ''policy administration'' to the list of insurer activities taken under the NFIP that must be governed exclusively by the National Flood Insurance Act of 1968, the regulations prescribed pursuant to the Act, and Federal common law. FEMA proposes this change to clarify that the NFIP insurer's policy issuance and policy administration operations are also governed solely by the Act, the NFIP's regulations, and Federal common law.

8. Signing Statement

The Dwelling Form of the Standard Flood Insurance Policy concludes with a signing statement that references the ''Federal Insurance Administration.'' FEMA proposes to changes this to the ''Federal Insurance and Mitigation Administration'' to align with the current organizational title.

*D. Appendix A(2) to Part 61: General Property Form*

FEMA proposes to revise the General Property Form of the SFIP in a manner consistent with the revisions to the Dwelling Form of the SFIP described above. Except as indicated in the sections below, the changes FEMA is proposing to the General Property Form are identical to those in the Dwelling Form.

1. Article I Agreement

In the current General Property Form, the first paragraph is a prefatory statement regarding what the policy does not cover, and it is outside of Article I. As FEMA proposed above in Article I of the Dwelling Form of the SFIP, FEMA proposes to move this statement so that it is included in Article I and labeled section ''A.'' FEMA proposes to further revise this section in the General Property Form to include a statement about what the General Property Form does cover. FEMA proposes to add language stating that except as provided in Article I.A.2 (the current language stating what the policy does not cover), ''this policy provides coverage for multifamily buildings (residential buildings designed for use by 5 or more families that is not a condominium building), non-residential buildings, and their contents.'' This clear statement would help differentiate the General Property Form from the other SFIP policy forms.

In addition, the proposed General Property Form would not include the proposed Dwelling Form's Art. I.G, which provides that a building may be covered under both a Dwelling Form policy and a RCBAP. General Property Form policies may only insure non-residential buildings, while RCBAP may only insure residential condominium buildings. Accordingly, Art. I.G would not apply similarly in the General Property Form.

2. Article II Definitions

The definitions FEMA proposes to add, delete, or revise in Article II of the General Property Form of the SFIP, ''Definitions,'' would be the same as those in the Dwelling Form of the SFIP, insofar as those terms are also defined in the General Property Form, with one exception. FEMA proposes to revise the definition of ''unit'' in the General Property form to mean ''a single-family residential or non-residential space you own in a condominium building.'' Although this is different from the definition used in the Dwelling Form (the Dwelling Form covers only residential properties, whereas the General Property Form covers both residential and non-residential properties), the reason for this proposed revision is the same—to remove the word ''unit'' within the definition of ''unit.''

3. Article III Property Covered

Article III.A. describes the conditions under which the policy covers building property. Article III.A.2 provides that the policy covers building property at a location other than the one described on the Declarations Page according to certain conditions. FEMA proposes to replace the phrase ''We also insure building property . . .'' with ''Building property located at another location . . .'' to reduce redundancy and improve readability with the first sentence of the paragraph, which states ''We insure against direct physical loss by or from flood to:''. Article III.A.6.a provides the conditions for coverage where the structure is not yet walled or roofed as described in the definition for ''building.'' The subsection erroneously cites to ''II. 6.a.'' rather than to ''II.B.6.a.'' as the location for the definition of ''building.'' FEMA proposes to add ''B'' to the citation to correct the typographical error.

Article III.B.1 describes the conditions under which the policy covers personal property inside a building. Current Article III.B.1.b contains an unnumbered paragraph after paragraph B.1.b. FEMA proposes to number this unnumbered paragraphs as ''2'', and to renumber subsequent paragraphs accordingly, to improve readability and organization.

E. Appendix A(3) to Part 61: Residential Condominium Building Association Policy

FEMA proposes to amend the Residential Condominium Building Association Policy (RCBAP) Form of the SFIP in a manner consistent with the revisions to the Dwelling Form of the SFIP. The changes made to the RCBAP Form would be identical to those in the Dwelling Form for all provisions that these two forms have in common. Additionally, FEMA proposes to replace reference to the ''FEMA Regional

Director'' with ''FEMA Regional Administrator'' in current VIII.T.2.h (proposed VIII.Q.2.h) to align with the current organizational title.

F. Part 62: Sale of Insurance and Adjustment of Claims

Part 62 sets forth the manner in which NFIP flood insurance is made available to the public in participating communities, prescribes the general method by which FEMA exercises its responsibility regarding the manner in which claims for losses are paid, and states reasons for which a policy may be nullified or cancelled and the associated refunds.

1. Part 62 Authority Citation

The current authority citation for part 62 is 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376. FEMA proposes to replace the citations to Reorganization Plan No. 3 and Executive Order 12127 with a citation to the codification of the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.* The authority citation would therefore read 42 U.S.C. 4001 *et seq.;* 6 U.S.C. 101 *et seq.* FEMA proposes this change because while Reorganization Plan No. 3 and Executive Order 12127 originally created FEMA as an executive agency, PKEMRA amended the Homeland Security Act of 2002, Public Law 107–296, by establishing the Agency in statute and defining the Agency's authorities and responsibilities. Accordingly, a citation to the codification of the Homeland Security Act is more appropriate.

2. Section 62.3 Servicing Agent

Section 62.3 currently describes the Flood Insurance Administrator's authority to enter into an agreement with a servicing agent that can service policies and claims on behalf of the Agency. Paragraph (a) currently states that the Federal Insurance Administrator ''has entered into the Agreement'' with a servicing agent. Section 62.3(b) currently names National Con-Serv, Inc. (NCSI) as FEMA's servicing agent for its direct side policies. FEMA proposes to make a change to paragraphs (a), remove paragraph (b), and renumber paragraph (c) as paragraph (b) to better describe the present status of the direct servicing agent.

In section 62.3(a), FEMA proposes to replace the words ''has entered into the Agreement'' with the words ''may enter into an agreement.'' The current formulation states a current fact, rather than defining the Agency's powers and duties, which is a traditional role of a rule. Further, the use of ''the Agreement'' seems to imply that a particular agreement must be entered into with the servicing agent. However, no such standard agreement exists in regards to contracting with a direct servicing agent. FEMA contracts with servicing agents in accord with the Federal Acquisition Regulations.[5] This adjustment better describes the Administrator's authority to decide whether or not to use the services of a servicing agent, and if choosing to do so, the terms of the agreement.

FEMA proposes to remove section 62.3(b) because the current regulation lists NCSI as the NFIP Direct Servicing Agent even though this is not accurate and it is uncessary to name a government contractor in the Code of Federal Regulations. Contact information for the Direct Servicing Agent is provided to each policyholder sold NFIP flood insurance through the Direct Servicing Agent. FEMA also provides this information on its website.[6] Removing this from regulation would reduce the burden on FEMA to undertake a rulemaking each time the Direct Servicing Agent changes, while not materially impacting the public.

After removing current paragraph (b), FEMA proposes to renumber current paragraph (c) as paragraph (b).

With respect to section 62.3(b), FEMA proposes to remove the paragraph because the named servicing agent is no longer accurate—NCSI is no longer FEMA's direct servicing agent. FEMA proposes to add a new paragraph (b) stating that FEMA will provide public notice of the name of the servicing agent in the **Federal Register**. This change will allow the agency greater flexibility in providing public notice of the identity of its direct servicing agent without having to undertake a full rulemaking to do so.

3. Section 62.5 Premium Refund

Section 62.5 describes reasons for which FEMA will allow cancellation of a policy. Section 62.5 currently allows a policyholder to cancel a policy for two reasons. First, the policyholder may cancel a policy that covers property for which the policyholder is no longer required to maintain flood insurance because a Letter of Map Amendment issued under part 70 has determined that the property is not located in an SFHA. Second, the policyholder may cancel a policy that is a three-year policy where the policyholder has either obtained a replacement flood insurance policy or the lender has provided the NFIP with actual notice that the mortgage has been paid off and/or the lender no longer requires the policyholder to maintain flood insurance.

In addition to section 62.5, section 61.5(c) and certain sections of the SFIP also describe the reasons for which FEMA will allow cancellation of a policy. FEMA proposes to remove current section 62.5 and replace these various regulatory provisions with a comprehensive new section 62.5 codifying all the reasons for which FEMA allows a policyholder to cancel or nullify a policy, as well as the handling of associated premium refunds. FEMA proposes to entitle section 62.5 ''Nullifications, Cancellations, and Premium Refunds.'' In this new section 62.5, FEMA proposes to incorporate the first policy cancellation reason (*e.g.,* the property is no longer in a SFHA), discussed in more detail below. FEMA proposes to remove the second reason because it refers to a three-year insurance policy the NFIP no longer uses. FEMA proposes to consolidate the remaining reasons for which the NFIP may nullify or cancel a policy in section 62.5.

i. Paragraph (a): Nullification

Paragraph (a) of this new section, entitled ''Nullification,'' would describe all the reasons for which FEMA may terminate a policy. Subparagraph (1), entitled ''Property Ineligible at Time of Application,'' would state that a policy for a property that was not eligible for coverage at the time of the initial application will be considered void from commencement. This paragraph would also provide the rules and limitations governing the applicability of this nullification reason, as well as the associated premium refunds. FEMA has previously handled situations where property was ineligible for flood insurance at the time of application via NFIP procedures. FEMA proposes to codify existing practice, found at Reason Code 6 from the Nullification/Cancellation section of the Flood Insurance Manual, into regulation to ensure consistent application of the procedures and to provide a comprehensive nullification section in regulation.

Subparagraph (2), entitled ''Property Later Becomes Ineligible,'' would state that a policy for a property that was eligible for coverage at the time of the initial application, but later became ineligible for coverage, may not be renewed and will be void from the first renewal date after the property became ineligible. This paragraph would also

[5] *See* 48 CFR part 37.

provide the rules and limitations governing the applicability of this nullification reason, as well as the associated premium refunds. This would further codify Reason Codes 1 and 6 from the Nullification/Cancellation section of the Flood Insurance Manual into regulation.

Paragraph (3), entitled ''Nullification Prior to Policy Effective Date,'' would clarify that in cases where a policy is nullified before it becomes effective, the NFIP will void the policy from the beginning of the policy term. Such a situation may arise where a policyholder's premium payment check is returned for insufficient balance or where a policyholder cancels his or her policy before it becomes effective. The provision would also clarify that in the rare instance where the NFIP pays a claim for a policy that was actually nullified before the policy's effective date, the policyholder would have to either return the claim payment or pay the premium using the claim payment. This paragraph would also provide the rules and limitations governing the applicability of this nullification reason, as well as the associated premium refunds. Overall, this provision will codify existing Reason Codes 5, 7, and 13 from the Nullification/Cancellation section of the Flood Insurance Manual into regulation. These reason codes are based on basic principles of insurance that the program has applied with regulatory instruction. FEMA proposes to codify these cancelation/nullification reasons in regulation to provide stakeholders with a comprehensive regulatory basis for nullification.

ii. Section 62.5(b): Cancellation Due to Lack of an Insurable Interest

Section (b), entitled ''Cancellation Due to Lack of an Insurable Interest,'' would be taken from the current 61.5(c) and would allow policy cancellations when a policyholder ceases to have an insurable interest in the insured property (*i.e.,* because the property was sold, destroyed, or removed). This subsection would state that for building coverage, a policyholder ceases to have an insurable interest if the building has been sold, destroyed, or removed. This subsection would further state that for contents coverage, a policyholder ceases to have an insurable interest if the contents were sold, transferred ownership, or have been removed from the described location. This paragraph would also provide the rules and limitations governing the applicability of this cancellation reason, as well as the associated premium refunds. This will codify Reason Codes 1 and 2 from the Nullification/Cancellation section of the Flood Insurance Manual into regulation. Reason Codes 1 and 2 are necessitated by basic principles of insurance that prevent an insurer from insuring property in which the policyholder does not have an insurable interest. FEMA proposes to codify these cancelation/nullification reasons in regulation to provide stakeholders with a comprehensive regulatory basis for nullification.

iii. Section 62.5(c): No Insurance Coverage Requirement

Paragraph (c), entitled ''No Insurance Coverage Requirement,'' would allow cancellation in cases where the policyholder is no longer required to maintain flood insurance on the property. The new paragraph would state that a policyholder may cancel a policy if there was a requirement by a lender, loss payee, or other Federal agency to obtain and maintain flood insurance pursuant to statute, regulation, or contract, but there no longer is such a requirement. Such situatons would include where (i) the policyholder has paid off his or her mortgage, (ii) the policy was required by the mortgagee in error, or (iii) the property has been removed from the SFHA, and accordingly from the mandatory purchase requirement, through a revision or amendment to the FIRM, including the issuance of a Letter of Map Amendment (LOMA) removing a property from an SFHA.

The paragraph will further state that in such instances, FEMA would only provide a pro rata refund of the premium for the current policy year, as calculated from the date of the cancellation request. Surcharges or other fees would not be refunded. This will codify into regulation FEMA's interpretation of 44 CFR 62.5, which is currently found in Reason Codes 9, 12, 15, 18, and 19 from the Nullification/Cancellation section of the Flood Insurance Manual.

iv. Subsection 62.5(d): Establishment of a Common Expiration Date

Subsection (d), entitled ''Establishment of a Common Expiration Date,'' would codify parts of current Article VII.U of the SFIP. The provision would allow policyholders to create duplicate policies, and then cancel the policy with the earlier effective date, to establish common expiration dates with other coverage. This paragraph would also provide the rules and limitations governing the applicability of this nullification reason, as well as the associated premium refunds. This would codify into regulation the NFIP's existing cancellation reason found under Reason Code 3 in the Nullification/Cancellation section of the Flood Insurance Manual.

v. Subsection 62.5(e): Cancellation or Nullification of Duplicate NFIP Policies

Subsection (e) would be entitled ''Cancellation or Nullification of Duplicate NFIP Policies.'' The subsection would incorporate provisions of current Article VII.U, which allow for cancellation of duplicate NFIP policies. The proposed subsection would include two paragraphs. Paragraph (1), entitled ''Generally,'' would have two paragraphs. Paragraph (i) would state that if more than one policy covers the same building not in accordance with applicable regulation and SFIP terms and conditions, FEMA must nullify the policy with the later effective date. This paragraph would also provide the rules and limitations governing the applicability of this nullification reason, as well as the associated premium refunds.

Paragraph (ii) would state that if both policies have the same effective date, the policyholder may choose which policy will remain in effect, at which point the same refund rules laid out in paragraph (i) apply. This paragraph would also provide the rules and limitations governing the applicability of this nullification reason.

Paragraph (2), entitled ''Exceptions,'' would establish the exceptions to Paragraph (1) and would state that in certain cases, the policy with the earlier effective date may be cancelled instead of the policy with the later effective date. The first exception, contained in paragraph (i) and entitled ''Earlier Policy Expired'' would allow the policy with the earlier effective date to be cancelled where that policy has expired for more than 30 days. The second exception, in paragraph (ii) entitled ''Group Flood Insurance Policy (GFIP)'' would provide that the policy with the earlier effective date may be cancelled if that policy is a GFIP. The third exception, in paragraph (iii) entitled ''Cancellations to Establish a Common Expiration Date'' would provide that the policy with the earlier effective date may be cancelled pursuant to paragraph (d) of this proposed section (*i.e.,* to establish a common expiration date). The fourth exception, in paragraph (iv) entitled ''Force-Placed Policy'' would allow the policy with the earlier effective date to be cancelled if the the mortgagee buys a flood insurance policy through the Mortgage Portfolio Protection Program after the property owner fails to obtain a flood insurance policy on their own. This is often

refered to as ''force placing'' a policy. The last exception, in paragraph (v) entitled ''Condominium Unit Covered by a Dwelling Form Policy and an RCBAP'' would provide that if the policy with the earlier effective date is a Dwelling Form policy with building coverage on a condominium unit that is also covered by an RCBAP with coverage that equals the statutory maximum building coverage limit, the Dwelling Form Policy may be cancelled.

Each paragraph establishing an exception would also provide the premium refunds associated with cancellations falling under the exception. This proposed section would clarify, in regulation, how FEMA has interpreted Article VII.U of the SFIP in practice. This cancellation reason is currently found in Reason Code 4 in the Nullification/Cancellation section of the Flood Insurance Manual.

vi. Subsection 62.5(f): Other Cancellations and Nullifications

Subsection (f) would be entitled ''Other Cancellations and Nullifications,'' and clarify the other current reasons for which a policy may be cancelled. This section would also state that the policyholder will not receive a refund of any premium, fees, or surcharges for policies cancelled pursuant to this section. Paragraph (1), entitled ''Fraud,'' would state that FEMA will cancel a policy for fraud committed by the policyholder or agent and may cancel a policy for misrepresentation of a material fact by the policyholder or agent. In either case, the cancellation would take effect as of the date of the fraudulent act or material misrepresentation of fact. This is taken from current Article VII.B of the SFIP, which states that fraud by the agent or the insured voids a policy. This nullification reason may be found under Reason Code 23 in the Nullification/Cancellation section of the Flood Insurance Manual.

Paragraph (2), entitled ''Administrative Cancellation,'' would allow a policy to be cancelled and rewritten to correct an administrative error, such as when the policy is written with the wrong effective date, and any excess premium, fees, or surcharges would be refunded. This cancellation reason may be found under Reason Code 20 in the Nullification/Cancellation section of the Flood Insurance Manual.

Paragraph (3), entitled ''Nullification for Properties Ineligible Due to Physical Alteration of Property,'' would state that a policy insuring a building or its contents, or both, may be cancelled if the building has been physically altered so that the building and its contents are no longer eligible for flood insurance coverage. This paragraph would also provide the rules and limitations governing the applicability of this nullification reason, as well as the associated premium refunds. This nullification may be found under Reason Codes 1 and 2 in the Nullification/Cancellation section of the Flood Insurance Manual.

4. Section 62.6 Minimum Commissions

Current section 62.6 contains provisions applicable to insurance agents and brokers writing NFIP policies through the NFIP Direct Services Agent. It does not apply to agents or brokers associated with WYO companies. FEMA proposes several nonsubstantive changes designed to clarify the existing section.

i. Section Heading

Currently, section 62.6 is titled, ''Minimum Commissions.'' FEMA proposes to revise the title of section 62.6 to ''Brokers and Agents Writing NFIP Policies through the NFIP Direct Servicing Agent'' because the section covers more than just commissions. FEMA believes the proposed title better reflects the contents of the section.

ii. Paragraph (a): Agent and Broker Licensing Requirements

Currently, section 62.6(a) defines the commissions paid to agents and brokers participating in the Direct Servicing Agent (DSA) portion of the NFIP. However, it also includes a requirement that such agents and brokers are ''duly licensed by a state insurance regulatory authority.'' FEMA proposes to move this important requirement from within the minimum commission provision and set it out in its own paragraph. Accordingly, FEMA proposes to add a new paragraph (a) that only includes the requirement and to redesignate current paragraphs (a) and (b) as paragraphs (b) and (c), respectively. Accordingly, FEMA also proposes to make corresponding changes to proposed paragraph (b) by removing the existing references to state licensing requirements. FEMA does not intend to substantively change the licensing requirements of DSA agents, but rather intends to separate this requirement from other subject matter to improve overall clarity of the section. FEMA also proposes to change the uses of ''shall'' to ''will'' to incorporate plainer language without making substantive change.

5. Section 62.22 Judicial Review

Section 62.22 provides that actions for disallowed claims must be instituted in the U.S. District Court for the district in which the insured property was situated and describes service of process requirements. FEMA proposes to revise section 62.22 to replace references to the ''Federal Insurance Administration'' with the current organizational title, ''Federal Insurance and Mitigation Administration.''

## IV. Regulatory and Economic Analysis

### *A. Executive Order 12866, Regulatory Planning and Review & Executive Order 13563, Improving Regulation and Regulatory Review*

Executive Orders 13563 (''Improving Regulation and Regulatory Review'') and 12866 (''Regulatory Planning and Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs'') directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB's Memorandum ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017).

In this rule, FEMA proposes to make several nonsubstantive changes to the National Flood Insurance Program's (NFIP) regulations at Parts 59, 61, and 62, as well as the Appendices to Part 61. FEMA proposes to codify in regulation certain provisions of the Biggert Waters Flood Insurance Reform Act of 2012 (BW–12) and the Homeowner Flood Insurance Affordability Act of 2014 (HFIAA) that have already been

implemented. FEMA implemented these changes via the Flood Insurance Manual or other related guidance documents as they were unambiguous changes that left no discretion on the part of the agency to implement. Now FEMA proposes to update the regulations accordingly. FEMA also proposes to clarify certain existing NFIP regulations relating to NFIP operations and the Standard Flood Insurance Policy unrelated to recent legislation by consolidating and stylistically updating the regulatory text and standardizing key terminology.

Overall, there are 34 identified proposed regulatory changes in this rule (itemized in Table 1 below). The vast majority of these changes are limited to nonsubtantive clarifications. The remaining provisions are considered ''Codifications,'' that codify in regulation either an existing practice or policy, or a process heretofore requiring special waiver by FEMA.

Following guidance in OMB Circular A–4, FEMA assesses the impacts of this rule against the no-action baseline as well as a pre-statutory baseline. The no action baseline is an assessment against what the world would be like if the proposed rule is not adopted. The pre-statutory baseline is an assessment against what the world would be like if the relevant statute(s) had not been adopted. By considering both baselines we are able to consider full costs of the action.

Under a no-action baseline, this proposed rule would carry no transfers or quantifiable costs. The proposed rulemaking would make material improvements to the language and organization of the NFIP's regulations, but such clarifications and codifications would not result in any quantifiable burden or benefit. The proposed rule also would codify certain changes pursuant to BW–12 and HFIAA that FEMA has already implemented via the Flood Insurance Manual or other related guidance documents. WYO companies would, however, incur opportunity costs as they spend time becoming familiar with the proposed changes. The proposed rule would result in cost savings associated with no longer requiring individual waivers for condominium loss assessment restrictions.

The below analysis adopts a consistent pre-statutory baseline of 2012 in order to capture the effects of the proposed rule, including those of modifications already implemented through interim actions. The summary table below (Table 1) presents the proposed rule's components based on the two categorizations above, including the related statutory mandates (BW–12, HFIAA or both), a description of their effects and their likely impact.

TABLE 1—SUMMARY OF PROPOSED CHANGES

| Current section No./ subject matter | Proposed change | Mandatory or discretionary action | Impact |
|---|---|---|---|
| **Nonsubstantive Clarifications & Consolidations** | | | |
| 1. § 59 Definitions ..... | FEMA proposes to add and revise definitions to support clarifications and codificatons described below. This is a nonsubstantive change that clarifies existing definitions and does not alter the administration of the program. | Discretionary ..... | No change in compliance burden. |
| 2. § 61.1 Purpose of part | FEMA proposes to remove irrelevant second sentence that does not relate to the substantive content of part 61. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 3. § 61.3 Coverage and benefits provided under the SFIP. | FEMA proposes to clarify language to provide a more complete statement of coverage and benefits provided by the SFIP. The coverage and benefits provided under the SFIP are already stated in regulations; this is just a consolidated, unified statement of coverage and benefits under the SFIP. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 4. § 61.5 Deductibles ..... | An application of BW–12 section 100210 and HFIAA section 12, that would clarify existing policy/practice by moving content of 61.5 to new unified cancellation/nullification section in 44 CFR 62.5 (discussed below). FEMA also proposes to replace the current deductible tables with provisions describing the minimum deductibles required by BW–12 section 100210 and the $10,000 deductible option required by HFIAA section 12. This is a nonsubstantive change because FEMA has always had this authority and has always made these deductible options available to policyholders despite not being explicitly provided for in the CFR. | Mandatory ..... | No change in compliance burden. |
| 5. § 61.6 Maximum amounts of coverage available. | FEMA proposes to clarify the maximum coverage limit tables in section 61.6 with nonsubstantive changes to improve readability and conformance with standard program terminology and terminology introduced by BW–12. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 6. § 61.10 Requirements for Issuance or Renewal of Flood Insurance Coverage. | FEMA proposes to clarify/consolide existing regulation language. This new provision would clarify that no flood insurance coverage will be issued unless there is (a) receipt of full amount due and (b) submission of a complete application with all the required rating information. Although this has always been the case, and these concepts are covered in sections 61.5 and 61.11, FEMA believes that increased clarity is needed by adding a consolidated statement in the regulations. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |

TABLE 1—SUMMARY OF PROPOSED CHANGES—Continued

| Current section No./ subject matter | Proposed change | Mandatory or discretionary action | Impact |
|---|---|---|---|
| 7. § 61.13 Standard Flood Insurance Policy. | This provision would clarify that SFIP is authorized only under terms and conditions established by Act, regulations, SFIP, and Administrator interpretations. FEMA also proposes to clarify that the agent acts only for policyholder and that the risk of loss is borne by the National Flood Insurance Fund, not the WYO company. This does not represent a substantive change in policy or terms and conditions of the SFIP, but instead would make terms clearer. | Discretionary ..... | No change in compliance burden. |
| 8. § 62.5 Policy Nullification and Cancellation. | FEMA proposes to make changes that would clarify and consolidate the existing reasons for which a policy may be cancelled or nullified. The current reasons for which a policy may be cancelled or nullified are spread throughout the regulations and FEMA's interpretations of those regulations in the Flood Insurance Manual. This would consolidate those reasons into one section for greater clarity and transparency to the public. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 9. § 62.6 Broker and Agents for Servicing Agent. | This provision would clarify FEMA's existing policy by adding it to regulation that a broker or agent selling NFIP policies must be licensed in the state in which the property is located. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 10. SFIP Article I ..... | FEMA proposes changes to SFIP Article I that would clarify the types of property covered by the SFIP. Proposed clarifications are about coverage limits and multiple policies covering one building. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 11. SFIP Article II-Definitions. | FEMA proposes to revise and add some definitions for clarity. In particular, the proposed changes would clarify that the named insured must also include the building owner if building coverage is purchased. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 12. SFIP Article III ..... | FEMA proposes to clarify that references to insured property do not extend coverage to any type or item of property not otherwise insured in accordance with the terms and conditions of SFIP. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 13. SFIP Article III.A ..... | FEMA proposes minor nonsubstantive changes to Article III.A.5.b.2 to improve the grammar of the section; revise Article III.A.8 to remove the phrase ''in a building enclosure.'' This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 14. SFIP Article III.B ..... | FEMA proposes to revise the numbering in this section to improve readability and organization; revise Article III.B.3 by removing the phrase ''in a building enclosure.'' This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 15. SFIP Article III.D ..... | FEMA proposes to revise the language in this section so that the word ''structure'' is replaced by the word ''building'' throughout the section except at III.D.5.c. The reason for this change is the NFIP insures SFIP defined ''buildings,'' not any structure that does not meet the definition of ''building'' as defined in the SFIP. FEMA also proposes to improve the language in III.D.3.d and III.D.3.e by replacing the phrase ''this coverage'' with the phrase ''Coverage D'' to clarify that the coverage referred to in these provisions is Coverage D. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 16. SFIP Article V.B ..... | FEMA proposes a nonsubstantive, clarifying adjustment to the Flood in Progress Exclusion at SFIP Art. V.B to align with reports required by BW–12 section 100227. This change does not impact the application of the exclusion, but will help support more consistent reading of the provison. | Discretionary ..... | No change in compliance burden. |
| 17. SFIP Article VII.B ..... | FEMA proposes to move the provision on concealment of fraud and policy voidance for consolidation into unified section on policy cancellations and nullifications (discussed below). This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 18. SFIP Article VII.E ..... | FEMA proposes to remove Article VII.E, Cancellation of the Policy by You, and incorporate the language into a new consolidated section on policy nullifications, cancellations, and non-renewals. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |

TABLE 1—SUMMARY OF PROPOSED CHANGES—Continued

| Current section No./ subject matter | Proposed change | Mandatory or discretionary action | Impact |
|---|---|---|---|
| 19. SFIP Article VII.F ..... | FEMA proposes to remove Article VII.F, Non-Renewal of the Policy by Us, and incorporate the language into a new Article VIII discussing policy nullifications, cancellations, and non-renewals. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 20. SFIP Article VII.G ..... | This provision would revise the reformation section for clarity/readability. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 21. SFIP Article VII.U ..... | FEMA proposes to move the provision on duplicate policies for consolidation into unified section on policy cancellations and nullifications (discussed below). This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 22. SFIP Article VII.V ..... | FEMA proposes to revise Article VII.V.1.a.1 of the current policy to remove all the language after ''It is your principal residence.'' The reason for this proposed change is that this language, which is essentially a definition of the term ''principal residence,'' has been incorporated into the new definition of ''principal residence'' being added to Definitions section in Article II. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 23. SFIP Article VIII ..... | FEMA proposes to clarify the existing reasons for which a policy may be cancelled, nullified, or not renewed. This would mirror similar section being established at 44 CFR 62.5 (discussed above). This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 24. SFIP Article IX ..... | FEMA proposes to clarify that the SFIP and all disputes arising from the insurer's policy issuance, policy administration, or the handling of any claim under the SFIP are governed by the National Flood Insurance Act and the regulations. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 25. Entire SFIP—Global Language Replacements. | FEMA proposes to replace the word ''covered'' with the word ''insured'' because the word ''covered'' does not conform to common industry or Agency usage. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 26. 62.22 Judicial Review (preamble sec. III.F.5). | FEMA proposes to replace references to the ''Federal Insurance Administration'' with the current organizational title, ''Federal Insurance and Mitigation Administration.'' This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 27. SFIP Article VII.D ..... | FEMA proposes to redesignate Article VII.D as Article VII.C. Replaces the phrase ''structure during the course of construction'' in Article VII.D.2 of the current rule with ''building under construction,'' which is the proper term of art, as used in Article III.A.5.a and Article VI.A. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 28. § 61.4 Limitations on Coverage. | FEMA proposes to delete this provision because some of the language is duplicative with language in other sections, and the rest of the language is more appropriately moved to other sections of the regulation. Move 61.5(a) and (b) to become a new 44 CFR 61.4. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 29. § 62.3 Servicing agent. | FEMA proposes to remove the name of specific direct servicing agent. This is a nonsubstantive change that codifies current practices that began more than a decade before the baseline regarding the public announcement of the direct servicing agent. | Discretionary ..... | No change in compliance burden. |
| 30. Part 59 Authority Citation. | FEMA proposes to replace the citations to Reorganization Plan No. 3 and Executive Order 12127 with a citation to the codification of the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.* This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 31. Part 61 Authority Citation. | FEMA proposes to update authority citations to reflect changes to FEMA's source of authority from Executive orders to statute. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |
| 32. Part 62 Authority Citation. | FEMA propose to update authority citations to reflect changes to FEMA's source of authority from Executive orders to statute. This is a nonsubstantive change that does not alter the administration of the program but rather provides greater clarity for the reader. | Discretionary ..... | No change in compliance burden. |

TABLE 1—SUMMARY OF PROPOSED CHANGES—Continued

| Current section No./ subject matter | Proposed change | Mandatory or discretionary action | Impact |
|---|---|---|---|
| **Codification of Existing Policy and Practice** | | | |
| 33. § 61.11 Effective date and time of coverage under the Standard Flood Insurance Policy—New Business Applications and Endorsements. | FEMA proposes to codify BW–12's addition of the Post-Wildfire Exception to the 30-day waiting period required by 42 U.S.C. 4013(c). This change does not alter the current administration of the program because FEMA immediately complied with the law.<br>FEMA also proposes a clarification by removing the second clause of the first sentence of 61.11(e) and 61.11(f) because thse clauses accommodate a business model that the WYO companies no longer use. This change does not alter the current administration of the program but rather provides greater clarity for the reader. | Mandatory ..... | No change in compliance burden. |
| 34. SFIP Article III.C ..... | FEMA proposes to codify BW–12 section 100214, which prohibits the application of SFIP Article III.C.3.b.4 (disallowing the payment of a condominium loss assessment on a unit policy if the condominium building is underinsured). Prior to BW–12, FEMA issued individual waivers of this provision as the need arose. The proposed changes would delete Article III.C.3.b.4, thus no longer requiring FEMA to issue individual waivers. | Mandatory ..... | Cost savings of $2,048 over 10 years ($1,799 at 3 percent and $1,539 at 7 percent discount rates). |

1. Costs of Rulemaking

While the proposed rulemaking would make material improvements to the language and organization of the NFIP's regulations, such changes would not result in any quantifiable burden or benefit. WYO companies would, however, incur opportunity costs as they spend time becoming familiar with the proposed changes.

FEMA proposes to revise section 61.11 to codify an additional exception to the 30-day waiting period before coverage on a flood insurance policy takes effect. Prior to BW–12, there were only two exceptions to this 30-day waiting period. The first exception was for the initial purchase of flood insurance in connection with the making, increasing, extension, or renewal of a loan. The second exception was for the initial purchase of flood insurance pursuant to a revision or updating of floodplain areas or flood risk zones, if such purchase took place within one year of the notice of such revision.

The proposed rule would codify in regulation Section 100241 of BW–12, which amended Section 1306(c) of the NFIA (42 U.S.C. 4013(c)), by placing a third exception to the 30-day new policy waiting period in regulation. This new exception applies to situations where the flooding to an insured privately owned property is the result of flooding on Federal land that was caused or exacerbated by post-wildfire conditions, also on Federal land. FEMA implemented this new exception via bulletin. *See* WYO Bulletin W–12045 (July 10, 2012) (announcing the implementation of Section 100241), *see also,* WYO Bulletin W–18001 (Jan. 16, 2018) (replacing WYO Bulletin W–12045). To date, circumstances have not existed requiring FEMA to apply this exception. The proposed change updates the regulations to reflect the revised statutory language and existing Agency practice.

When looking at the NFIP claim data from FEMA, since implementation of this exception in July 2012, no parties have made claims that would apply to this provision. Additionally, due to both the brief window of applicability (the 30-day waiting period after initial enrollment in the NFIP) and the narrow circumstances to which this exception applies (flood damage due to flood on Federal land caused, or exacerbated, by post-wildfire conditions), FEMA believes the exception would continue to be rarely invoked. This provision serves as an added enticement to potential enrollees of the NFIP to join the NFIP if they believe that a wildfire on Federal land may cause, or exacerbate, flooding on their property. This provision serves mostly as an added comfort to potential enrollees of the NFIP. In accordance with the data examined, there has not been and FEMA estimates that there would continue to be no additional burden on any party. This provision would ensure that FEMA's regulation concerning the application of the 30-day waiting period includes all statutory exceptions. FEMA requests comments regarding this assumption and estimated frequency of applicable occurrence.

2. Benefits of Rulemaking

The vast majority of provisions represent clarifications to the regulation or program documents, or remove regulations that are no longer applicable. The few non-clarifying provisions reflect in regulations certain provisions that have already been implemented through policy that streamline operations, or meet greater potential needs of policyholders (codifications). It is only with codifications where any quantifiable impacts appear. This analysis considers the following as possible benefits of this rule:

i. Clarification of NFIP Terms and Conditions

This analysis looks at the many efficiencies of the proposed rule, however, the bulk of these benefits are unquantifiable. Although they have not been quantified, they are essential to the justification of the proposed rule and should be considered as they provide significant benefits that will be seen for all stakeholders involved.

Under current conditions, the NFIP-related sections of the CFR contain inconsistencies or vague language that may cause confusion to stakeholders. The following are selected examples of proposed changes presented in Table 1 that would be introduced by the rule:

a. Making Explicit the Implicit

The NFIP deductible charts currently in the regulations at 44 CFR 61.5(d) show several possible deductible options, but not all the deductible options available under the program. A note to these tables indicates that policyholders may submit any other other deductible amounts not currently listed in this chart (including the $10,000 deductible option required under HFIAA). Notwithstanding this note, the current regulation's listing of

deductible options may give readers the impression that the list is exhaustive. FEMA proposes to remove the deductible charts and replace them with a requirement that FEMA must provide policyholders with deductible options in various amounts, up to and including $10,000, subject to certain minimum deductibles. This change would not expand or contract the deductible options offered by the NFIP under current regulations; rather, it would clarify that FEMA offers various options, including the $10,000 deductible, subject to other restrictions.

FEMA also proposes to change the language in Appendix A(1) of Part 61 to clarify that personal property is also insured under this policy. FEMA has always insured personal property under this policy, but the proposed change will make this more explicit in the initial coverage statement. Also under Appendix A(2) to Part 61, FEMA would state that the policy will only cover one building and that the building covered is the one specifically described in the Flood Insurance Application. Coverage under the SFIP has always been limited to one building, but FEMA is proposing that this language be clearly stated at the very beginning of the SFIP.

b. Modifying, Adding or Removing Definitions

FEMA proposes to revise definitions such as ''deductible,'' ''emergency program,'' ''act,'' or ''basement.'' FEMA believes these non-substantive changes will be clearer and more consistent with the language in the Articles of the SFIP. The same can be said of the proposed changes to add acronyms for ease of repetitive use (such as that for the Special Flood Hazard Area as ''SFHA'') or to remove a term or definition that is no longer used (*e.g.,* ''Expense Constant'' which no longer applies, or ''Probation Premium'' which is better changed to ''Probation Surcharge'').

FEMA believes that this increased precision and consistent use of terms would increase clarity of FEMA's NFIP regulations for the insurance companies, flood insurance policyholders, academic researchers, and private citizens. This improved accuracy will help to minimize confusion.

ii. Codification of Dwelling Policy Underinsurance Exception

Presently, Article III.C.3.b.4 of the SFIP, found in Appendix A(1) to Part 61, prevents payment of condominium loss assessments on a unit policy if the condominium building itself is underinsured. The SFIP also requires the coverage limits of the RCBAP policy (the primary policy) to be exhausted before the Dwelling Policy (the secondary policy). This poses a challenge in the event the primary policy was disallowed in the above circumstance. Since 2007, policyholders facing such a predicament were required to obtain a waiver from FEMA to process such claims.

As directed by Section 100214 of BW–12, the proposed changes would delete Article III.C.3.b.4 of the SFIP, which would otherwise prohibit such claim payments and necessitate the submission and processing of waivers. As a result, waivers for this prohibition would no longer be required.

To estimate the cost savings that would result from omitting this process, FEMA considered the frequency these specific circumstances have occurred. Between 2007, when FEMA began issuing the waivers, and 2013 when FEMA terminated the waiver process (following the passage and FEMA's provisional implementation of BW–12), there have been four occurrences of the aforementioned conditions. The applicable cases were reported twice in Illinois, once in Texas and once in Tennessee. Four occurrences over six years equate to an estimated frequency of 0.667 instances each year, assuming that the rate remains consistent in the future.

The reported time required for FEMA to process the resulting waiver requests is around three hours per wavier. This process is undertaken by two General Schedule (GS) Federal employees in the National Capital Region, at the GS–14 and GS–15 levels, in equal proportion. Obtaining 2018 GS scale [7] published hourly wage rates from the Office of Personnel Management (OPM) for the midpoint (step 5) of these grade levels produces fully loaded [8] wage rates of $90.85 and $106.87 per hour, respectively. At approximately 90 minutes per officer for each expected waiver, the subtotal is $136.28 [9] and $160.30,[10] respectively. The waivers also require concurrence, cleared by the appropriate Assistant Administrator. This review and approval takes approximately five minutes at the estimated midpoint in the Senior Executive Service (SES).[11] FEMA estimates that a fully loaded SES hourly rate is $126.66 per hour.[12] The subtotal of the SES time is $10.56.[13] The total opportunity cost of FEMA processing each wavier is $307.16.[14]

[7] GS Scale based on 2018 OPM tables, hourly basic wage rates by grade and step for the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA Accessed March 1st, 2018. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB_h.aspx.*

[8] Bureau of Labor Statistics, Employer Cost for Employee Compensation News Release, Table 1. Employer costs per hour worked for employee compensation and costs as a percent of total compensation; civilian workers, by major occupational and industry group, December 2017. *https://www.bls.gov/news.release/archives/ecec_03202018.htm.*

The per hour benefits multiplier is calculated by dividing total compensation for all workers ($35.87) by wages and salaries for all workers ($24.49), which yields a per hour benefits multiplier of 1.46. ($35.87 ÷ $24.49 = 1.46468). Fully-loaded wage rates are calculated by multiplying the per hour benefits multiplier by the applicable wage rate. GS–14: $62.23 × 1.46 = $90.85 and GS–15: $73.20 × 1.46 = $106.87.

[9] $90.85 (hourly wage rate of $62.23 × 1.46) * 1.5 hours = $136.28.

[10] $106.87 (hourly wage rate of $73.20 × 1.46) * 1.5 hours = $160.30.

[11] FEMA bases SES salary estimates on OPM's Senior Executive Service Report. The latest report available is for 2016. Across all agencies the median SES pay is $173,882 (see table 13 at the following link) *https://www.opm.gov/policy-data-oversight/data-analysis-documentation/federal-employment-reports/reports-publications/ses-summary-2016.pdf.* Accessed June 4, 2018.

[12] $173,882 annual wage/2087 annual hours = $83.32 hourly wage rate × 1.46 benefits multiplier = $121.65 fully loaded hourly wage × 1.04115 inflation adjustment = $126.66 fully loaded $2018 hourly wage.

We calculated the inflation adjustment by subtracting the July 2016 CPI–U (240.6) from the April 2018 CPI–U (250.5). We divided the result (9.9) by the July 2016 CPI–U (240.0). Calculation: (250.5 − 240.6)/240.6 = 0.04115. BLS CPI–U data is available at *http://data.bls.gov/cgi-bin/surveymost?bls.* Select CPI for All Urban Consumers (CPI–U) 1982 − 84 = 100 (Unadjusted) − CUUR0000SA0 and click the Retrieve data button. Accessed June 8, 2018.

[13] $126.96 * 5 minutes = $10.56.

[14] $136.28 + $160.30 + $10.56 = $307.14.

**Table 2: Projected Cost Savings of Codification of Dwelling Policy Underinsurance Exception**

| | Avg Frequency of Waivers | Total Cost Per Waiver | Annual Cost Savings | NPV at 3% (m) | NPV at 7% (m) |
|---|---|---|---|---|---|
| Year 1 | 0.67 | $ 307 | $ 205 | 205 | 205 |
| Year 2 | 0.67 | $ 307 | $ 205 | 199 | 191 |
| Year 3 | 0.67 | $ 307 | $ 205 | 193 | 179 |
| Year 4 | 0.67 | $ 307 | $ 205 | 187 | 167 |
| Year 5 | 0.67 | $ 307 | $ 205 | 182 | 156 |
| Year 6 | 0.67 | $ 307 | $ 205 | 177 | 146 |
| Year 7 | 0.67 | $ 307 | $ 205 | 171 | 136 |
| Year 8 | 0.67 | $ 307 | $ 205 | 166 | 128 |
| Year 9 | 0.67 | $ 307 | $ 205 | 162 | 119 |
| Year 10 | 0.67 | $ 307 | $ 205 | 157 | 111 |
| TOTAL | $ 6.67 | $ 3,072 | $ 2,048 | $ 1,799 | $ 1,539 |

Applying this cost to the estimated frequency of occurrence of 0.67 waivers per year and extending the avoided costs over a ten-year period would project a total undiscounted cost savings of $2,048. The ten-year total would equate to $1,799 and $1,539, when discounted at three percent and seven percent respectively.

3. Alternatives Considered

Given that this rule has no direct compliance costs, no less burdensome alternatives to the proposed rule are available. In the absence of this proposed rule, stakeholders would continue to experience the negative repercussions of inconsistences between the statutes, regulations, and agency policy documents.

FEMA invites all interested parties to submit data and information regarding the potential economic impact that would result from adoption of the proposals in this NPRM. FEMA will consider all comments received in the public comment process.

4. Summary

For the 10-year period analyzed, FEMA does not anticipate any costs resulting from the selected provisions of BW–12 and HFIAA that the rule is implementing. During that same period analyzed, the estimated quantified benefits total $2,048. The present value, discounted at 7 percent, of the estimated quantified benefits is approximately $1,539 and $1,799 discounted at 3 percent. FEMA's ability to administer the NFIP in a more streamlined manner, and the public's enhanced understanding of the terms and conditions of the program would justify the proposed rule, compliant with the respective Congressional mandates.

*B. Regulatory Flexibility Act*

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires agency review of proposed and final rules to assess their impact on small entities. When an agency is required by 5 U.S.C. 553, or any other law, to publish a general notice of proposed rulemaking for any proposed rule, the agency must prepare an initial regulatory flexibility analysis (IRFA) or have the head of the agency certify pursuant to 5 U.S.C. 605(b) that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. FEMA believes this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. However, FEMA is publishing this IRFA to aid the public in commenting on the potential impacts of the proposed requirements in this NPRM on small entities. FEMA invites all interested parties to submit data and information regarding the potential economic impact on small entities that would result from the adoption of this NPRM. FEMA will consider all comments received in the public comment process when making a final determination.

In accordance with the Regulatory Flexibility Act, an IFRA must contain: (1) A description of the reasons why the action by the agency is being considered; (2) A succinct statement of the objectives of, and legal basis for, the proposed rule; (3) A description—and, where feasible, an estimate of the number—of small entities to which the proposed rule will apply; (4) A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the types of professional skills necessary for preparation of the report or record; (5) An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule; and (6) A description of significant alternatives to the rule.

1. A Description of the Reasons Why Action by the Agency Is Being Considered

The proposed rule would revise the NFIP implementing regulations at parts 59, 61, and 62, as well as the Appendices to part 61, to codify in regulation certain provisions of the Biggert-Waters Flood Insurance Reform Act of 2012 and the Homeowner Flood Insurance Affordability Act of 2014 that FEMA has already implemented and to clarify certain existing NFIP rules relating to NFIP operations and the SFIP.

2. A Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The proposed changes to the regulation would codify FEMA's implementation of the legislative requirements of the Biggert-Waters Flood Insurance Reform Act of 2012 and the Homeowner Flood Insurance Affordability Act of 2014, and clarify existing rules. These required changes have already been implemented and this rule would conform NFIP regulations with existing policies and practices.

FEMA anticipates that this rulemaking will result in a more streamlined operation of the NFIP and enhance customer service because of greater information and clarity for policyholders and all stakeholders.

The NFIA authorizes FEMA to ''enter into any contracts, agreements, or other arrangements'' with private insurance companies to utilize their facilities and services in administering the NFIP, and on such terms and conditions as may be agreed upon. *See* 42 U.S.C. 4081. Pursuant to this authority, FEMA enters into a standard Financial Assistance/Subsidy Arrangement with private sector property insurers, also known as the WYO companies. Under this

arrangement, WYO companies sell NFIP flood insurance policies under their own names and adjust and pay claims arising under the policy. It is in reference to these specific authorities to administer the NFIP, and the WYO program that is encompassed within it, that FEMA is proposing to continue to streamline operations and remove confusing obsolete or redundant language that may confuse stakeholders, including its policyholders, the WYO companies, and FEMA.

3. A Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

''Small entity'' is defined in 5 U.S.C. 601. The term ''small entity'' can have the same meaning as the terms ''small business,'' ''small organization'' and ''small governmental jurisdiction.'' Section 601(3) defines a ''small business'' as having the same meaning as ''small business concern'' under Section 3 of the Small Business Act. This includes any small business concern that is independently owned and operated, and is not dominant in its field of operation. Section 601(4) defines a ''small organization'' as any not-for-profit enterprises that are independently owned and operated, and are not dominant in their field of operation. Section 601(5) defines ''small governmental jurisdictions'' as governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000. No small organization or governmental jurisdiction is a party to the WYO program and therefore would be affected.

The SBA stipulates in its size standards the largest business may be and still be classified as a ''small entity.'' [15] The small business size standard for North American Industry Classification System (NAICS) code 524126 (direct property and casualty insurance carriers) is 1,500 employees. The size standard for 524210 (Insurance Agencies and Brokerages) is $7.5 million, and $32.5 million for 524292 (Third Party Administration of Insurance and Pension Funds). For the two remaining applicable codes of 524113 (Direct Life Insurance Carriers), and 524128 (Other Direct Insurance), the threshold is $38.5 million in revenue as modified by the SBA, effective October 1, 2017.

There are currently 67 companies [16] participating in the WYO Program. These 67 companies are subject to the terms of the Arrangement and the standards and requirements in the Financial Control Plan. FEMA researched each WYO company to determine the NAICS code, number of employees, and revenue for the individual companies. FEMA used the open-access database, *www.manta.com,* as well as *www.cortera.com* to find this information for the size determination. The database was used to help determine the metric of company size, compliant with the SBA thresholds based on the assigned NAICS code. Of the 67 WYO companies, we found a majority of 46 firms were under code 524210 (Insurance Agencies and Brokerages), of which 17 firms, or 37 percent, were small (with only one lacking full data but presumed to be small). The second largest contingent of 16 firms were under 524126 (direct property and casualty insurance carriers), of which 10 firms, or 63 percent, were small (with only one missing data points but presumed to be small). Of the other three aforementioned industry codes, 524113, 524292 and 524128, there was one firm under each and none were small. Finally, two firms were missing industry classifications, and FEMA assumes these are small firms. In total, we found that 29 of the 67 companies are below this maximum, and therefore would be considered small entities. Consequently, small entities comprise 43 percent of participating companies.

4. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Types of Professional Skills Necessary for Preparation of the Report or Record

FEMA believes that the rule would impose no burdens on any participating company because it does not consist of any substantive policy changes, but instead would make changes for clarity and to accurately reflect current FEMA policies and practices. There may be familiarization costs incurred by WYO companies as they review these changes, despite the lack of any substantive changes that would ultimately affect them. Therefore, FEMA anticipates that the rule would not have a significant economic impact on a substantial number of small entities.

5. An Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

There are no relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

6. A Description of Any Significant Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

Given that this rule has no direct compliance costs, no less burdensome alternatives to the proposed rule are available. In the absence of this proposed rule, small entities would continue to experience the negative repercussions of inconsistences between the statutes, regulations and agency policy documents.

FEMA invites all interested parties to submit data and information regarding the potential economic impact that would result from adoption of the proposals in this NPRM. FEMA will consider all comments received in the public comment process.

*C. Unfunded Mandates Reform Act*

Pursuant to section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that ''before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement'' detailing the effect on State, local, and Tribal governments and the private sector. The proposed rule would not result in such an expenditure, and thus preparation of such a statement is not required.

[15] U.S. Small Business Administration Table of Small Business Size Standards Matched to North American Industry Classification System Codes effective October 1, 2017. Available at *https://www.sba.gov/content/small-business-size-standards.*

[16] Number of firms participating in the WYO Program as of May 2018. *https://www.fema.gov/wyo_company.*

*D. National Environmental Policy Act of 1969 (NEPA)*

Section 102 of the National Environmental Policy Act of 1969 (NEPA), 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*) requires agencies to consider the impacts of their proposed actions on the quality of the human environment. The Council on Environmental Quality's procedures for implementing NEPA, 40 CFR 1500 *et seq.,* require Federal agencies to prepare Environmental Impact Statements (EIS) for major Federal actions significantly affecting the quality of the human environment. Each agency can develop categorical exclusions to cover actions that have been demonstrated to not typically trigger significant impacts to the human environment individually or cumulatively. Agencies develop environmental assessments (EA) to evaluate those actions that do not fit an agency's categorical exclusion and for which the need for an EIS is not readily apparent. At the end of the EA process, the agency will determine whether to make a Finding of No Significant Impact (FONSI) or whether to initiate the EIS process.

Rulemaking is a major Federal action subject to NEPA. The List of exclusion categories at DHS Instruction Manual 023–01–001–01, Appendix A excludes the promulgation of rules that are of a strictly administrative or procedural nature and rules that implement, without substantive change, statutory or regulatory requirements from the preparation of an EA or EIS. (Catex A3(a) and (b)). The purpose of this rule is to implement some statutory requirements of BW–12 and HFIAA, along with making non-substantive clarifications designed to improve overall clarity and readability. These changes are administrative-related changes that are categorically excluded under Catex A3(a) and (b) of DHS Instruction Manual 023–01–001–01, Appendix A. No extraordinary circumstances exist that will trigger the need to develop an EA or EIS. *See* DHS Instruction Manual 023–01–001–01 V(B)(2). An EA will not be prepared because a categorical exclusion applies to this rulemaking action and no extraordinary circumstances exist.

*E. Privacy Act/E-Government Act*

Under the Privacy Act of 1974, 5 U.S.C. 552a, an agency must determine whether implementation of a proposed regulation will result in a system of records. A ''record'' is any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his/her education, financial transactions, medical history, and criminal or employment history and that contains his/her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. *See* 5 U.S.C. 552a(a)(4). A ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbols, or other identifying particular assigned to the individual. An agency cannot disclose any record that is contained in a system of records except by following specific procedures. The E-Government Act of 2002, 44 U.S.C. 3501 note, also requires specific procedures when an agency takes action to develop or procure information technology that collects, maintains, or disseminates information that is in an identifiable form. This Act also applies when an agency initiates a new collection of information that will be collected, maintained, or disseminated using information technology if it includes any information in an identifiable form permitting the physical or online contacting of a specific individual.

In accordance with DHS policy, FEMA has completed a Privacy Threshold Analysis (PTA) for this proposed rule. DHS/FEMA has determined that this proposed rulemaking does not affect the 1660–0006 OMB Control Number's current compliance with the E-Government Act of 2002 or the Privacy Ac of 1974, as amended. As a result, DHS/FEMA has concluded that the 1660–0006 OMB Control Number is covered by the DHS/FEMA/PIA–011—National Flood Insurance Program Information Technology Systems (NFIP ITS) Privacy Impact Assessment (PIA). Additionally, DHS/FEMA has decided that the 1660–0006 OMB Control Number is covered by the DHS/FEMA–003 National Flood Insurance Program Files, 79 FR 28747, May 19, 2014 System of Records Notice (SORN).

*F. Paperwork Reduction Act of 1995*

Under the Paperwork Reduction Act of 1995 (PRA), as amended, 44 U.S.C. 3501–3520, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency obtains approval from the Office of Management and Budget (OMB) for the collection and the collection displays a valid OMB control number. *See* 44 U.S.C. 3506, 3507. This proposed rulemaking does not call for a new collection of information under the PRA. There is an existing collection of information, 1660–0006, the National Flood Insurance Program Policy Forms, Public Law 90–448 (1968) (expanded by Pub. L. 93–234 (1973)) included in this rulemaking. BW–12 and HFIAA require modifications to the NFIP. Program changes resulting from BW–12 and HFIAA necessitated revision of the NFIP Policy Forms to assure proper classification of properties for rating purposes and to rate and issue the policies in accordance with the provisions of BW–12 and HFIAA. However, this proposed rule will not impact this collection because the forms have already been updated as needed.

*G. Executive Order 13175 Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249 (Nov. 9, 2000), applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects 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. Under this Executive Order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government in complying with the regulation are provided by the Federal Government or the agency consults with Tribal officials. Nor, to the extent practicable by law, may an agency promulgate a regulation that has Tribal implications and preempts Tribal law, unless the agency consults with Tribal officials. This proposed rule involves no policies that have Tribal implications under Executive Order 13175. This rulemaking makes limited changes to the comprehensive, longstanding National Flood Insurance Program regulations applicable to communities, including participating Indian Tribal governments and Tribes, which voluntarily choose to participate in the program. Because these program updates are limited, they will not have substantial direct effects on Indian Tribes, on the relationship between the national government and Indian Tribes, or the distribution of power between the Federal Government and Indian Tribes.

*H. Executive Order 13132 Federalism*

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' For the purposes of this Executive Order, the term States also includes local governments or other subdivisions established by the States. Under this Executive Order, Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States. Further, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute, unless the Federal Government provides funds necessary to pay the direct costs incurred by the State and local governments in complying with the regulation, or the agency consults with State and local officials. Nor, to the extent practicable by law, may an agency promulgate a regulation that has federalism implications and preempts State law, unless the agency consults with State and local officials.

FEMA has reviewed this proposed rule under Executive Order 13132 and has determined that does 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, and therefore does not have federalism implications as defined by the Executive Order. This rulemaking makes limited changes to the comprehensive, longstanding National Flood Insurance Program regulations governing the communities' participation in the program. Because these program updates are limited, they will not have substantial direct effects on the States or participating communities, on the relationship between the national government and the States or participating communities, or the distribution of power among the various levels of government.

*I. Executive Order 11988 Floodplain Management*

Pursuant to Executive Order 11988, ''Floodplain Management,'' 42 FR 26951 (May 24, 1977), each agency must provide leadership and take action to reduce the risk of flood loss, to minimize the impact of floods on human safety, health and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for (1) acquiring, managing, and disposing of Federal lands and facilities; (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. In carrying out these responsibilities, each agency must evaluate the potential effects of any actions it may take in a floodplain; ensure that its planning programs and budget requests reflect consideration of flood hazards and floodplain management; and prescribe procedures to implement the policies and requirements of the Executive Order.

Before promulgating any regulation, an agency must determine whether the proposed regulations will affect a floodplain(s), and if so, the agency must consider alternatives to avoid adverse effects and incompatible development in the floodplain(s). If the head of the agency finds that the only practicable alternative consistent with the law and with the policy set forth in Executive Order 11988 is to promulgate a regulation that affects a floodplain(s), the agency must, prior to promulgating the regulation, design or modify the regulation in order to minimize potential harm to or within the floodplain, consistent with the agency's floodplain management regulations. It must also prepare and circulate a notice containing an explanation of why the action is proposed to be located in the floodplain.

The purpose of this proposed rule is to implement insurance-related administrative changes to clarify coverage, rates, and terms and conditions. The changes proposed in this rule would not have an effect on land use, floodplain management, or wetlands.

*J. Executive Order 11990 Protection of Wetlands*

Executive Order 11990, ''Protection of Wetlands,'' 42 FR 26961 (May 24, 1977) sets forth that each agency must provide leadership and take action to minimize the destruction, loss or degradation of wetlands, and to preserve and enhance the natural and beneficial values of wetlands in carrying out the agency's responsibilities. These responsibilities include (1) acquiring, managing, and disposing of Federal lands and facilities; and (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. Each agency, to the extent permitted by law, must avoid undertaking or providing assistance for new construction located in wetlands unless the head of the agency finds (1) that there is no practicable alternative to such construction, and (2) that the proposed action includes all practicable measures to minimize harm to wetlands which may result from such use. In making this finding, the head of the agency may take into account economic, environmental and other pertinent factors.

In carrying out the activities described in Executive Order 11990, each agency must consider factors relevant to a proposal's effect on the survival and quality of the wetlands. These include public health, safety, and welfare, including water supply, quality, recharge and discharge; pollution; flood and storm hazards; sediment and erosion; maintenance of natural systems, including conservation and long term productivity of existing flora and fauna, species and habitat diversity and stability, hydrologic utility, fish, wildlife, timber, and food and fiber resources. They also include other uses of wetlands in the public interest, including recreational, scientific, and cultural uses. The purpose of this proposed rule is to implement insurance-related administrative changes to clarify coverage, rates, and terms and conditions. The changes proposed in this rule would not have an effect on land use, floodplain management, or wetlands.

*K. Executive Order 12898 Environmental Justice*

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' 59 FR 7629 (Feb. 16, 1994), as amended by Executive Order 12948, 60 FR 6381, (Feb. 1, 1995), FEMA incorporates environmental justice into its policies and programs. The Executive Order requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in programs, denying

persons the benefits of programs, or subjecting persons to discrimination because of race, color, or national origin.

This rulemaking will not have a disproportionately high or adverse effect on human health or the environment, nor will it exclude persons from participation in FEMA programs, deny persons the benefits of FEMA programs, or subject persons to discrimination because of race, color, or national origin.

*L. Congressional Review of Agency Rulemaking*

Before a rule can take effect, the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801–808, requires the Federal agency promulgating the rule to submit to Congress and to the Government Accountability Office (GAO) a copy of the rule, a concise general statement relating to the rule, including whether it is a major rule, the proposed effective date of the rule, a copy of any cost-benefit analysis, descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act, and any other information or statements required by relevant Executive orders.

FEMA will send this rule to the Congress and to GAO pursuant to the CRA if the rule is finalized. This proposed rule is not a ''major rule'' within the meaning of the CRA. It will not have an annual effect on the economy of $100,000,000 or more or result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Nor will it have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

**List of Subjects**

*44 CFR Parts 59 and 61*

Flood insurance, Reporting and recordkeeping requirements.

*44 CFR Part 62*

Claims, Flood insurance, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, FEMA proposes to amend 44 CFR Chapter I as follows:

## PART 59—GENERAL PROVISIONS

■ 1. Revise authority citation for part 59 to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.*; 6 U.S.C. 101 *et seq.*

■ 2. In section 59.1, add definitions, in alphabetical order, for ''Condominium Building,'' ''Mixed Use Building,'' ''Multifamily Building,'' ''Non-Residential Building,'' ''Non-Residential Property,'' ''Other Residential Building,'' ''Other Residential Property,'' ''Residential Building,'' ''Residential Property,'' ''Single Family Dwelling,'' and ''Two to Four Family Building'' and revise the definitions for ''Act,'' ''Deductible,'' and ''Emergency Program'' to read as follows:

**§ 59.1 Definitions.**

* * * * *

*Act* means the statutes authorizing the National Flood Insurance Program that are incorporated in 42 U.S.C. 4001—*et seq.*

* * * * *

*Condominium Building* means a type of building in the form of ownership in which each unit owner has an undivided interest in common elements of the building.

* * * * *

*Deductible* means the amount of an insured loss that is the responsibility of the insured and that is incurred before any amounts are paid for the insured loss under the insurance policy.

* * * * *

*Emergency Program* means the initial phase of a community's participation in the National Flood Insurance Program, as prescribed by Section 1306 of the Act.

* * * * *

*Mixed Use Building* means a building that has both residential and non-residential uses.

* * * * *

*Multifamily Building* means an other residential building that is not a condominium building.

* * * * *

*Non-Residential Building* means a commercial or mixed-use building where the primary use is commercial or non-habitational.

*Non-Residential Property* means either a non-residential building, the contents within a non-residential building, or both.

* * * * *

*Other Residential Building* means a residential building that is designed for use as a residential space for 5 or more families or a mixed use building in which the total floor area devoted to non-residential uses is less than 25 percent of the total floor area within the building.

*Other Residential Property* means either an other residential building, the contents within an other residential building, or both.

* * * * *

*Residential Building* means a non-commercial building designed for habitation by one or more families or a mixed use building that qualifies as a single-family, two to four family, or other residential building.

*Residential Property* means either a residential building or the contents within a residential building, or both.

* * * * *

*Single Family Dwelling* means either (a) a residential single-family building in which the total floor area devoted to non-residential uses is less than 50 percent of the building's total floor area, or (b) a single-family residential unit within a two to four family building, other-residential building, business, or non-residential building, in which commercial uses within the unit are limited to less than 50 percent of the unit's total floor area.

* * * * *

*Two to Four Family Building* means a residential building, including an apartment building, containing two to four residential spaces and in which commercial uses are limited to less than 25 percent of the building's total floor area.

* * * * *

## PART 61—INSURANCE COVERAGE AND RATES

■ 3. Revise the authority citation for part 61 to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.*; 6 U.S.C. 101 *et seq.*

■ 4. Revise § 61.1 to read as follows:

**§ 61.1 Purpose of part.**

This part describes the types of properties eligible for flood insurance coverage under the Program, the limits of such coverage, and the premium rates actually to be paid by insureds.

■ 5. Revise § 61.3 to read as follows:

**§ 61.3 Coverage and benefits provided under the Standard Flood Insurance Policy.**

(a) Insurance coverage under the Program is available for buildings and their contents. Coverage for each may be purchased separately.

(b) In addition to building and contents coverage, the Dwelling Form of the Standard Flood Insurance Policy (SFIP) covers debris removal, loss avoidance measures, and condominium loss assessments. The General Property Form of the SFIP covers debris removal, loss avoidance measures, and pollution damage. The Residential Condominium Policy Form of the SFIP covers debris removal and loss avoidance measures.

(c) With the purchase of building coverage, the Standard Flood Insurance Policy covers the costs associated with bringing the building into compliance with local floodplain ordinances.

■ 6. Revise § 61.4 to read as follows:

**§ 61.4 Special terms and conditions.**

(a) No new flood insurance or renewal of flood insurance policies will be written for properties declared by a duly constituted State or local zoning or other authority to be in violation of any flood plain, mudslide (*i.e.,* mudflow), or flood-related erosion area management or control law, regulation, or ordinance.

(b) In order to reduce the administrative costs of the Program, of which the Federal Government pays a major share, applicants must pay the full policy premium at the time of application.

■ 7. Revise § 61.5 to read as follows:

**§ 61.5 Deductibles.**

FEMA must provide policyholders with deductible options in various amounts, up to and including $10,000, subject to the following minimum deductible amounts:

(a) The minimum deductible for policies covering pre-FIRM buildings charged less than full-risk rates with building coverage amounts less than or equal to $100,000 is $1,500.

(b) The minimum deductible for policies covering pre-FIRM buildings charged less than full-risk rates with building coverage amounts greater than $100,000 is $2,000.

(c) The minimum deductible for policies covering post-FIRM buildings and pre-FIRM buildings charged full risk rates, with building coverage amounts equal to or less than $100,000 is $1,000.

(d) The minimum deductible for policies covering post-FIRM buildings and pre-FIRM buildings charged full risk rates, with building coverage amounts greater than $100,000 is $1,250

■ 8. Revise § 61.6 to read as follows:

**§ 61.6 Maximum amounts of coverage available.**

(a) Pursuant to section 1306 of the Act, the following are the limits of coverage available under the emergency program and under the regular program.

MAXIMUM AMOUNTS OF COVERAGE AVAILABLE [1]

| Occupancy | Emergency program | Regular program |
|---|---|---|
| | Amount | Amount |
| Building Coverage: | | |
| Single Family Dwelling | * $35,000 | $250,000. |
| Two to Four Family Building | * 35,000 | $250,000. |
| Other Residential Building (including Multifamily Building) | ** 100,000 | $500,000. |
| Condominium Building | N/A | $250,000 times the number of units in the building. |
| Non-Residential Building | ** 100,000 | $500,000. |
| Contents Coverage: [2] | | |
| Residential Property [3] | 10,000 | 100,000. |
| Non-Residential Property | $100,000 | $500,000. |

[1] This Table provides the maximum coverage amounts available under the Emergency Program and the Regular Program, and the columns cannot be aggregated to exceed the limits in the Regular Program, which are established by statute. The aggregate limits for building coverage are the maximum coverage amounts allowed by statute for each building included in the relevant Occupancy Category.

[2] The policy limits for contents coverage are not per building. Although a single insured may not have more than one policy covering contents in a building, several insureds may have separate policies of up to the policy limits.

[3] The Residential Property occupancy category includes the Single Family Dwelling, Two to Four Family Building, Other Residential Building, and Condominium Building occupancies categories.

* In Alaska, Guam, Hawaii, and U.S. Virgin Islands, the amount available is $50,000.

** In Alaska, Guam, Hawaii, and U.S. Virgin Islands, the amount available is $150,000.

(b) Coverage and benefits payable under the SFIP pursuant to § 61.3(b) and § 61.3(c) are included in, not in addition to, the coverage limits provided by the Act or stated in paragraph (a) of this section.

■ 9. Add § 61.10 to read as follows:

**§ 61.10 Requirements for issuance or renewal of flood insurance coverage.**

FEMA will not issue or renew flood insurance unless FEMA receives:

(a) The full amount due (including applicable premiums, surcharges, and fees); and

(b) A complete application, including the information necessary to establish a premium rate for the policy, or submission of corrected or additional information necessary to calculate the premium for the renewal of the policy.

**§ 61.11 Effective date and time of coverage under the Standard Flood Insurance Policy—New Business Applications and Endorsements.**

■ 10. Amend § 61.11 by revising paragraphs (c) through (g) to read as follows:

* * * * *

(c) Where the following conditions are met, the effective date and time of any initial purchase of flood insurance coverage for any privately-owned property will be 12:01 a.m. (local time) on the first calendar day after the application date and the presentment of payment of premium or initial installment payment:

(1) The Administrator has determined that the property is affected by flooding on Federal land that is a result of, or is exacerbated by, post-wildfire conditions, after consultation with an authorized employee of the Federal agency that has jurisdiction of the land on which the wildfire that caused the post-wildfire conditions occurred; and

(2) The flood insurance coverage was purchased not later than 60 calendar days after the fire containment date, as determined by the appropriate Federal employee, relating to the wildfire that caused the post-wildfire conditions described in clause (1).

(d) Except as provided by paragraphs (a), (b), and (c) of this section, the effective date and time of any new policy or added coverage or increase in the amount of coverage will be 12:01 a.m. (local time) on the 30th calendar day after the application date and the presentment of payment of premium; for example, a flood insurance policy applied for with the payment of the premium on May 1 will become effective at 12:01 a.m. on May 31.

(e) Adding new coverage or increasing the amount of coverage in force is permitted during the term of any policy,

subject to any applicable waiting periods. The additional premium for any new coverage or increase in the amount of coverage will be calculated pro rata in accordance with the rates currently in force.

(f) With respect to any submission of an application in connection with new business, the payment by an insured to an agent or the issuance of premium payment by the agent does not constitute payment to the NFIP. Therefore, it is important that an application for flood insurance, as well as the full amount due, be mailed to the NFIP promptly in order to have the effective date of the coverage based on the application date plus the waiting period. If the application and the full amount due are received at the office of the NFIP within ten (10) calendar days from the date of application, the waiting period will be calculated from the date of application. Also, as an alternative, in those cases where the application and premium payment are mailed by certified mail within four (4) calendar days from the date of application, the waiting period will be calculated from the date of application even though the application and full amount due are received at the office of the NFIP after ten (10) calendar days following the date of application. Thus, if the application and premium payment are received after ten (10) calendar days from the date of the application or are not mailed by certified mail within four (4) calendar days from the date of application, the waiting period will be calculated from the date of receipt at the office of the NFIP. To determine the effective date of any coverage added by endorsement to a flood insurance policy already in effect, substitute the term *endorsement* for the term *application* in this paragraph (f).

(g) The rules set forth in paragraphs (a) through (f) of this section apply to Write Your Own (WYO) companies, except that agents must mail the premium payments and accompanying applications and endorsements to the WYO company and the WYO company must receive the applications and endorsements, rather than the NFIP.

**§ 61.13 Standard Flood Insurance Policy.**

■ 11. Amend § 61.13 by revising paragraphs (e) and (f) and adding paragraphs (g) and (h) to read as follows:

* * * * *

(e) *Authorized only under terms and conditions established by the Act and Regulation.* The Standard Flood Insurance Policy is authorized only under terms and conditions established by Federal statute, the program's regulations, the Federal Insurance Administrator's interpretations, and the express terms of the policy itself. Accordingly, representations regarding the extent and scope of coverage that are not consistent with Federal statute, the program's regulations, the Federal Insurance Administrator's interpretations, and the express terms of the policy itself, are void.

(f) *Agent acts only for policyholder.* The duly licensed property or casualty agent acts for the policyholder and does not act as agent for the Federal Government, the Federal Emergency Management Agency, the Write Your Own (WYO) program participating insurance company authorized by part 62 of this chapter, or the NFIP servicing agent.

(g) *Oral and written binders.* No oral binder or contract will be effective. No written binder will be effective unless issued with express authorization of the Federal Insurance Administrator.

(h) The Standard Flood Insurance Policy and endorsements may be issued by private sector Write Your Own (WYO) property insurance companies, based upon flood insurance applications and renewal forms, all of which instruments of flood insurance may bear the name, as Insurer, of the issuing WYO company. In the case of any Standard Flood Insurance Policy, and its related forms, issued by a WYO company, wherever the names ''Federal Emergency Management Agency'' and ''Federal Insurance and Mitigation Administration'' appear, a WYO company must substitute its own name therefor. Standard Flood Insurance Policies issued by WYO companies may be executed by the issuing WYO company as Insurer, in the place and stead of the Federal Insurance Administrator, but the risk of loss is borne by the National Flood Insurance Fund, not the WYO company.

■ 12. Revise Appendix A(1) to part 61 to read as follows:

## Appendix A(1) to Part 61

**Federal Emergency Management Agency, Federal Insurance and Mitigation Administration**

**Standard Flood Insurance Policy**

**Dwelling Form**

Please read the policy carefully. The flood insurance provided is subject to limitations, restrictions, and exclusions.

**I. Agreement**

A. This policy covers the following types of property only:

1. A one to four family residential building, not under a condominium form of ownership;

2. A single family dwelling unit in a condominium building; and

3. Personal property in a building.

B. The Federal Emergency Management Agency (FEMA) provides flood insurance under the terms of the National Flood Insurance Act of 1968 and its amendments, and Title 44 of the Code of Federal Regulations.

C. We will pay you for direct physical loss by or from flood to your insured property if you:

1. Have paid the full amount due (including applicable premiums, surcharges, and fees);

2. Comply with all terms and conditions of this policy; and

3. Have furnished accurate information and statements.

D. We have the right to review the information you give us at any time and revise your policy based on our review.

E. This policy insures only one building. If you own more than one building, coverage will apply to the single building specifically described in the Flood Insurance Application.

F. Subject to the exception in I.G below, multiple policies with building coverage cannot be issued to insure a single building to one insured or to different insureds, even if separate policies were issued through different NFIP insurers. Payment for damages may only be made under a single policy for building damages under Coverage A—Building Property.

G. A Dwelling Form policy with building coverage may be issued to a unit owner in a condominium building that is also insured under a Residential Condominium Building Association Policy (RCBAP). However, no more than $250,000 may be paid in combined benefits for a single unit under the Dwelling Form policy and the RCBAP. We will only pay for damage once. Items of damage paid for under an RCBAP cannot also be claimed under the Dwelling Form policy.

**II. Definitions**

A. In this policy, ''you'' and ''your'' refer to the named insured(s) shown on the Declarations Page of this policy and the spouse of the named insured, if a resident of the same household. Insured(s) also includes: Any mortgagee and loss payee named in the Application and Declarations Page, as well as any other mortgagee or loss payee determined to exist at the time of loss, in the order of precedence. ''We,'' ''us,'' and ''our'' refer to the insurer.

Some definitions are complex because they are provided as they appear in the law or regulations, or result from court cases.

B. *Flood,* as used in this flood insurance policy, means:

1. A general and temporary condition of partial or complete inundation of two or more acres of normally dry land area or of two or more properties (one of which is your property) from:

a. Overflow of inland or tidal waters,

b. Unusual and rapid accumulation or runoff of surface waters from any source,

c. Mudflow.

2. Collapse or subsidence of land along the shore of a lake or similar body of water as a result of erosion or undermining caused by waves or currents of water exceeding

anticipated cyclical levels that result in a flood as defined in B.1.a above.

C. The following are the other key definitions we use in this policy:

1. *Act.* The National Flood Insurance Act of 1968 and any amendments to it.

2. *Actual Cash Value.* The cost to replace an insured item of property at the time of loss, less the value of its physical depreciation.

3. *Application.* The statement made and signed by you or your agent in applying for this policy. The application gives information we use to determine the eligibility of the risk, the kind of policy to be issued, and the correct premium payment. The application is part of this flood insurance policy.

4. *Base Flood.* A flood having a one percent chance of being equaled or exceeded in any given year.

5. *Basement.* Any area of a building, including any sunken room or sunken portion of a room, having its floor below ground level on all sides.

6. *Building.*

a. A structure with two or more outside rigid walls and a fully secured roof that is affixed to a permanent site;

b. A manufactured home, also known as a mobile home, is a structure: built on a permanent chassis, transported to its site in one or more sections, and affixed to a permanent foundation); or

c. A travel trailer without wheels, built on a chassis and affixed to a permanent foundation, that is regulated under the community's floodplain management and building ordinances or laws.

*Building* does not mean a gas or liquid storage tank, shipping container, or a recreational vehicle, park trailer, or other similar vehicle, except as described in C.6.c above.

7. *Cancellation.* The ending of the insurance coverage provided by this policy before the expiration date.

8. *Condominium.* That form of ownership of one or more buildings in which each unit owner has an undivided interest in common elements.

9. *Condominium Association.* The entity made up of the unit owners responsible for the maintenance and operation of:

a. Common elements owned in undivided shares by unit owners; and

b. Other buildings in which the unit owners have use rights; where membership in the entity is a required condition of ownership.

10. *Condominium Building.* A type of building for which the form of ownership is one in which each unit owner has an undivided interest in common elements of the building.

11. *Declarations Page.* A computer-generated summary of information you provided in your application for insurance. The Declarations Page also describes the term of the policy, limits of coverage, and displays the premium and our name. The Declarations Page is a part of this flood insurance policy.

12. *Deductible.* The amount of an insured loss that is your responsibility and that is incurred by you before any amounts are paid for the insured loss under this policy.

13. *Described Location.* The location where the insured building(s) or personal property are found. The described location is shown on the Declarations Page.

14. *Direct Physical Loss By or From Flood.* Loss or damage to insured property, directly caused by a flood. There must be evidence of physical changes to the property.

15. *Dwelling.* A building designed for use as a residence for no more than four families or a single-family unit in a condominium building.

16. *Elevated Building.* A building that has no basement and that has its lowest elevated floor raised above ground level by foundation walls, shear walls, posts, piers, pilings, or columns.

17. *Emergency Program.* The initial phase of a community's participation in the National Flood Insurance Program. During this phase, only limited amounts of insurance are available under the Act and the regulations prescribed pursuant to the Act.

18. *Federal Policy Fee.* A flat rate charge you must pay on each new or renewal policy to defray certain administrative expenses incurred in carrying out the National Flood Insurance Program.

19. *Improvements.* Fixtures, alterations, installations, or additions comprising a part of the dwelling or apartment in which you reside.

20. *Mudflow.* A river of liquid and flowing mud on the surface of normally dry land areas, as when earth is carried by a current of water. Other earth movements, such as landslide, slope failure, or a saturated soil mass moving by liquidity down a slope, are not mudflows.

21. *National Flood Insurance Program (NFIP).* The program of flood insurance coverage and floodplain management administered under the Act and applicable Federal regulations in Title 44 of the Code of Federal Regulations, Subchapter B.

22. *Policy.* The entire written contract between you and us. It includes:

a. This printed form;

b. The application and Declarations Page;

c. Any endorsement(s) that may be issued; and

d. Any renewal certificate indicating that coverage has been instituted for a new policy and new policy term. Only one dwelling, which you specifically described in the application, may be insured under this policy.

23. *Pollutants.* Substances that include, but are not limited to, any solid, liquid, gaseous, or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals, and waste. ''Waste'' includes, but is not limited to, materials to be recycled, reconditioned, or reclaimed.

24. *Post-FIRM Building.* A building for which construction or substantial improvement occurred after December 31, 1974, or on or after the effective date of an initial Flood Insurance Rate Map (FIRM), whichever is later.

25. *Principal Residence.* The dwelling in which you or your spouse have lived for at least 80 percent of (a) the 365 days immediately preceding the time of loss; or (b) the period of ownership of you or your spouse, if either you or your spouse owned the dwelling for less than 365 days immediately preceding the time of loss.

26. *Probation Surcharge.* A flat charge you must pay on each new or renewal policy issued covering property in a community the NFIP has placed on probation under the provisions of 44 CFR 59.24.

27. *Regular Program.* The final phase of a community's participation in the National Flood Insurance Program. In this phase, a Flood Insurance Rate Map is in effect and full limits of coverage are available under the Act and the regulations prescribed pursuant to the Act.

28. *Special Flood Hazard Area (SFHA).* An area having special flood or mudflow, and/or flood-related erosion hazards, and shown on a Flood Hazard Boundary Map or Flood Insurance Rate Map as Zone A, AO, A1–A30, AE, A99, AH, AR, AR/A, AR/AE, AR/AH, AR/AO, AR/A1–A30, V1–V30, VE, or V.

29. *Unit.* A single-family residential space you own in a condominium building.

30. *Valued Policy.* A policy in which the insured and the insurer agree on the value of the property insured, that value being payable in the event of a total loss. The Standard Flood Insurance Policy is not a valued policy.

## III. Property Covered

### *A. Coverage A—Building Property*

We insure against direct physical loss by or from flood to:

1. The dwelling at the described location, or for a period of 45 days at another location as set forth in III.C.2.b, Property Removed to Safety.

2. Additions and extensions attached to and in contact with the dwelling by means of a rigid exterior wall, a solid load-bearing interior wall, a stairway, an elevated walkway, or a roof. At your option, additions and extensions connected by any of these methods may be separately insured. Additions and extensions attached to and in contact with the building by means of a common interior wall that is not a solid load-bearing wall are always considered part of the dwelling and cannot be separately insured.

3. A detached garage at the described location. Coverage is limited to no more than 10 percent of the limit of liability on the dwelling. Use of this insurance is at your option but reduces the building limit of liability. We do not cover any detached garage used or held for use for residential (*i.e.,* dwelling), business, or farming purposes.

4. Materials and supplies to be used for construction, alteration, or repair of the dwelling or a detached garage while the materials and supplies are stored in a fully enclosed building at the described location or on an adjacent property.

5. A building under construction, alteration, or repair at the described location.

a. If the structure is not yet walled or roofed as described in the definition for building (*see* II.B.6.a) then coverage applies:

(1) Only while such work is in progress; or

(2) If such work is halted, only for a period of up to 90 continuous days thereafter.

b. However, coverage does not apply until the building is walled and roofed if the

lowest floor, including the basement floor, of a non-elevated building or the lowest elevated floor of an elevated building is:

(1) Below the base flood elevation in Zones AH, AE, A1–A30, AR, AR/AE, AR/AH, AR/A1–A30, AR/A, AR/AO; or

(2) Below the base flood elevation adjusted to include the effect of wave action in Zones VE or V1–V30.

The lowest floor level is based on the bottom of the lowest horizontal structural member of the floor in Zones VE or V1–V30 or the top of the floor in Zones AH, AE, A1–A30, AR, AR/AE, AR/AH, AR/A1–A30, AR/A, and AR/AO.

6. A manufactured home or a travel trailer, as described in the II.C.6. If the manufactured home or travel trailer is in a special flood hazard area, it must be anchored in the following manner at the time of the loss:

a. By over-the-top or frame ties to ground anchors; or

b. In accordance with the manufacturer's specifications; or

c. In compliance with the community's floodplain management requirements unless it has been continuously insured by the NFIP at the same described location since September 30, 1982.

7. The following items of property which are insured under Coverage A only:

a. Awnings and canopies;

b. Blinds;

c. Built-in dishwashers;

d. Built-in microwave ovens;

e. Carpet permanently installed over unfinished flooring;

f. Central air conditioners;

g. Elevator equipment;

h. Fire sprinkler systems;

i. Walk-in freezers;

j. Furnaces and radiators;

k. Garbage disposal units;

l. Hot water heaters, including solar water heaters;

m. Light fixtures;

n. Outdoor antennas and aerials fastened to buildings;

o. Permanently installed cupboards, bookcases, cabinets, paneling, and wallpaper;

p. Plumbing fixtures;

q. Pumps and machinery for operating pumps;

r. Ranges, cooking stoves, and ovens;

s. Refrigerators; and

t. Wall mirrors, permanently installed.

8. Items of property below the lowest elevated floor of an elevated post-FIRM building located in Zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone. Coverage is limited to the following:

a. Any of the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:

(1) Central air conditioners;

(2) Cisterns and the water in them;

(3) Drywall for walls and ceilings in a basement and the cost of labor to nail it, unfinished and unfloated and not taped, to the framing;

(4) Electrical junction and circuit breaker boxes;

(5) Electrical outlets and switches;

(6) Elevators, dumbwaiters and related equipment, except for related equipment installed below the base flood elevation after September 30, 1987;

(7) Fuel tanks and the fuel in them;

(8) Furnaces and hot water heaters;

(9) Heat pumps;

(10) Nonflammable insulation in a basement;

(11) Pumps and tanks used in solar energy systems;

(12) Stairways and staircases attached to the building, not separated from it by elevated walkways;

(13) Sump pumps;

(14) Water softeners and the chemicals in them, water filters, and faucets installed as an integral part of the plumbing system;

(15) Well water tanks and pumps;

(16) Required utility connections for any item in this list; and

(17) Footings, foundations, posts, pilings, piers, or other foundation walls and anchorage systems required to support a building.

b. Clean-up.

*B. Coverage B—Personal Property*

1. If you have purchased personal property coverage, we insure against direct physical loss by or from flood to personal property inside a building at the described location, if:

a. The property is owned by you or your household family members; and

b. At your option, the property is owned by guests or servants.

2. Personal property is also insured for a period of 45 days at another location as set forth in III.C.2.b, Property Removed to Safety.

3. Personal property in a building that is not fully enclosed must be secured to prevent flotation out of the building. If the personal property does float out during a flood, it will be conclusively presumed that it was not reasonably secured. In that case, there is no coverage for such property.

4. Coverage for personal property includes the following property, subject to B.1 above, which is insured under Coverage B only:

a. Air conditioning units, portable or window type;

b. Carpets, not permanently installed, over unfinished flooring;

c. Carpets over finished flooring;

d. Clothes washers and dryers;

e. ''Cook-out'' grills;

f. Food freezers, other than walk-in, and food in any freezer; and

g. Portable microwave ovens and portable dishwashers.

5. Coverage for items of property below the lowest elevated floor of an elevated post-FIRM building located in Zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone, is limited to the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:

a. Air conditioning units, portable or window type;

b. Clothes washers and dryers; and

c. Food freezers, other than walk-in, and food in any freezer.

6. If you are a tenant and have insured personal property under Coverage B in this policy, we will cover such property, including your cooking stove or range and refrigerator. The policy will also cover improvements made or acquired solely at your expense in the dwelling or apartment in which you reside, but for not more than 10 percent of the limit of liability shown for personal property on the Declarations Page. Use of this insurance is at your option but reduces the personal property limit of liability.

7. If you are the owner of a unit and have insured personal property under Coverage B in this policy, we will also cover your interior walls, floor, and ceiling (not otherwise insured under a flood insurance policy purchased by your condominium association) for not more than 10 percent of the limit of liability shown for personal property on the Declarations Page. Use of this insurance is at your option but reduces the personal property limit of liability.

8. Special Limits. We will pay no more than $2,500 for any one loss to one or more of the following kinds of personal property:

a. Artwork, photographs, collectibles, or memorabilia, including but not limited to, porcelain or other figures, and sports cards;

b. Rare books or autographed items;

c. Jewelry, watches, precious and semi-precious stones, or articles of gold, silver, or platinum;

d. Furs or any article containing fur that represents its principal value; or

e. Personal property used in any business.

9. We will pay only for the functional value of antiques.

*C. Coverage C—Other Coverages*

1. *Debris Removal.*

a. We will pay the expense to remove non-owned debris that is on or in insured property and debris of insured property anywhere.

b. If you or a member of your household perform the removal work, the value of your work will be based on the Federal minimum wage.

c. This coverage does not increase the Coverage A or Coverage B limit of liability.

2. *Loss Avoidance Measures.*

a. Sandbags, Supplies, and Labor.

(1) We will pay up to $1,000 for costs you incur to protect the insured building from a flood or imminent danger of flood, for the following:

(a) Your reasonable expenses to buy:

(i) Sandbags, including sand to fill them;

(ii) Fill for temporary levees;

(iii) Pumps; and

(iv) Plastic sheeting and lumber used in connection with these items.

(b) The value of work, at the Federal minimum wage, that you or a member of your household perform.

(2) This coverage for Sandbags, Supplies and Labor only applies if damage to insured property by or from flood is imminent and the threat of flood damage is apparent enough to lead a person of common prudence to anticipate flood damage. One of the following must also occur:

(a) A general and temporary condition of flooding in the area near the described location must occur, even if the flood does not reach the building; or

(b) A legally authorized official must issue an evacuation order or other civil order for the community in which the building is located calling for measures to preserve life and property from the peril of flood.

This coverage does not increase the Coverage A or Coverage B limit of liability.

b. Property Removed to Safety.

(1) We will pay up to $1,000 for the reasonable expenses you incur to move insured property to a place other than the described location that contains the property in order to protect it from flood or the imminent danger of flood. Reasonable expenses include the value of work, at the Federal minimum wage, you or a member of your household perform.

(2) If you move insured property to a location other than the described location that contains the property, in order to protect it from flood or the imminent danger of flood, we will cover such property while at that location for a period of 45 consecutive days from the date you begin to move it there. The personal property that is moved must be placed in a fully enclosed building or otherwise reasonably protected from the elements.

(3) Any property removed, including a moveable home described in II.6.b and c, must be placed above ground level or outside of the special flood hazard area.

(4) This coverage does not increase the Coverage A or Coverage B limit of liability.

3. *Condominium Loss Assessments.*

a. Subject to III.C.3.b below, if this policy insures a condominium unit, we will pay, up to the Coverage A limit of liability, your share of loss assessments charged against you by the condominium association in accordance with the condominium association's articles of association, declarations and your deed.

The assessment must be made because of direct physical loss by or from flood during the policy term, to the unit or to the common elements of the NFIP insured condominium building in which this unit is located.

b. We will not pay any loss assessment:

(1) Charged against you and the condominium association by any governmental body;

(2) That results from a deductible under the insurance purchased by the condominium association insuring common elements;

(3) That results from a loss to personal property, including contents of a condominium building,

(4) In which the total payment combined under all policies exceeds the maximum amount of coverage available under the Act for a single unit in a condominium building where the unit is insured under both a Dwelling Policy and a RCBAP.

(5) On any item of damage that has already been paid under a RCBAP where a single unit in a condominium building is insured by both a Dwelling Policy and a RCBAP.

c. Condominium Loss Assessment coverage does not increase the Coverage A Limit of Liability and is subject to the maximum coverage limits available for a single family dwelling under the Act, payable between all policies issued and covering the unit, under the Act.

*D. Coverage D—Increased Cost of Compliance*

1. *General.*

This policy pays you to comply with a State or local floodplain management law or ordinance affecting repair or reconstruction of a building suffering flood damage. Compliance activities eligible for payment are: Elevation, floodproofing, relocation, or demolition (or any combination of these activities) of your building. Eligible floodproofing activities are limited to:

a. Non-residential buildings.

b. Residential buildings with basements that satisfy FEMA's standards published in the Code of Federal Regulations [44 CFR 60.6(b) or (c)].

2. *Limit of Liability.*

We will pay you up to $30,000 under this Coverage D—Increased Cost of Compliance, which only applies to policies with building coverage (Coverage A). Our payment of claims under Coverage D is in addition to the amount of coverage which you selected on the application and which appears on the Declarations Page. But the maximum you can collect under this policy for both Coverage A—Building Property and Coverage D—Increased Cost of Compliance cannot exceed the maximum permitted under the Act. We do not charge a separate deductible for a claim under Coverage D.

3. *Eligibility.*

a. A building covered under Coverage A—Building Property sustaining a loss caused by a flood as defined by this policy must:

(1) Be a ''repetitive loss building.'' A repetitive loss building is one that meets the following conditions:

(a) The building is insured by a contract of flood insurance issued under the NFIP.

(b) The building has suffered flood damage on two occasions during a 10-year period which ends on the date of the second loss.

(c) The cost to repair the flood damage, on average, equaled or exceeded 25 percent of the market value of the building at the time of each flood loss.

(d) In addition to the current claim, the NFIP must have paid the previous qualifying claim, and the State or community must have a cumulative, substantial damage provision or repetitive loss provision in its floodplain management law or ordinance being enforced against the building; or

(2) Be a building that has had flood damage in which the cost to repair equals or exceeds 50 percent of the market value of the building at the time of the flood. The State or community must have a substantial damage provision in its floodplain management law or ordinance being enforced against the building.

b. This Coverage D pays you to comply with State or local floodplain management laws or ordinances that meet the minimum standards of the National Flood Insurance Program found in the Code of Federal Regulations at 44 CFR 60.3. We pay for compliance activities that exceed those standards under these conditions:

(1) 3.a.1 above.

(2) Elevation or floodproofing in any risk zone to preliminary or advisory base flood elevations provided by FEMA which the State or local government has adopted and is enforcing for flood-damaged buildings in such areas. (This includes compliance activities in B, C, X, or D zones which are being changed to zones with base flood elevations. This also includes compliance activities in zones where base flood elevations are being increased, and a flood-damaged building must comply with the higher advisory base flood elevation.) Increased Cost of Compliance coverage does not apply to situations in B, C, X, or D zones where the community has derived its own elevations and is enforcing elevation or floodproofing requirements for flood-damaged buildings to elevations derived solely by the community.

(3) Elevation or floodproofing above the base flood elevation to meet State or local ''free-board'' requirements, *i.e.,* that a building must be elevated above the base flood elevation.

c. Under the minimum NFIP criteria at 44 CFR 60.3(b)(4), States and communities must require the elevation or floodproofing of buildings in unnumbered A zones to the base flood elevation where elevation data is obtained from a Federal, State, or other source. Such compliance activities are eligible for Coverage D.

d. Coverage D will pay for the incremental cost, after demolition or relocation, of elevating or floodproofing a building during its rebuilding at the same or another site to meet State or local floodplain management laws or ordinances, subject to Coverage D Exclusion 5.g below.

e. Coverage D will pay to bring a flood-damaged building into compliance with State or local floodplain management laws or ordinances even if the building had received a variance before the present loss from the applicable floodplain management requirements.

4. *Conditions.*

a. When a building insured under Coverage A—Building Property sustains a loss caused by a flood, our payment for the loss under this Coverage D will be for the increased cost to elevate, floodproof, relocate, or demolish (or any combination of these activities) caused by the enforcement of current State or local floodplain management ordinances or laws. Our payment for eligible demolition activities will be for the cost to demolish and clear the site of the building debris or a portion thereof caused by the enforcement of current State or local floodplain management ordinances or laws. Eligible activities for the cost of clearing the site will include those necessary to discontinue utility service to the site and ensure proper abandonment of on-site utilities.

b. When the building is repaired or rebuilt, it must be intended for the same occupancy as the present building unless otherwise required by current floodplain management ordinances or laws.

5. *Exclusions.*

Under this Coverage D (Increased Cost of Compliance), we will not pay for:

a. The cost to comply with any floodplain management law or ordinance in communities participating in the Emergency Program.

b. The cost associated with enforcement of any ordinance or law that requires any

insured or others to test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of pollutants.

c. The loss in value to any insured building due to the requirements of any ordinance or law.

d. The loss in residual value of the undamaged portion of a building demolished as a consequence of enforcement of any State or local floodplain management law or ordinance.

e. Any Increased Cost of Compliance under this Coverage D:

(1) Until the building is elevated, floodproofed, demolished, or relocated on the same or to another premises; and

(2) Unless the building is elevated, floodproofed, demolished, or relocated as soon as reasonably possible after the loss, not to exceed two years.

f. Any code upgrade requirements, *e.g.,* plumbing or electrical wiring, not specifically related to the State or local floodplain management law or ordinance.

g. Any compliance activities needed to bring additions or improvements made after the loss occurred into compliance with State or local floodplain management laws or ordinances.

h. Loss due to any ordinance or law that you were required to comply with before the current loss.

i. Any rebuilding activity to standards that do not meet the NFIP's minimum requirements. This includes any situation where the insured has received from the State or community a variance in connection with the current flood loss to rebuild the property to an elevation below the base flood elevation.

j. Increased Cost of Compliance for a garage or carport.

k. Any building insured under an NFIP Group Flood Insurance Policy.

l. Assessments made by a condominium association on individual condominium unit owners to pay increased costs of repairing commonly owned buildings after a flood in compliance with State or local floodplain management ordinances or laws.

6. *Other Provisions.*

a. Increased Cost of Compliance coverage will not be included in the calculation to determine whether coverage meets the 80 percent insurance-to-value requirement for replacement cost coverage as set forth in Art. VII.R (''Loss Settlement'') of this policy.

b. All other conditions and provisions of this policy apply.

**IV. Property Not Covered**

We do not insure any of the following:

1. Personal property not inside a building;

2. A building, and personal property in it, located entirely in, on, or over water or seaward of mean high tide if it was constructed or substantially improved after September 30, 1982;

3. Open structures, including a building used as a boathouse or any structure or building into which boats are floated, and personal property located in, on, or over water;

4. Recreational vehicles other than travel trailers described in the Definitions section (see II.B.6.c) whether affixed to a permanent foundation or on wheels;

5. Self-propelled vehicles or machines, including their parts and equipment. However, we do cover self-propelled vehicles or machines not licensed for use on public roads that are:

a. Used mainly to service the described location or

b. Designed and used to assist handicapped persons, while the vehicles or machines are inside a building at the described location;

6. Land, land values, lawns, trees, shrubs, plants, growing crops, or animals;

7. Accounts, bills, coins, currency, deeds, evidences of debt, medals, money, scrip, stored value cards, postage stamps, securities, bullion, manuscripts, or other valuable papers;

8. Underground structures and equipment, including wells, septic tanks, and septic systems;

9. Those portions of walks, walkways, decks, driveways, patios and other surfaces, all whether protected by a roof or not, located outside the perimeter, exterior walls of the insured building or the building in which the insured unit is located;

10. Containers, including related equipment, such as, but not limited to, tanks containing gases or liquids;

11. Buildings or units and all their contents if more than 49 percent of the actual cash value of the building is below ground, unless the lowest level is at or above the base flood elevation and is below ground by reason of earth having been used as insulation material in conjunction with energy efficient building techniques;

12. Fences, retaining walls, seawalls, bulkheads, wharves, piers, bridges, and docks;

13. Aircraft or watercraft, or their furnishings and equipment;

14. Hot tubs and spas that are not bathroom fixtures, and swimming pools, and their equipment, such as, but not limited to, heaters, filters, pumps, and pipes, wherever located;

15. Property not eligible for flood insurance pursuant to the provisions of the Coastal Barrier Resources Act and the Coastal Barrier Improvement Act and amendments to these Acts;

16. Personal property you own in common with other unit owners comprising the membership of a condominium association.

**V. Exclusions**

A. We only pay for direct physical loss by or from flood, which means that we do not pay you for:

1. Loss of revenue or profits;

2. Loss of access to the insured property or described location;

3. Loss of use of the insured property or described location;

4. Loss from interruption of business or production;

5. Any additional living expenses incurred while the insured building is being repaired or is unable to be occupied for any reason;

6. The cost of complying with any ordinance or law requiring or regulating the construction, demolition, remodeling, renovation, or repair of property, including removal of any resulting debris. This exclusion does not apply to any eligible activities we describe in Coverage D—Increased Cost of Compliance; or

7. Any other economic loss you suffer.

B. *Flood in Progress.* If this policy became effective as of the time of a loan closing, as provided by 44 CFR 61.11(b), we will not pay for a loss caused by a flood that is a continuation of a flood that existed prior to coverage becoming effective. In all other circumstances, we will not pay for a loss caused by a flood that is a continuation of a flood that existed on or before the day you submitted the application for coverage under this policy and the full amount due. We will determine the date of application using 44 CFR 61.11(f).

C. We do not insure for loss to property caused directly by earth movement even if the earth movement is caused by flood. Some examples of earth movement that we do not cover are:

1. Earthquake;

2. Landslide;

3. Land subsidence;

4. Sinkholes;

5. Destabilization or movement of land that results from accumulation of water in subsurface land area; or

6. Gradual erosion.

We do, however, pay for losses from mudflow and land subsidence as a result of erosion that are specifically insured under our definition of flood (*see* II.B.1.c and II.B.2).

D. We do not insure for direct physical loss caused directly or indirectly by any of the following:

1. The pressure or weight of ice;

2. Freezing or thawing;

3. Rain, snow, sleet, hail, or water spray;

4. Water, moisture, mildew, or mold damage that results primarily from any condition:

a. Substantially confined to the dwelling; or

b. That is within your control, including but not limited to:

(1) Design, structural, or mechanical defects;

(2) Failure, stoppage, or breakage of water or sewer lines, drains, pumps, fixtures, or equipment; or

(3) Failure to inspect and maintain the property after a flood recedes;

5. Water or water-borne material that:

a. Backs up through sewers or drains;

b. Discharges or overflows from a sump, sump pump or related equipment; or

c. Seeps or leaks on or through the insured property; unless there is a flood in the area and the flood is the proximate cause of the sewer or drain backup, sump pump discharge or overflow, or the seepage of water;

6. The pressure or weight of water unless there is a flood in the area and the flood is the proximate cause of the damage from the pressure or weight of water;

7. Power, heating, or cooling failure unless the failure results from direct physical loss by or from flood to power, heating, or cooling equipment on the described location;

8. Theft, fire, explosion, wind, or windstorm;

9. Anything you or any member of your household do or conspire to do to deliberately cause loss by flood; or

10. Alteration of the insured property that significantly increases the risk of flooding.

E. We do not insure for loss to any building or personal property located on land leased from the Federal Government, arising from or incident to the flooding of the land by the Federal Government, where the lease expressly holds the Federal Government harmless under flood insurance issued under any Federal Government program.

F. We do not pay for the testing for or monitoring of pollutants unless required by law or ordinance.

**VI. Deductibles**

A. When a loss is insured under this policy, we will pay only that part of the loss that exceeds your deductible amount, subject to the limit of liability that applies. The deductible amount is shown on the Declarations Page.

However, when a building under construction, alteration, or repair does not have at least two rigid exterior walls and a fully secured roof at the time of loss, your deductible amount will be two times the deductible that would otherwise apply to a completed building.

B. In each loss from flood, separate deductibles apply to the building and personal property insured by this policy.

C. The deductible does NOT apply to:

1. III.C.2. Loss Avoidance Measures;

2. III.C.3. Condominium Loss Assessments; or

3. III.D. Increased Cost of Compliance.

**VII. General Conditions**

*A. Pair and Set Clause*

In case of loss to an article that is part of a pair or set, we will have the option of paying you:

1. An amount equal to the cost of replacing the lost, damaged, or destroyed article, minus its depreciation, or

2. The amount that represents the fair proportion of the total value of the pair or set that the lost, damaged, or destroyed article bears to the pair or set.

*B. Other Insurance*

1. If a loss insured by this policy is also insured by other insurance that includes flood coverage not issued under the Act, we will not pay more than the amount of insurance you are entitled to for lost, damaged, or destroyed property insured under this policy subject to the following:

a. We will pay only the proportion of the loss that the amount of insurance that applies under this policy bears to the total amount of insurance covering the loss, unless VII.B.1.b or c immediately below applies.

b. If the other policy has a provision stating that it is excess insurance, this policy will be primary.

c. This policy will be primary (but subject to its own deductible) up to the deductible in the other flood policy (except another policy as described in VII.B.1.b above). When the other deductible amount is reached, this policy will participate in the same proportion that the amount of insurance under this policy bears to the total amount of both policies, for the remainder of the loss.

2. If there is other insurance issued under the Act in the name of your condominium association covering the same property insured by this policy, then this policy will be in excess over the other insurance, except where a condominium loss assessment to the unit owner results from a loss sustained by the condominium association that was not reimbursed under a flood insurance policy written in the name of the association under the Act because the building was not, at the time of loss, insured for an amount equal to the lesser of:

a. 80 percent or more of its full replacement cost; or

b. The maximum amount of insurance permitted under the Act;

The combined coverage payment under the other NFIP insurance and this policy cannot exceed the maximum coverage available under the Act, of $250,000 per single unit.

*C. Amendments, Waivers, Assignment*

This policy cannot be changed, nor can any of its provisions be waived, without the express written consent of the Federal Insurance Administrator. No action we take under the terms of this policy constitutes a waiver of any of our rights. You may assign this policy in writing when you transfer title of your property to someone else except under these conditions:

a. When this policy insures only personal property; or

b. When this policy insures a building under construction.

*D. Insufficient Premium or Rating Information*

1. Applicability. The following provisions apply to all instances where the premium paid on this policy is insufficient or where the rating information is insufficient, such as where an Elevation Certificate is not provided.

2. Reforming the Policy with Reduced Coverage. Except as otherwise provided in VII.D.1, if the premium we received from you was not sufficient to buy the kinds and amounts of coverage you requested, we will provide only the kinds and amounts of coverage that can be purchased for the premium payment we received.

a. For the purpose of determining whether your premium payment is sufficient to buy the kinds and amounts of coverage you requested, we will first deduct the costs of all applicable fees and surcharges.

b. If the amount paid, after deducting the costs of all applicable fees and surcharges, is not sufficient to buy any amount of coverage, your payment will be refunded. Unless the policy is reformed to increase the coverage amount to the amount originally requested pursuant to VII.D.3, this policy will be cancelled, and no claims will be paid under this policy.

c. Coverage limits on the reformed policy will be based upon the amount of premium submitted per type of coverage, but will not exceed the amount originally requested.

3. Discovery of Insufficient Premium or Rating Information. If we discover that your premium payment was not sufficient to buy the requested amount of coverage, the policy will be reformed as described in VII.D.2. You have the option of increasing the amount of coverage resulting from this reformation to the amount you requested as follows:

a. Insufficient Premium. If we discover that your premium payment was not sufficient to buy the requested amount of coverage, we will send you, and any mortgagee or trustee known to us, a bill for the required additional premium for the current policy term (or that portion of the current policy term following any endorsement changing the amount of coverage). If it is discovered that the initial amount charged to you for any fees or surcharges is incorrect, the difference will be added or deducted, as applicable, to the total amount in this bill.

(1) If you or the mortgagee or trustee pays the additional premium amount due within 30 days from the date of our bill, we will reform the policy to increase the amount of coverage to the originally requested amount, effective to the beginning of the current policy term (or subsequent date of any endorsement changing the amount of coverage).

(2) If you or the mortgagee or trustee do not pay the additional amount due within 30 days of the date of our bill, any flood insurance claim will be settled based on the reduced amount of coverage.

(3) As applicable, you have the option of paying all or part of the amount due out of a claim payment based on the originally requested amount of coverage.

b. Insufficient Rating Information. If we determine that the rating information we have is insufficient and prevents us from calculating the additional premium, we will ask you to send the required information. You must submit the information within 60 days of our request.

(1) If we receive the information within 60 days of our request, we will determine the amount of additional premium for the current policy term, and follow the procedure in VII.D.3.a above.

(2) If we do not receive the information within 60 days of our request, no claims will be paid until the requested information is provided. Coverage will be limited to the amount of coverage that can be purchased for the payments we received, as determined when the requested information is provided.

4. Coverage Increases. If we do not receive the amounts requested in VII.D.3.a or the additional information requested in VII.D.3.b by the date it is due, the amount of coverage under this policy can only be increased by endorsement subject to the appropriate waiting period. However, no coverage increases will be allowed until you have provided the information requested in VII.D.3.b.

5. Falsifying Information. However, if we find that you or your agent intentionally did not tell us, or falsified any important fact or circumstance or did anything fraudulent relating to this insurance, the provisions of VIII.A apply.

*E. Policy Renewal*

1. This policy will expire at 12:01 a.m. on the last day of the policy term.

2. We must receive the payment of the appropriate renewal premium within 30 days of the expiration date.

3. If we find, however, that we did not place your renewal notice into the U.S. Postal Service, or if we did mail it, we made a mistake, *e.g.,* we used an incorrect, incomplete, or illegible address, which delayed its delivery to you before the due date for the renewal premium, then we will follow these procedures:

a. If you or your agent notified us, not later than one year after the date on which the payment of the renewal premium was due, of non-receipt of a renewal notice before the due date for the renewal premium, and we determine that the circumstances in the preceding paragraph apply, we will mail a second bill providing a revised due date, which will be 30 days after the date on which the bill is mailed.

b. If we do not receive the premium requested in the second bill by the revised due date, then we will not renew the policy. In that case, the policy will remain an expired policy as of the expiration date shown on the Declarations Page.

4. In connection with the renewal of this policy, we may ask you during the policy term to recertify, on a Recertification Questionnaire we will provide to you, the rating information used to rate your most recent application for or renewal of insurance.

*F. Conditions Suspending or Restricting Insurance*

We are not liable for loss that occurs while there is a hazard that is increased by any means within your control or knowledge.

*G. Requirements in Case of Loss*

In case of a flood loss to insured property, you must:

1. Give prompt written notice to us;

2. As soon as reasonably possible, separate the damaged and undamaged property, putting it in the best possible order so that we may examine it;

3. Prepare an inventory of damaged property showing the quantity, description, actual cash value, and amount of loss. Attach all bills, receipts, and related documents;

4. Within 60 days after the loss, send us a proof of loss, which is your statement of the amount you are claiming under the policy signed and sworn to by you, and which furnishes us with the following information:

a. The date and time of loss;

b. A brief explanation of how the loss happened;

c. Your interest (for example, ''owner'') and the interest, if any, of others in the damaged property;

d. Details of any other insurance that may cover the loss;

e. Changes in title or occupancy of the insured property during the term of the policy;

f. Specifications of damaged buildings and detailed repair estimates;

g. Names of mortgagees or anyone else having a lien, charge, or claim against the insured property;

h. Details about who occupied any insured building at the time of loss and for what purpose; and

i. The inventory of damaged personal property described in G.3 above.

5. In completing the proof of loss, you must use your own judgment concerning the amount of loss and justify that amount.

6. You must cooperate with the adjuster or representative in the investigation of the claim.

7. The insurance adjuster whom we hire to investigate your claim may furnish you with a proof of loss form, and she or he may help you complete it. However, this is a matter of courtesy only, and you must still send us a proof of loss within 60 days after the loss even if the adjuster does not furnish the form or help you complete it.

8. We have not authorized the adjuster to approve or disapprove claims or to tell you whether we will approve your claim.

9. At our option, we may accept the adjuster's report of the loss instead of your proof of loss. The adjuster's report will include information about your loss and the damages you sustained. You must sign the adjuster's report. At our option, we may require you to swear to the report.

*H. Our Options After a Loss*

Options we may, in our sole discretion, exercise after loss include the following:

1. At such reasonable times and places that we may designate, you must:

a. Show us or our representative the damaged property;

b. Submit to examination under oath, while not in the presence of another insured, and sign the same; and

c. Permit us to examine and make extracts and copies of:

(1) Any policies of property insurance insuring you against loss and the deed establishing your ownership of the insured real property;

(2) Condominium association documents including the Declarations of the condominium, its Articles of Association or Incorporation, Bylaws, rules and regulations, and other relevant documents if you are a unit owner in a condominium building; and

(3) All books of accounts, bills, invoices and other vouchers, or certified copies pertaining to the damaged property if the originals are lost.

2. We may request, in writing, that you furnish us with a complete inventory of the lost, damaged or destroyed property, including:

a. Quantities and costs;

b. Actual cash values or replacement cost (whichever is appropriate);

c. Amounts of loss claimed;

d. Any written plans and specifications for repair of the damaged property that you can reasonably make available to us; and

e. Evidence that prior flood damage has been repaired.

3. If we give you written notice within 30 days after we receive your signed, sworn proof of loss, we may:

a. Repair, rebuild, or replace any part of the lost, damaged, or destroyed property with material or property of like kind and quality or its functional equivalent; and

b. Take all or any part of the damaged property at the value that we agree upon or its appraised value.

*I. No Benefit to Bailee*

No person or organization, other than you, having custody of insured property will benefit from this insurance.

*J. Loss Payment*

1. We will adjust all losses with you. We will pay you unless some other person or entity is named in the policy or is legally entitled to receive payment. Loss will be payable 60 days after we receive your proof of loss (or within 90 days after the insurance adjuster files the adjuster's report signed and sworn to by you in lieu of a proof of loss) and:

a. We reach an agreement with you;

b. There is an entry of a final judgment; or

c. There is a filing of an appraisal award with us, as provided in VII.M.

2. If we reject your proof of loss in whole or in part you may:

a. Accept our denial of your claim;

b. Exercise your rights under this policy; or

c. File an amended proof of loss as long as it is filed within 60 days of the date of the loss.

*K. Abandonment*

You may not abandon to us damaged or undamaged property insured under this policy.

*L. Salvage*

We may permit you to keep damaged property insured under this policy after a loss, and we will reduce the amount of the loss proceeds payable to you under the policy by the value of the salvage.

*M. Appraisal*

If you and we fail to agree on the actual cash value or, if applicable, replacement cost of your damaged property to settle upon the amount of loss, then either may demand an appraisal of the loss. In this event, you and we will each choose a competent and impartial appraiser within 20 days after receiving a written request from the other. The two appraisers will choose an umpire. If they cannot agree upon an umpire within 15 days, you or we may request that the choice be made by a judge of a court of record in the state where the insured property is located. The appraisers will separately state the actual cash value, the replacement cost, and the amount of loss to each item. If the appraisers submit a written report of an agreement to us, the amount agreed upon will be the amount of loss. If they fail to agree, they will submit their differences to the umpire. A decision agreed to by any two will set the amount of actual cash value and loss, or if it applies, the replacement cost and loss.

Each party will:

1. Pay its own appraiser; and

2. Bear the other expenses of the appraisal and umpire equally.

*N. Mortgage Clause*

1. The word ''mortgagee'' includes trustee.

2. Any loss payable under Coverage A—Building Property will be paid to any mortgagee of whom we have actual notice, as well as any other mortgagee or loss payee determined to exist at the time of loss, and

you, as interests appear. If more than one mortgagee is named, the order of payment will be the same as the order of precedence of the mortgages.

3. If we deny your claim, that denial will not apply to a valid claim of the mortgagee, if the mortgagee:

a. Notifies us of any change in the ownership or occupancy, or substantial change in risk of which the mortgagee is aware;

b. Pays any premium due under this policy on demand if you have neglected to pay the premium; and

c. Submits a signed, sworn proof of loss within 60 days after receiving notice from us of your failure to do so.

4. All of the terms of this policy apply to the mortgagee.

5. The mortgagee has the right to receive loss payment even if the mortgagee has started foreclosure or similar action on the building.

6. If we decide to cancel or not renew this policy, it will continue in effect for the benefit of the mortgagee only for 30 days after we notify the mortgagee of the cancellation or non-renewal.

7. If we pay the mortgagee for any loss and deny payment to you, we are subrogated to all the rights of the mortgagee granted under the mortgage on the property. Subrogation will not impair the right of the mortgagee to recover the full amount of the mortgagee's claim.

*O. Suit Against Us*

You may not sue us to recover money under this policy unless you have complied with all the requirements of the policy. If you do sue, you must start the suit within one year after the date of the written denial of all or part of the claim, and you must file the suit in the United States District Court of the district in which the insured property was located at the time of loss. This requirement applies to any claim that you may have under this policy and to any dispute that you may have arising out of the handling of any claim under the policy.

*P. Subrogation*

Whenever we make a payment for a loss under this policy, we are subrogated to your right to recover for that loss from any other person. That means that your right to recover for a loss that was partly or totally caused by someone else is automatically transferred to us, to the extent that we have paid you for the loss. We may require you to acknowledge this transfer in writing. After the loss, you may not give up our right to recover this money or do anything that would prevent us from recovering it. If you make any claim against any person who caused your loss and recover any money, you must pay us back first before you may keep any of that money.

*Q. Continuous Lake Flooding*

1. If an insured building has been flooded by rising lake waters continuously for 90 days or more and it appears reasonably certain that a continuation of this flooding will result in an insured loss to the insured building equal to or greater than the building policy limits plus the deductible or the maximum payable under the policy for any one building loss, we will pay you the lesser of these two amounts without waiting for the further damage to occur if you sign a release agreeing:

a. To make no further claim under this policy;

b. Not to seek renewal of this policy;

c. Not to apply for any flood insurance under the Act for property at the described location;

d. Not to seek a premium refund for current or prior terms.

If the policy term ends before the insured building has been flooded continuously for 90 days, the provisions of this paragraph Q.1 will apply when the insured building suffers a covered loss before the policy term ends.

2. If your insured building is subject to continuous lake flooding from a closed basin lake, you may elect to file a claim under either paragraph Q.1 above or Q.2 (A ''closed basin lake'' is a natural lake from which water leaves primarily through evaporation and whose surface area now exceeds or has exceeded one square mile at any time in the recorded past. Most of the nation's closed basin lakes are in the western half of the United States where annual evaporation exceeds annual precipitation and where lake levels and surface areas are subject to considerable fluctuation due to wide variations in the climate. These lakes may overtop their basins on rare occasions.) Under this paragraph Q.2, we will pay your claim as if the building is a total loss even though it has not been continuously inundated for 90 days, subject to the following conditions:

a. Lake floodwaters must damage or imminently threaten to damage your building.

b. Before approval of your claim, you must:

(1) Agree to a claim payment that reflects your buying back the salvage on a negotiated basis; and

(2) Grant the conservation easement described in FEMA's ''Policy Guidance for Closed Basin Lakes'' to be recorded in the office of the local recorder of deeds. FEMA, in consultation with the community in which the property is located, will identify on a map an area or areas of special consideration (ASC) in which there is a potential for flood damage from continuous lake flooding. FEMA will give the community the agreed-upon map showing the ASC. This easement will only apply to that portion of the property in the ASC. It will allow certain agricultural and recreational uses of the land. The only structures it will allow on any portion of the property within the ASC are certain simple agricultural and recreational structures. If any of these allowable structures are insurable buildings under the NFIP and are insured under the NFIP, they will not be eligible for the benefits of this paragraph Q.2. If a U.S. Army Corps of Engineers certified flood control project or otherwise certified flood control project later protects the property, FEMA will, upon request, amend the ASC to remove areas protected by those projects. The restrictions of the easement will then no longer apply to any portion of the property removed from the ASC; and

(3) Comply with paragraphs Q.1.a through Q.1.d above.

c. Within 90 days of approval of your claim, you must move your building to a new location outside the ASC. FEMA will give you an additional 30 days to move if you show there is sufficient reason to extend the time.

d. Before the final payment of your claim, you must acquire an elevation certificate and a floodplain development permit from the local floodplain administrator for the new location of your building.

e. Before the approval of your claim, the community having jurisdiction over your building must:

(1) Adopt a permanent land use ordinance, or a temporary moratorium for a period not to exceed 6 months to be followed immediately by a permanent land use ordinance that is consistent with the provisions specified in the easement required in paragraph Q.2.b above.

(2) Agree to declare and report any violations of this ordinance to FEMA so that under Section 1316 of the National Flood Insurance Act of 1968, as amended, flood insurance to the building can be denied; and

(3) Agree to maintain as deed-restricted, for purposes compatible with open space or agricultural or recreational use only, any affected property the community acquires an interest in. These deed restrictions must be consistent with the provisions of paragraph Q.2.b above, except that, even if a certified project protects the property, the land use restrictions continue to apply if the property was acquired under the Hazard Mitigation Grant Program or the Flood Mitigation Assistance Program. If a non-profit land trust organization receives the property as a donation, that organization must maintain the property as deed-restricted, consistent with the provisions of paragraph Q2.b above.

f. Before the approval of your claim, the affected State must take all action set forth in FEMA's ''Policy Guidance for Closed Basin Lakes.''

g. You must have NFIP flood insurance coverage continuously in effect from a date established by FEMA until you file a claim under paragraph Q.2. If a subsequent owner buys NFIP insurance that goes into effect within 60 days of the date of transfer of title, any gap in coverage during that 60-day period will not be a violation of this continuous coverage requirement. For the purpose of honoring a claim under this paragraph Q.2, we will not consider to be in effect any increased coverage that became effective after the date established by FEMA. The exception to this is any in-creased coverage in the amount suggested by your insurer as an inflation adjustment.

h. This paragraph Q.2 will be in effect for a community when the FEMA Regional Administrator for the affected region provides to the community, in writing, the following:

(1) Confirmation that the community and the State are in compliance with the conditions in paragraphs Q.2.e and Q.2.f above, and

(2) The date by which you must have flood insurance in effect.

*R. Loss Settlement*

1. Introduction

This policy provides three methods of settling losses: Replacement Cost, Special Loss Settlement, and Actual Cash Value. Each method is used for a different type of property, as explained in paragraphs a-c below.

a. Replacement Cost Loss Settlement, described in R.2 below, applies to a single family dwelling provided:

(1) It is your principal residence and (2) At the time of loss, the amount of insurance in this policy that applies to the dwelling is 80 percent or more of its full replacement cost immediately before the loss, or is the maximum amount of insurance available under the NFIP.

b. Special Loss Settlement, described in R.3 below, applies to a single family dwelling that is a manufactured or mobile home or a travel trailer.

c. Actual Cash Value loss settlement applies to a single family dwelling not subject to replacement cost or special loss settlement, and to the property listed in R.4 below.

2. Replacement Cost Loss Settlement

The following loss settlement conditions apply to a single-family dwelling described in R.1.a above:

a. We will pay to repair or replace the damaged dwelling after application of the deductible and without deduction for depreciation, but not more than the least of the following amounts:

(1) The building limit of liability shown on your Declarations Page;

(2) The replacement cost of that part of the dwelling damaged, with materials of like kind and quality and for like use; or

(3) The necessary amount actually spent to repair or replace the damaged part of the dwelling for like use.

b. If the dwelling is rebuilt at a new location, the cost described above is limited to the cost that would have been incurred if the dwelling had been rebuilt at its former location.

c. When the full cost of repair or replacement is more than $1,000, or more than 5 percent of the whole amount of insurance that applies to the dwelling, we will not be liable for any loss under R.2.a above or R.4.a.2 below unless and until actual repair or replacement is completed.

d. You may disregard the replacement cost conditions above and make claim under this policy for loss to dwellings on an actual cash value basis. You may then make claim for any additional liability according to R.2.a, b, and c above, provided you notify us of your intent to do so within 180 days after the date of loss.

e. If the community in which your dwelling is located has been converted from the Emergency Program to the Regular Program during the current policy term, then we will consider the maximum amount of available NFIP insurance to be the amount that was available at the beginning of the current policy term.

3. Special Loss Settlement

a. The following loss settlement conditions apply to a single family dwelling that:

(1) is a manufactured or mobile home or a travel trailer, as defined in II.C.6.b and c,

(2) is at least 16 feet wide when fully assembled and has an area of at least 600 square feet within its perimeter walls when fully assembled, and

(3) is your principal residence as specified in R.1.a.1 above.

b. If such a dwelling is totally destroyed or damaged to such an extent that, in our judgment, it is not economically feasible to repair, at least to its pre-damage condition, we will, at our discretion pay the least of the following amounts:

(1) The lesser of the replacement cost of the dwelling or 1.5 times the actual cash value, or

(2) The building limit of liability shown on your Declarations Page.

c. If such a dwelling is partially damaged and, in our judgment, it is economically feasible to repair it to its pre-damage condition, we will settle the loss according to the Replacement Cost conditions in R.2 above.

4. Actual Cash Value Loss Settlement

The types of property noted below are subject to actual cash value (or in the case of R.4.a.2., below, proportional) loss settlement.

a. A dwelling, at the time of loss, when the amount of insurance on the dwelling is both less than 80 percent of its full replacement cost immediately before the loss and less than the maximum amount of insurance available under the NFIP. In that case, we will pay the greater of the following amounts, but not more than the amount of insurance that applies to that dwelling:

(1) The actual cash value, as defined in II.C.2, of the damaged part of the dwelling; or

(2) A proportion of the cost to repair or replace the damaged part of the dwelling, without deduction for physical depreciation and after application of the deductible.

This proportion is determined as follows: If 80 percent of the full replacement cost of the dwelling is less than the maximum amount of insurance available under the NFIP, then the proportion is determined by dividing the actual amount of insurance on the dwelling by the amount of insurance that represents 80 percent of its full replacement cost. But if 80 percent of the full replacement cost of the dwelling is greater than the maximum amount of insurance available under the NFIP, then the proportion is determined by dividing the actual amount of insurance on the dwelling by the maximum amount of insurance available under the NFIP.

b. A two-, three-, or four-family dwelling.

c. A unit that is not used exclusively for single-family dwelling purposes.

d. Detached garages.

e. Personal property.

f. Appliances, carpets, and carpet pads.

g. Outdoor awnings, outdoor antennas or aerials of any type, and other outdoor equipment.

h. Any property insured under this policy that is abandoned after a loss and remains as debris anywhere on the described location.

i. A dwelling that is not your principal residence.

5. Amount of Insurance Required

To determine the amount of insurance required for a dwelling immediately before the loss, we do not include the value of:

a. Footings, foundations, piers, or any other structures or devices that are below the undersurface of the lowest basement floor and support all or part of the dwelling;

b. Those supports listed in R.5.a above, that are below the surface of the ground inside the foundation walls if there is no basement; and

c. Excavations and underground flues, pipes, wiring, and drains.

**Note:** The Coverage D—Increased Cost of Compliance limit of liability is not included in the determination of the amount of insurance required.

## VIII. Policy Nullification, Cancellation, and Non-Renewal

*A. Policy Nullification for Fraud, Misrepresentation, or Making False Statements*

1. With respect to all insureds under this policy, this policy is void and has no legal force and effect if at any time, before or after a loss, you or any other insured or your agent have, with respect to this policy or any other NFIP insurance:

a. Concealed or misrepresented any material fact or circumstance;

b. Engaged in fraudulent conduct; or

c. Made false statements.

2. Policies voided under A.1 cannot be renewed or replaced by a new NFIP policy.

3. Policies are void as of the date the acts described in A.1 above were committed.

4. Fines, civil penalties, and imprisonment under applicable Federal laws may also apply to the acts of fraud or concealment described above.

*B. Policy Nullification for Reasons Other Than Fraud*

1. This policy is void from its inception, and has no legal force or effect, if:

a. The property listed on the application is located in a community that was not participating in the NFIP on this policy's inception date and did not join or reenter the program during the policy term and before the loss occurred;

b. The property listed on the application is otherwise not eligible for coverage under the NFIP at the time of the initial application;

c. You never had an insurable interest in the property listed on the application;

d. You provided an agent with an application and payment, but the payment did not clear; or

e. We receive notice from you, prior to the policy effective date, that you have determined not to take the policy and you are not subject a requirement to obtain and maintain flood insurance pursuant to any statute, regulation, or contract.

2. In such cases, you will be entitled to a full refund of all premium, fees, and surcharges received. However, if a claim was paid for a policy that is void, the claim payment must be returned to FEMA or offset from the premiums to be refunded before the refund will be processed.

*C. Cancellation of the Policy by You*

1. You may cancel this policy in accordance with the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

2. If you cancel this policy, you may be entitled to a full or partial refund of premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

*D. Cancellation of the Policy by Us*

1. Cancellation for Underpayment of Amounts Owed on Policy. This policy will be cancelled, pursuant to VII.D.2, if it is determined that the premium amount you paid is not sufficient to buy any amount of coverage, and you do not pay the additional amount of premium owed to increase the coverage to the originally requested amount within the required time period.

2. Cancellation Due to Lack of an Insurable Interest.

a. If you no longer have an insurable interest in the insured property, we will cancel this policy. You will cease to have an insurable interest if:

(1) For building coverage, the building was sold, destroyed, or removed.

(2) For contents coverage, the contents were sold or transferred ownership, or the contents were completely removed from the described location.

b. If your policy is cancelled for this reason, you may be entitled to a partial refund of premium under the applicable rules and regulations of the NFIP.

3. Cancellation of Duplicate Policies.

a. Except as allowed under Article I.G, your property may not be insured by more than one NFIP policy, and payment for damages to your property will only be made under one policy.

b. Except as allowed under Article I.G, if the property is insured by more than one NFIP policy, we will cancel all but one of the policies. The policy, or policies, will be selected for cancellation in accordance with 44 CFR 62.5 and the applicable rules and guidance of the NFIP.

c. If this policy is cancelled pursuant to VIII.D.4.b, you may be entitled to a full or partial refund of premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

4. Cancellation Due to Physical Alteration of Property.

a. If the insured building has been physically altered in such a manner that it is no longer eligible for flood insurance coverage, we will cancel this policy.

b. If your policy is cancelled for this reason, you may be entitled to a partial refund of premium under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

*E. Non-Renewal of the Policy by Us*

Your policy will not be renewed if:

1. The community where your insured property is located is suspended or stops participating in the NFIP;

2. Your building is otherwise ineligible for flood insurance under the Act;

3. You have failed to provide the information we requested for the purpose of rating the policy within the required deadline.

**IX. Liberalization Clause**

If we make a change that broadens your coverage under this edition of our policy, but does not re-quire any additional premium, then that change will automatically apply to your insurance as of the date we implement the change, provided that this implementation date falls within 60 days before or during the policy term stated on the Declarations Page.

**X. What Law Governs**

This policy and all disputes arising from the insurer's policy issuance, policy administration, or the handling of any claim under the policy are governed exclusively by the flood insurance regulations issued by FEMA, the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4001, *et seq.*), and Federal common law.

*In Witness Whereof,* we have signed this policy below and hereby enter into this Insurance Agreement.

Administrator, Federal Insurance and Mitigation Administration

■ 13. Revise Appendix A(2) to Part 61 to read as follows:

## Appendix A(2) to Part 61

**Federal Emergency Management Agency, Federal Insurance and Mitigation Administration**

**Standard Flood Insurance Policy**

**GENERAL PROPERTY FORM**

Please read the policy carefully. The flood insurance provided is subject to limitations, restrictions, and exclusions.

**I. Agreement**

A. Coverage Under This Policy.

1. Except as provided in I.A.2, this policy provides coverage for multifamily buildings (residential buildings designed for use by 5 or more families that are not condominmum buildings), non-residential buildings, and their contents.

2. There is no coverage for a residential condominium building in a regular program community, except for personal property coverage for a unit in a condominium building.

B. The Federal Emergency Management Agency (FEMA) provides flood insurance under the terms of the National Flood Insurance Act of 1968 and its amendments, and Title 44 of the Code of Federal Regulations.

C. We will pay you for direct physical loss by or from flood to your insured property if you:

1. Have paid the full amount due (including applicable premiums, surcharges, and fees);

2. Comply with all terms and conditions of this policy; and

3. Have furnished accurate information and statements.

D. We have the right to review the information you give us at any time and revise your policy based on our review.

E. This policy insures only one building. If you own more than one building, coverage will apply to the single building specifically described in the Flood Insurance Application.

F. Multiple policies with building coverage cannot be issued to insure a single building to one insured or to different insureds, even if issued through different NFIP insurers. Payment for damages may only be made under a single policy for building damages under Coverage A—Building Property.

**II. Definitions**

A. In this policy, ''you'' and ''your'' refer to the named insured(s) shown on the Declarations Page of this policy and the spouse of the named insured, if a resident of the same household. Insured(s) also includes: Any mortgagee and loss payee named in the Application and Declarations Page, as well as any other mortgagee or loss payee determined to exist at the time of loss, in the order of precedence. ''We,'' ''us,'' and ''our'' refer to the insurer.

Some definitions are complex because they are provided as they appear in the law or regulations, or result from court cases.

B. *Flood,* as used in this flood insurance policy, means:

1. A general and temporary condition of partial or complete inundation of two or more acres of normally dry land area or of two or more properties (one of which is your property) from:

a. Overflow of inland or tidal waters,

b. Unusual and rapid accumulation or runoff of surface waters from any source,

c. Mudflow

2. Collapse or subsidence of land along the shore of a lake or similar body of water as a result of erosion or undermining caused by waves or currents of water exceeding anticipated cyclical levels that result in a flood as defined in B.1.a above.

C. The following are the other key definitions we use in this policy:

1. *Act.* The National Flood Insurance Act of 1968 and any amendments to it.

2. *Actual Cash Value.* The cost to replace an insured item of property at the time of loss, less the value of its physical depreciation.

3. *Application.* The statement made and signed by you or your agent in applying for this policy. The application gives information we use to determine the eligibility of the risk, the kind of policy to be issued, and the correct premium payment. The application is part of this flood insurance policy.

4. *Base Flood.* A flood having a one percent chance of being equaled or exceeded in any given year.

5. *Basement.* Any area of a building, including any sunken room or sunken portion of a room, having its floor below ground level on all sides.

6. *Building.*

a. A structure with two or more outside rigid walls and a fully secured roof, that is affixed to a permanent site;

b. A manufactured home, also known as a mobile home, is a structure built on a permanent chassis, transported to its site in one or more sections, and affixed to a permanent foundation); or

c. A travel trailer without wheels, built on a chassis and affixed to a permanent

foundation, that is regulated under the community's floodplain management and building ordinances or laws.

*Building* does not mean a gas or liquid storage tank, shipping container, or a recreational vehicle, park trailer, or other similar vehicle, except as described in C.6.c above.

7. *Cancellation.* The ending of the insurance coverage provided by this policy before the expiration date.

8. *Condominium.* That form of ownership of one or more buildings in which each unit owner has an undivided interest in common elements.

9. *Condominium Association.* The entity made up of the unit owners responsible for the maintenance and operation of:

a. Common elements owned in undivided shares by unit owners; and

b. Other buildings in which the unit owners have use rights where membership in the entity is a required condition of unit ownership.

10. *Condominium Building.* A type of building for which the form of ownership is one in which each unit owner has an undivided interest in common elements of the building.

11. *Declarations Page.* A computer-generated summary of information you provided in your application for insurance. The Declarations Page also describes the term of the policy, limits of coverage, and displays the premium and our name. The Declarations Page is a part of this flood insurance policy.

12. *Deductible.* The fixed amount of an insured loss that is your responsibility and that is incurred by you before any amounts are paid for the insured loss under this policy.

13. *Described Location.* The location where the insured building(s) or personal property are found. The described location is shown on the Declarations Page.

14. *Direct Physical Loss By or From Flood.* Loss or damage to insured property, directly caused by a flood. There must be evidence of physical changes to the property.

15. *Elevated Building.* A building that has no basement and that has its lowest elevated floor raised above ground level by foundation walls, shear walls, posts, piers, pilings, or columns.

16. *Emergency Program.* The initial phase of a community's participation in the National Flood Insurance Program. During this phase, only limited amounts of insurance are available under the Act and the regulations prescribed pursuant to the Act.

17. *Federal Policy Fee.* A flat rate charge you must pay on each new or renewal policy to defray certain administrative expenses incurred in carrying out the National Flood Insurance Program.

18. *Improvements.* Fixtures, alterations, installations, or additions comprising a part of the dwelling or apartment in which you reside.

19. *Mudflow.* A river of liquid and flowing mud on the surface of normally dry land areas, as when earth is carried by a current of water. Other earth movements, such as landslide, slope failure, or a saturated soil mass moving by liquidity down a slope, are not mudflows.

20. *National Flood Insurance Program (NFIP).* The program of flood insurance coverage and floodplain management administered under the Act and applicable Federal regulations in Title 44 of the Code of Federal Regulations, Subchapter B.

21. *Policy.* The entire written contract between you and us. It includes:

a. This printed form;

b. The application and Declarations Page;

c. Any endorsement(s) that may be issued; and

d. Any renewal certificate indicating that coverage has been instituted for a new policy and new policy term. Only one building, which you specifically described in the application, may be insured under this policy.

22. *Pollutants.* Substances that include, but are not limited to, any solid, liquid, gaseous, or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals, and waste. ''Waste'' includes, but is not limited to, materials to be recycled, reconditioned, or reclaimed.

23. *Post-FIRM Building.* A building for which construction or substantial improvement occurred after December 31, 1974, or on or after the effective date of an initial Flood Insurance Rate Map (FIRM), whichever is later.

24. *Probation Surcharge.* A flat charge you must pay on each new or renewal policy issued covering property in a community the NFIP has placed on probation under the provisions of 44 CFR 59.24.

25. *Regular Program.* The final phase of a community's participation in the National Flood Insurance Program. In this phase, a Flood Insurance Rate Map is in effect and full limits of coverage are available under the Act and the regulations prescribed pursuant to the Act.

26. *Residential Condominium Building.* A condominium building, containing one or more family units and in which at least 75 percent of the floor area is residential.

27. *Special Flood Hazard Area (SFHA).* An area having special flood or mudflow, and/or flood-related erosion hazards, and shown on a Flood Hazard Boundary Map or Flood Insurance Rate Map as Zone A, AO, A1–A30, AE, A99, AH, AR, AR/A, AR/AE, AR/AH, AR/AO, AR/A1–A30, V1–V30, VE, or V.

28. *Stock* means merchandise held in storage or for sale, raw materials, and in-process or finished goods, including supplies used in their packing or shipping. Stock does not include any property not covered under Section IV. Property Not Covered, except the following:

a. Parts and equipment for self-propelled vehicles;

b. Furnishings and equipment for watercraft;

c. Spas and hot-tubs, including their equipment; and

d. Swimming pool equipment.

29. *Unit.* A single-family residential or non-residential space you own in a condominium building.

30. *Valued Policy.* A policy in which the insured and the insurer agree on the value of the property insured, that value being payable in the event of a total loss. The Standard Flood Insurance Policy is not a valued policy.

**III. Property Covered**

*A. Coverage A—Building Property*

We insure against direct physical loss by or from flood to:

1. The building described on the Declarations Page at the described location. If the building is a condominium building and the named insured is the condominium association, Coverage A includes all units within the building and the improvements within the units, provided the units are owned in common by all unit owners.

2. Building property located at another location for a period of 45 days at another location, as set forth in III.C.2.b, Property Removed to Safety.

3. Additions and extensions attached to and in contact with the building by means of a rigid exterior wall, a solid load-bearing interior wall, a stairway, an elevated walkway, or a roof. At your option, additions and extensions connected by any of these methods may be separately insured. Additions and extensions attached to and in contact with the building by means of a common interior wall that is not a solid load-bearing wall are always considered part of the building and cannot be separately insured.

4. The following fixtures, machinery, and equipment, which are insured under Coverage A only:

a. Awnings and canopies;

b. Blinds;

c. Carpet permanently installed over unfinished flooring;

d. Central air conditioners;

e. Elevator equipment;

f. Fire extinguishing apparatus;

g. Fire sprinkler systems;

h. Walk-in freezers;

i. Furnaces;

j. Light fixtures;

k. Outdoor antennas and aerials attached to buildings;

l. Permanently installed cupboards, bookcases, paneling, and wallpaper;

m. Pumps and machinery for operating pumps;

n. Ventilating equipment; and

o. Wall mirrors, permanently installed;

p. In the units within the building, installed:

(1) Built-in dishwashers;

(2) Built-in microwave ovens;

(3) Garbage disposal units;

(4) Hot water heaters, including solar water heaters;

(5) Kitchen cabinets;

(6) Plumbing fixtures;

(7) Radiators;

(8) Ranges;

(9) Refrigerators; and

(10) Stoves.

5. Materials and supplies to be used for construction, alteration, or repair of the insured building while the materials and supplies are stored in a fully enclosed building at the described location or on an adjacent property.

6. A building under construction, alteration, or repair at the described location.

a. If the structure is not yet walled or roofed as described in the definition for building (*see* II.B.6.a.) then coverage applies:

(1) Only while such work is in progress; or

(2) If such work is halted, only for a period of up to 90 continuous days thereafter.

b. However, coverage does not apply until the building is walled and roofed if the lowest floor, including the basement floor, of a non-elevated building or the lowest elevated floor of an elevated building is:

(1) Below the base flood elevation in Zones AH, AE, A1–A30, AR, AR/AE, AR/AH, AR/A1–A30, AR/A, AR/AO; or

(2) Below the base flood elevation adjusted to include the effect of wave action in Zones VE or V1–V30.

The lowest floor level is based on the bottom of the lowest horizontal structural member of the floor in Zones VE or V1–V30 or the top of the floor in Zones AH, AE, A1–A30, AR, AR/AE, AR/AH, AR/A1–A30, AR/A, and AR/AO.

7. A manufactured home or a travel trailer, as described in the II.C.6. If the manufactured home or travel trailer is in a special flood hazard area, it must be anchored in the following manner at the time of the loss:

a. By over-the-top or frame ties to ground anchors; or

b. In accordance with the manufacturer's specifications; or

c. In compliance with the community's floodplain management requirements unless it has been continuously insured by the NFIP at the same described location since September 30, 1982.

8. Items of property below the lowest elevated floor of an elevated post-FIRM building located in zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone. Coverage is limited to the following:

a. Any of the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:

(1) Central air conditioners;

(2) Cisterns and the water in them;

(3) Drywall for walls and ceilings in a basement and the cost of labor to nail it, unfinished and unfloated and not taped, to the framing;

(4) Electrical junction and circuit breaker boxes;

(5) Electrical outlets and switches;

(6) Elevators, dumbwaiters, and related equipment, except for related equipment installed below the base flood elevation after September 30, 1987;

(7) Fuel tanks and the fuel in them;

(8) Furnaces and hot water heaters;

(9) Heat pumps;

(10) Nonflammable insulation in a basement;

(11) Pumps and tanks used in solar energy systems;

(12) Stairways and staircases attached to the building, not separated from it by elevated walkways;

(13) Sump pumps;

(14) Water softeners and the chemicals in them, water filters, and faucets installed as an integral part of the plumbing system;

(15) Well water tanks and pumps;

(16) Required utility connections for any item in this list; and

(17) Footings, foundations, posts, pilings, piers, or other foundation walls and anchorage systems required to support a building.

b. Clean-up.

*B. Coverage B—Personal Property*

1. If you have purchased personal property coverage, we insure, subject to B.2–4 below, against direct physical loss by or from flood to personal property inside the fully enclosed insured building:

a. Owned solely by you, or in the case of a condominium, owned solely by the condominium association and used exclusively in the conduct of the business affairs of the condominium association; or

b. Owned in common by the unit owners of the condominium association.

2. We also insure such personal property for 45 days while stored at a temporary location, as set forth in III.C.2.b, Property Removed to Safety.

3. When this policy covers personal property, coverage will be either for household personal property or other than household personal property, while within the insured building, but not both.

a. If this policy covers household personal property, it will insure household personal property usual to a living quarters, that:

(1) Belongs to you, or a member of your household, or at your option:

(a) Your domestic worker;

(b) Your guest; or

(2) You may be legally liable for.

b. If this policy covers other than household personal property, it will insure your:

(1) Furniture and fixtures;

(2) Machinery and equipment;

(3) Stock; and

(4) Other personal property owned by you and used in your business, subject to IV, Property Not Covered.

4. Coverage for personal property includes the following property, subject to B.1.a and B.1.b above, which is insured under Coverage B, only:

a. Air conditioning units, portable or window type;

b. Carpets, not permanently installed, over unfinished flooring;

c. Carpets over finished flooring;

d. Clothes washers and dryers;

e. ''Cook-out'' grills;

f. Food freezers, other than walk-in, and food in any freezer;

g. Outdoor equipment and furniture stored inside the insured building;

h. Ovens and the like; and

i. Portable microwave ovens and portable dishwashers.

5. Coverage for items of property below the lowest elevated floor of an elevated post-FIRM building located in Zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone, is limited to the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:

a. Air conditioning units, portable or window type;

b. Clothes washers and dryers; and

c. Food freezers, other than walk-in, and food in any freezer.

6. Special Limits. We will pay no more than $2,500 for any loss to one or more of the following kinds of personal property:

a. Artwork, photographs, collectibles, or memorabilia, including but not limited to, porcelain or other figures, and sports cards;

b. Rare books or autographed items;

c. Jewelry, watches, precious and semi-precious stones, or articles of gold, silver, or platinum;

d. Furs or any article containing fur that represents its principal value.

7. We will pay only for the functional value of antiques.

8. If you are a tenant, you may apply up to 10 percent of the Coverage B limit to improvements:

a. Made a part of the building you occupy; and

b. You acquired, or made at your expense, even though you cannot legally remove.

This coverage does not increase the amount of insurance that applies to insured personal property.

9. If you are a condominium unit owner, you may apply up to 10 percent of the Coverage B limit to cover loss to interior:

a. Walls,

b. floors, and

c. ceilings,

that are not covered under a policy issued to the condominium association insuring the condominium building.

This coverage does not increase the amount of insurance that applies to insured personal property.

10. If you are a tenant, personal property must be inside the fully enclosed building.

*C. Coverage C—Other Coverages*

1. Debris Removal

a. We will pay the expense to remove non-owned debris that is on or in insured property and debris of insured property anywhere.

b. If you or a member of your household perform the removal work, the value of your work will be based on the Federal minimum wage.

c. This coverage does not increase the Coverage A or Coverage B limit of liability.

2. Loss Avoidance Measures

a. Sandbags, Supplies, and Labor

(1) We will pay up to $1,000 for costs you incur to protect the insured building from a flood or imminent danger of flood, for the following:

(a) Your reasonable expenses to buy:

(i) Sandbags, including sand to fill them;

(ii) Fill for temporary levees;

(iii) Pumps; and

(iv) Plastic sheeting and lumber used in connection with these items.

(b) The value of work, at the Federal minimum wage, that you perform.

(2) This coverage for Sandbags, Supplies and Labor only applies if damage to insured property by or from flood is imminent and the threat of flood damage is apparent enough to lead a person of common prudence to anticipate flood damage. One of the following must also occur:

(a) A general and temporary condition of flooding in the area near the described

location must occur, even if the flood does not reach the building; or

(b) A legally authorized official must issue an evacuation order or other civil order for the community in which the building is located calling for measures to preserve life and property from the peril of flood.

This coverage does not increase the Coverage A or Coverage B limit of liability.

b. Property Removed to Safety

(1) We will pay up to $1,000 for the reasonable expenses you incur to move insured property to a place other than the described location that contains the property in order to protect it from flood or the imminent danger of flood. Reasonable expenses include the value of work, at the Federal minimum wage, you or a member of your household perform.

(2) If you move insured property to a location other than the described location that contains the property, in order to protect it from flood or the imminent danger of flood, we will cover such property while at that location for a period of 45 consecutive days from the date you begin to move it there. The personal property that is moved must be placed in a fully enclosed building or otherwise reasonably protected from the elements.

(3) Any property removed, including a moveable home described in II.6, must be placed above ground level or outside of the special flood hazard area.

(4) This coverage does not increase the Coverage A or Coverage B limit of liability.

3. Pollution Damage

We will pay for damage caused by pollutants to covered property if the discharge, seepage, migration, release, or escape of the pollutants is caused by or results from flood. The most we will pay under this coverage is $10,000. This coverage does not increase the Coverage A or Coverage B limits of liability. Any payment under this provision when combined with all other payments for the same loss cannot exceed the replacement cost or actual cash value, as appropriate, of the covered property. This coverage does not include the testing for or monitoring of pollutants unless required by law or ordinance.

*D. Coverage D—Increased Cost of Compliance*

*1. General.*

This policy pays you to comply with a State or local floodplain management law or ordinance affecting repair or reconstruction of a building suffering flood damage. Compliance activities eligible for payment are: Elevation, floodproofing, relocation, or demolition (or any combination of these activities) of your building. Eligible floodproofing activities are limited to:

a. Non-residential buildings.

b. Residential buildings with basements that satisfy FEMA's standards published in the Code of Federal Regulations [44 CFR 60.6(b) or (c)].

*2. Limits of Liability.*

We will pay you up to $30,000 under this Coverage D (Increased Cost of Compliance), which only applies to policies with building coverage (Coverage A). Our payment of claims under Coverage D is in addition to the amount of coverage which you selected on the application and which appears on the Declarations Page. However, the maximum you can collect under this policy for both Coverage A (Building Property) and Coverage D (Increased Cost of Compliance) cannot exceed the maximum permitted under the Act. We do NOT charge a separate deductible for a claim under Coverage D.

*3. Eligibility.*

a. A building covered under Coverage A (Building Property) sustaining a loss caused by a flood as defined by this policy must:

(1) Be a ''repetitive loss building.'' A repetitive loss building is one that meets the following conditions:

(a) The building is insured by a contract of flood insurance issued under the NFIP.

(b) The building has suffered flood damage on two occasions during a 10-year period which ends on the date of the second loss.

(c) The cost to repair the flood damage, on average, equaled or exceeded 25 percent of the market value of the building at the time of each flood loss.

(d) In addition to the current claim, the NFIP must have paid the previous qualifying claim, and the State or community must have a cumulative, substantial damage provision or repetitive loss provision in its floodplain management law or ordinance being enforced against the building; or

(2) Be a building that has had flood damage in which the cost to repair equals or exceeds 50 percent of the market value of the building at the time of the flood. The State or community must have a substantial damage provision in its floodplain management law or ordinance being enforced against the building.

b. This Coverage D pays you to comply with State or local floodplain management laws or ordinances that meet the minimum standards of the National Flood Insurance Program found in the Code of Federal Regulations at 44 CFR 60.3. We pay for compliance activities that exceed those standards under these conditions:

(1) 3.a.1 above.

(2) Elevation or floodproofing in any risk zone to preliminary or advisory base flood elevations provided by FEMA which the State or local government has adopted and is enforcing for flood-damaged buildings in such areas. (This includes compliance activities in B, C, X, or D zones which are being changed to zones with base flood elevations. This also includes compliance activities in zones where base flood elevations are being increased, and a flood-damaged building must comply with the higher advisory base flood elevation.) Increased Cost of Compliance coverage does not apply to situations in B, C, X, or D zones where the community has derived its own elevations and is enforcing elevation or floodproofing requirements for flood-damaged buildings to elevations derived solely by the community.

(3) Elevation or floodproofing above the base flood elevation to meet State or local ''free-board'' requirements, *i.e.,* that a building must be elevated above the base flood elevation.

c. Under the minimum NFIP criteria at 44 CFR 60.3(b)(4), States and communities must require the elevation or floodproofing of buildings in unnumbered A zones to the base flood elevation where elevation data is obtained from a Federal, State, or other source. Such compliance activities are also eligible for Coverage D.

d. This coverage will pay for the incremental cost, after demolition or relocation, of elevating or floodproofing a building during its rebuilding at the same or another site to meet State or local floodplain management laws or ordinances, subject to the exclusion at III.D.5.g.

e. This coverage will pay to bring a flood-damaged building into compliance with State or local floodplain management laws or ordinances even if the building had received a variance before the present loss from the applicable floodplain management requirements.

*4. Conditions.*

a. When a building insured under Coverage A—Building Property sustains a loss caused by a flood, our payment for the loss under this Coverage D will be for the increased cost to elevate, floodproof, relocate, or demolish (or any combination of these activities) caused by the enforcement of current State or local floodplain management ordinances or laws. Our payment for eligible demolition activities will be for the cost to demolish and clear the site of the building debris or a portion thereof caused by the enforcement of current State or local floodplain management ordinances or laws. Eligible activities for the cost of clearing the site will include those necessary to discontinue utility service to the site and ensure proper abandonment of on-site utilities.

b. When the building is repaired or rebuilt, it must be intended for the same occupancy as the present building unless otherwise required by current floodplain management ordinances or laws.

*5. Exclusions.*

Under this Coverage D (Increased Cost of Compliance), we will not pay for:

a. The cost to comply with any floodplain management law or ordinance in communities participating in the Emergency Program.

b. The cost associated with enforcement of any ordinance or law that requires any insured or others to test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of pollutants.

c. The loss in value to any insured building due to the requirements of any ordinance or law.

d. The loss in residual value of the undamaged portion of a building demolished as a consequence of enforcement of any State or local floodplain management law or ordinance.

e. Any Increased Cost of Compliance under this Coverage D:

(1) Until the building is elevated, floodproofed, demolished, or relocated on the same or to another premises; and

(2) Unless the building is elevated, floodproofed, demolished, or relocated as soon as reasonably possible after the loss, not to exceed two years.

f. Any code upgrade requirements, *e.g.,* plumbing or electrical wiring, not

specifically related to the State or local floodplain management law or ordinance.

g. Any compliance activities needed to bring additions or improvements made after the loss occurred into compliance with State or local floodplain management laws or ordinances.

h. Loss due to any ordinance or law that you were required to comply with before the current loss.

i. Any rebuilding activity to standards that do not meet the NFIP's minimum requirements. This includes any situation where the insured has received from the State or community a variance in connection with the current flood loss to rebuild the property to an elevation below the base flood elevation.

j. Increased Cost of Compliance for a garage or carport.

k. Any building insured under an NFIP Group Flood Insurance Policy.

l. Assessments made by a condominium association on individual condominium unit owners to pay increased costs of repairing commonly owned buildings after a flood in compliance with State or local floodplain management ordinances or laws.

*6. Other Provisions.*

All other conditions and provisions of the policy apply.

**IV. Property not Covered**

We do not insure any of the following property:

1. Personal property not inside the fully enclosed building;

2. A building, and personal property in it, located entirely in, on, or over water or seaward of mean high tide if it was constructed or substantially improved after September 30, 1982;

3. Open structures, including a building used as a boathouse or any structure or building into which boats are floated, and personal property located in, on, or over water;

4. Recreational vehicles other than travel trailers described in the II.C.6.c, whether affixed to a permanent foundation or on wheels;

5. Self-propelled vehicles or machines, including their parts and equipment. However, we do cover self-propelled vehicles or machines not licensed for use on public roads and are:

a. Used mainly to service the described location; or

b. Designed and used to assist handicapped persons, while the vehicles or machines are inside a building at the described location;

6. Land, land values, lawns, trees, shrubs, plants, growing crops, or animals;

7. Accounts, bills, coins, currency, deeds, evidences of debt, medals, money, scrip, stored value cards, postage stamps, securities, bullion, manuscripts, or other valuable papers;

8. Underground structures and equipment, including wells, septic tanks, and septic systems;

9. Those portions of walks, walkways, decks, driveways, patios, and other surfaces, all whether protected by a roof or not, located outside the perimeter, exterior walls of the insured building;

10. Containers, including related equipment, such as, but not limited to, tanks containing gases or liquids;

11. Buildings or units and all their contents if more than 49 percent of the actual cash value of the building is below ground, unless the lowest level is at or above the base flood elevation and is be-low ground by reason of earth having been used as insulation material in conjunction with energy efficient building techniques;

12. Fences, retaining walls, seawalls, bulkheads, wharves, piers, bridges, and docks;

13. Aircraft or watercraft, or their furnishings and equipment;

14. Hot tubs and spas that are not bathroom fixtures, and swimming pools, and their equipment, such as, but not limited to, heaters, filters, pumps, and pipes, wherever located;

15. Property not eligible for flood insurance pursuant to the provisions of the Coastal Barrier Resources Act and the Coastal Barrier Improvement Act and amendments to these Acts;

16. Personal property owned by or in the care, custody or control of a unit owner, except for property of the type and under the circumstances set forth under III. Coverage B—Personal Property of this policy;

17. A residential condominium building located in a Regular Program community.

**V. Exclusions**

A. We only pay for ''direct physical loss by or from flood,'' which means that we do not pay you for:

1. Loss of revenue or profits;

2. Loss of access to the insured property or described location;

3. Loss of use of the insured property or described location;

4. Loss from interruption of business or production;

5. Any additional living expenses incurred while the insured building is being repaired or is unable to be occupied for any reason;

6. The cost of complying with any ordinance or law requiring or regulating the construction, demolition, remodeling, renovation, or repair of property, including removal of any resulting debris. This exclusion does not apply to any eligible activities we describe in Coverage D—Increased Cost of Compliance; or

7. Any other economic loss you suffer.

B. *Flood in Progress.* If this policy became effective as of the time of a loan closing, as provided by 44 CFR 61.11(b), we will not pay for a loss caused by a flood that is a continuation of a flood that existed prior to coverage becoming effective. In all other circumstances, we will not pay for a loss caused by a flood that is a continuation of a flood that existed on or before the day you submitted the application for coverage under this policy and the correct premium. We will determine the date of application using 44 CFR 611.11(f).

C. We do not insure for loss to property caused directly by earth movement even if the earth movement is caused by flood. Some examples of earth movement that we do not cover are:

1. Earthquake;

2. Landslide;

3. Land subsidence;

4. Sinkholes;

5. Destabilization or movement of land that results from accumulation of water in subsurface land areas; or

6. Gradual erosion.

We do, however, pay for losses from mudflow and land subsidence as a result of erosion that are specifically insured under our definition of flood (*see* II.B.1.c and II.B.2).

D. We do not insure for direct physical loss caused directly or indirectly by:

1. The pressure or weight of ice;

2. Freezing or thawing;

3. Rain, snow, sleet, hail, or water spray;

4. Water, moisture, mildew, or mold damage that results primarily from any condition:

a. Substantially confined to the insured building; or

b. That is within your control including, but not limited to:

(1) Design, structural, or mechanical defects;

(2) Failures, stoppages, or breakage of water or sewer lines, drains, pumps, fixtures, or equipment; or

(3) Failure to inspect and maintain the property after a flood recedes;

5. Water or water-borne material that:

a. Backs up through sewers or drains;

b. Discharges or overflows from a sump, sump pump or related equipment; or

c. Seeps or leaks on or through the insured property; unless there is a flood in the area and the flood is the proximate cause of the sewer or drain backup, sump pump discharge or overflow, or the seepage of water;

6. The pressure or weight of water unless there is a flood in the area and the flood is the proximate cause of the damage from the pressure or weight of water;

7. Power, heating, or cooling failure unless the failure results from direct physical loss by or from flood to power, heating, or cooling equipment on the described location;

8. Theft, fire, explosion, wind, or windstorm;

9. Anything you or any member of your household do or conspires to do to deliberately cause loss by flood; or

10. Alteration of the insured property that significantly increases the risk of flooding.

E. We do not insure for loss to any building or personal property located on land leased from the Federal Government, arising from or incident to the flooding of the land by the Federal Government, where the lease expressly holds the Federal Government harmless under flood insurance issued under any Federal Government program.

**VI. Deductibles**

A. When a loss is insured under this policy, we will pay only that part of the loss that exceeds your deductible amount, subject to the limit of liability that applies. The deductible amount is shown on the Declarations Page.

However, when a building under construction, alteration, or repair does not have at least two rigid exterior walls and a fully secured roof at the time of loss, your deductible amount will be two times the

deductible that would otherwise apply to a completed building.

B. In each loss from flood, separate deductibles apply to the building and personal property insured by this policy.

C. The deductible does NOT apply to:

1. III.C.2. Loss Avoidance Measures; or

2. III.D. Increased Cost of Compliance.

**VII. General Conditions**

*A. Pair and Set Clause*

In case of loss to an article that is part of a pair or set, we will have the option of paying you:

1. An amount equal to the cost of replacing the lost, damaged, or destroyed article, minus its depreciation, or

2. The amount that represents the fair proportion of the total value of the pair or set that the lost, damaged, or destroyed article bears to the pair or set.

*B. Other Insurance*

1. If a loss insured by this policy is also insured by other insurance that includes flood coverage not issued under the Act, we will not pay more than the amount of insurance that you are entitled to for lost, damaged, or destroyed property insured under this policy subject to the following:

a. We will pay only the proportion of the loss that the amount of insurance that applies under this policy bears to the total amount of insurance covering the loss, unless VII.B.1.b or c below applies.

b. If the other policy has a provision stating that it is excess insurance, this policy will be primary.

c. This policy will be primary (but subject to its own deductible) up to the deductible in the other flood policy (except another policy as described in VII.B.1.b above). When the other deductible amount is reached, this policy will participate in the same proportion that the amount of insurance under this policy bears to the total amount of both policies, for the remainder of the loss.

2. Where this policy covers a condominium association and there is a National Flood Insurance Program flood insurance policy in the name of a unit owner that insures the same loss as this policy, then this policy will be primary.

*C. Amendments, Waivers, Assignment*

This policy cannot be changed, nor can any of its provisions be waived, without the express written consent of the Federal Insurance Administrator. No action that we take under the terms of this policy can constitute a waiver of any of our rights. You may assign this policy in writing when you transfer title of your property to someone else except under these conditions:

1. When this policy covers only personal property; or

2. When this policy covers a building under construction.

*D. Insufficient Premium or Rating Information*

1. Applicability. The following provisions apply to all instances where the premium paid on this policy is insufficient or where the rating information is insufficient, such as where an Elevation Certificate is not provided.

2. Reforming the Policy with Reduced Coverage. Except as otherwise provided in VII.D.1 and VII.D.4, if the premium we received from you was not sufficient to buy the kinds and amounts of coverage you requested, we will provide only the kinds and amounts of coverage that can be purchased for the premium payment we received.

a. For the purpose of determining whether your premium payment is sufficient to buy the kinds and amounts of coverage you requested, we will first deduct the costs of all applicable fees and surcharges.

b. If the amount paid, after deducting the costs of all applicable fees and surcharges, is not sufficient to buy any amount of coverage, your payment will be refunded. Unless the policy is reformed to increase the coverage amount to the amount originally requested pursuant to VII.D.3, this policy will be cancelled, and no claims will be paid under this policy.

c. Coverage limits on the reformed policy will be based upon the amount of premium submitted per type of coverage, but will not exceed the amount originally requested.

3. Discovery of Insufficient Premium or Rating Information. If we discover that your premium payment was not sufficient to buy the requested amount of coverage, the policy will be reformed as described in VII.D.2. You have the option of increasing the amount of coverage resulting from this reformation to the amount you requested as follows:

a. Insufficient Premium. If we discover that your premium payment was not sufficient to buy the requested amount of coverage, we will send you, and any mortgagee or trustee known to us, a bill for the required additional premium for the current policy term (or that portion of the current policy term following any endorsement changing the amount of coverage). If it is discovered that the initial amount charged to you for any fees or surcharges is incorrect, the difference will be added or deducted, as applicable, to the total amount in this bill.

(1) If you or the mortgagee or trustee pay the additional amount due within 30 days from the date of our bill, we will reform the policy to increase the amount of coverage to the originally requested amount, effective to the beginning of the current policy term (or subsequent date of any endorsement changing the amount of coverage).

(2) If you or the mortgagee or trustee do not pay the additional amount due within 30 days of the date of our bill, any flood insurance claim will be settled based on the reduced amount of coverage.

(3) As applicable, you have the option of paying all or part of the amount due out of a claim payment based on the originally requested amount of coverage.

b. Insufficient Rating Information. If we determine that the rating information we have is insufficient and prevents us from calculating the additional premium, we will ask you to send the required information. You must submit the information within 60 days of our request.

(1) If we receive the information within 60 days of our request, we will determine the amount of additional premium for the current policy term and follow the procedure in VII.D.3.a above.

(2) If we do not receive the information within 60 days of our request, no claims will be paid until the requested information is provided. Coverage will be limited to the amount of coverage that can be purchased for the payments we received, as determined when the requested information is provided.

4. Coverage Increases. If we do not receive the amounts requested in VII.D.3.a or the additional information requested in VII.D.3.b by the date it is due, the amount of coverage under this policy can only be increased by endorsement subject to the appropriate waiting period. However, no coverage increases will be allowed until you have provided the information requested in VII.D.3.b is provided.

5. Falsifying Information. However, if we find that you or your agent intentionally did not tell us, or falsified, any important fact or circumstance or did anything fraudulent relating to this insurance, the provisions of VIII.A apply.

*E. Policy Renewal*

1. This policy will expire at 12:01 a.m. on the last day of the policy term.

2. We must receive the payment of the appropriate renewal premium within 30 days of the expiration date.

3. If we find, however, that we did not place your renewal notice into the U.S. Postal Service, or if we did mail it, we made a mistake, *e.g.,* we used an incorrect, incomplete, or illegible address, which delayed its delivery to you before the due date for the renewal premium, then we will follow these procedures:

a. If you or your agent notified us, not later than one year after the date on which the payment of the renewal premium was due, of non-receipt of a renewal notice before the due date for the renewal premium, and we determine that the circumstances in the preceding paragraph apply, we will mail a second bill providing a revised due date, which will be 30 days after the date on which the bill is mailed.

b. If we do not receive the premium requested in the second bill by the revised due date, then we will not renew the policy. In that case, the policy will remain as an expired policy as of the expiration date shown on the Declarations Page.

4. In connection with the renewal of this policy, we may ask you during the policy term to recertify, on a Recertification Questionnaire that we will provide to you, the rating information used to rate your most recent application for or renewal of insurance.

*F. Conditions Suspending or Restricting Insurance*

We are not liable for loss that occurs while there is a hazard that is increased by any means within your control or knowledge.

*G. Requirements in Case of Loss*

In case of a flood loss to insured property, you must:

1. Give prompt written notice to us;

2. As soon as reasonably possible, separate the damaged and undamaged property, putting it in the best possible order so that we may examine it;

3. Prepare an inventory of damaged property showing the quantity, description, actual cash value, and amount of loss. Attach all bills, receipts, and related documents;

4. Within 60 days after the loss, send us a proof of loss, which is your statement of the amount you are claiming under the policy signed and sworn to by you, and which furnishes us with the following information:

a. The date and time of loss;

b. A brief explanation of how the loss happened;

c. Your interest (for example, ''owner'') and the interest, if any, of others in the damaged property;

d. Details of any other insurance that may cover the loss;

e. Changes in title or occupancy of the insured property during the term of the policy;

f. Specifications of damaged buildings and detailed repair estimates;

g. Names of mortgagees or anyone else having a lien, charge, or claim against the insured property;

h. Details about who occupied any insured building at the time of loss and for what purpose; and

i. The inventory of damaged personal property described in G.3 above.

5. In completing the proof of loss, you must use your own judgment concerning the amount of loss and justify that amount.

6. You must cooperate with the adjuster or representative in the investigation of the claim.

7. The insurance adjuster whom we hire to investigate your claim may furnish you with a proof of loss form, and she or he may help you complete it. However, this is a matter of courtesy only, and you must still send us a proof of loss within 60 days after the loss even if the adjuster does not furnish the form or help you complete it.

8. We have not authorized the adjuster to approve or disapprove claims or to tell you whether we will approve your claim.

9. At our option, we may accept the adjuster's report of the loss instead of your proof of loss. The adjuster's report will include information about your loss and the damages you sustained. You must sign the adjuster's report. At our option, we may require you to swear to the report.

*H. Our Options After a Loss*

Options we may, in our sole discretion, exercise after loss include the following:

1. At such reasonable times and places that we may designate, you must:

a. Show us or our representative the damaged property;

b. Submit to examination under oath, while not in the presence of another insured, and sign the same; and

c. Permit us to examine and make extracts and copies of:

(1) Any policies of property insurance insuring you against loss and the deed establishing your ownership of the insured real property;

(2) Condominium association documents including the Declarations of the condominium, its Articles of Association or Incorporation, Bylaws, rules and regulations, and other relevant documents if you are a unit owner in a condominium building; and

(3) All books of accounts, bills, invoices and other vouchers, or certified copies pertaining to the damaged property if the originals are lost.

2. We may request, in writing, that you furnish us with a complete inventory of the lost, damaged or destroyed property, including:

a. Quantities and costs;

b. Actual cash values or replacement cost (whichever is appropriate);

c. Amounts of loss claimed;

d. Any written plans and specifications for repair of the damaged property that you can reasonably make available to us; and

e. Evidence that prior flood damage has been repaired.

3. If we give you written notice within 30 days after we receive your signed, sworn proof of loss, we may:

a. Repair, rebuild, or replace any part of the lost, damaged, or destroyed property with material or property of like kind and quality or its functional equivalent; and

b. Take all or any part of the damaged property at the value that we agree upon or its appraised value.

*I. No Benefit to Bailee*

No person or organization, other than you, having custody of insured property will benefit from this insurance.

*J. Loss Payment*

1. We will adjust all losses with you. We will pay you unless some other person or entity is named in the policy or is legally entitled to receive payment. Loss will be payable 60 days after we receive your proof of loss (or within 90 days after the insurance adjuster files the adjuster's report signed and sworn to by you in lieu of a proof of loss) and:

a. We reach an agreement with you;

b. There is an entry of a final judgment; or

c. There is a filing of an appraisal award with us, as provided in VII.M.

2. If we reject your proof of loss in whole or in part you may:

a. Accept our denial of your claim;

b. Exercise your rights under this policy; or

c. File an amended proof of loss as long as it is filed within 60 days of the date of the loss.

*K. Abandonment*

You may not abandon damaged or undamaged insured property to us.

*L. Salvage*

We may permit you to keep damaged insured property after a loss, and we will reduce the amount of the loss proceeds payable to you under the policy by the value of the salvage.

*M. Appraisal*

If you and we fail to agree on the actual cash value of the damaged property so as to determine the amount of loss, either may demand an appraisal of the loss. In this event, you and we will each choose a competent and impartial appraiser within 20 days after receiving a written request from the other. The two appraisers will choose an umpire. If they cannot agree upon an umpire within 15 days, you or we may request that the choice be made by a judge of a court of record in the state where the insured property is located. The appraisers will separately state the actual cash value and the amount of loss to each item. If the appraisers submit a written report of an agreement to us, the amount agreed upon will be the amount of loss. If they fail to agree, they will submit their differences to the umpire. A decision agreed to by any two will set the amount of actual cash value and loss.

Each party will:

1. Pay its own appraiser; and

2. Bear the other expenses of the appraisal and umpire equally.

*N. Mortgage Clause*

1. The word ''mortgagee'' includes trustee.

2. Any loss payable under Coverage A—Building Property will be paid to any mortgagee of whom we have actual notice, as well as any other mortgagee or loss payee determined to exist at the time of loss, and you, as interests appear. If more than one mortgagee is named, the order of payment will be the same as the order of precedence of the mortgages.

3. If we deny your claim, that denial will not apply to a valid claim of the mortgagee, if the mortgagee:

a. Notifies us of any change in the ownership or occupancy, or substantial change in risk of which the mortgagee is aware;

b. Pays any premium due under this policy on demand if you have neglected to pay the premium; and

c. Submits a signed, sworn proof of loss within 60 days after receiving notice from us of your failure to do so.

4. All terms of this policy apply to the mortgagee.

5. The mortgagee has the right to receive loss payment even if the mortgagee has started foreclosure or similar action on the building.

6. If we decide to cancel or not renew this policy, it will continue in effect for the benefit of the mortgagee only for 30 days after we notify the mortgagee of the cancellation or non-renewal.

7. If we pay the mortgagee for any loss and deny payment to you, we are subrogated to all the rights of the mortgagee granted under the mortgage on the property. Subrogation will not impair the right of the mortgagee to recover the full amount of the mortgagee's claim.

*O. Suit Against Us*

You may not sue us to recover money under this policy unless you have complied with all the requirements of the policy. If you do sue, you must start the suit within one year of the date of the written denial of all or part of the claim, and you must file the suit in the United States District Court of the district in which the insured property was located at the time of loss. This requirement applies to any claim that you may have under this policy and to any dispute that you may have arising out of the handling of any claim under the policy.

*P. Subrogation*

Whenever we make a payment for a loss under this policy, we are subrogated to your

right to re-cover for that loss from any other person. That means that your right to recover for a loss that was partly or totally caused by someone else is automatically transferred to us, to the extent that we have paid you for the loss. We may require you to acknowledge this transfer in writing. After the loss, you may not give up our right to recover this money or do anything that would prevent us from recovering it. If you make any claim against any person who caused your loss and recover any money, you must pay us back first before you may keep any of that money.

*Q. Continuous Lake Flood*

1. If an insured building has been flooded by rising lake waters continuously for 90 days or more and it appears reasonably certain that a continuation of this flooding will result in an insured loss to the insured building equal to or greater than the building policy limits plus the deductible or the maximum payable under the policy for any one building loss, we will pay you the lesser of these two amounts without waiting for the further damage to occur if you sign a release agreeing:

a. To make no further claim under this policy;

b. Not to seek renewal of this policy;

c. Not to apply for any flood insurance under the Act for property at the described location;

d. Not to seek a premium refund for current or prior terms.

If the policy term ends before the insured building has been flooded continuously for 90 days, the provisions of this paragraph Q.1 will apply when the insured building suffers a covered loss before the policy term ends.

2. If your insured building is subject to continuous lake flooding from a closed basin lake, you may elect to file a claim under either paragraph Q.1 above or Q.2 (A ''closed basin lake'' is a natural lake from which water leaves primarily through evaporation and whose surface area now exceeds or has exceeded one square mile at any time in the recorded past. Most of the nation's closed basin lakes are in the western half of the United States where annual evaporation exceeds annual precipitation and where lake levels and surface areas are subject to considerable fluctuation due to wide variations in the climate. These lakes may overtop their basins on rare occasions.) Under this paragraph Q.2, we will pay your claim as if the building is a total loss even though it has not been continuously inundated for 90 days, subject to the following conditions:

a. Lake floodwaters must damage or imminently threaten to damage your building.

b. Before approval of your claim, you must:

(1) Agree to a claim payment that reflects your buying back the salvage on a negotiated basis; and

(2) Grant the conservation easement described in FEMA's ''Policy Guidance for Closed Basin Lakes'' to be recorded in the office of the local recorder of deeds. FEMA, in consultation with the community in which the property is located, will identify on a map an area or areas of special consideration (ASC) in which there is a potential for flood damage from continuous lake flooding. FEMA will give the community the agreed-upon map showing the ASC. This easement will only apply to that portion of the property in the ASC. It will allow certain agricultural and recreational uses of the land. The only structures it will allow on any portion of the property within the ASC are certain simple agricultural and recreational structures. If any of these allowable structures are insurable buildings under the NFIP and are insured under the NFIP, they will not be eligible for the benefits of this paragraph Q.2. If a U.S. Army Corps of Engineers certified flood control project or otherwise certified flood control project later protects the property, FEMA will, upon request, amend the ASC to remove areas protected by those projects. The restrictions of the easement will then no longer apply to any portion of the property removed from the ASC; and

(3) Comply with paragraphs Q.1.a through Q.1.d above.

c. Within 90 days of approval of your claim, you must move your building to a new location outside the ASC. FEMA will give you an additional 30 days to move if you show there is sufficient reason to extend the time.

d. Before the final payment of your claim, you must acquire an elevation certificate and a floodplain development permit from the local floodplain administrator for the new location of your building.

e. Before the approval of your claim, the community having jurisdiction over your building must:

(1) Adopt a permanent land use ordinance, or a temporary moratorium for a period not to exceed 6 months to be followed immediately by a permanent land use ordinance that is consistent with the provisions specified in the easement required in paragraph Q.2.b above.

(2) Agree to declare and report any violations of this ordinance to FEMA so that under Section 1316 of the National Flood Insurance Act of 1968, as amended, flood insurance to the building can be denied; and

(3) Agree to maintain as deed-restricted, for purposes compatible with open space or agricultural or recreational use only, any affected property the community acquires an interest in. These deed restrictions must be consistent with the provisions of paragraph Q.2.b above, except that, even if a certified project protects the property, the land use restrictions continue to apply if the property was acquired under the Hazard Mitigation Grant Program or the Flood Mitigation Assistance Program. If a non-profit land trust organization receives the property as a donation, that organization must maintain the property as deed-restricted, consistent with the provisions of paragraph Q2.b. above.

f. Before the approval of your claim, the affected State must take all action set forth in FEMA's ''Policy Guidance for Closed Basin Lakes.''

g. You must have NFIP flood insurance coverage continuously in effect from a date established by FEMA until you file a claim under paragraph Q.2. If a subsequent owner buys NFIP insurance that goes into effect within 60 days of the date of transfer of title, any gap in coverage during that 60-day period will not be a violation of this continuous coverage requirement. For the purpose of honoring a claim under this paragraph Q.2, we will not consider to be in effect any increased coverage that became effective after the date established by FEMA. The exception to this is any in-creased coverage in the amount suggested by your insurer as an inflation adjustment.

h. This paragraph Q.2 will be in effect for a community when the FEMA Regional Administrator for the affected region provides to the community, in writing, the following:

(1) Confirmation that the community and the State are in compliance with the conditions in paragraphs Q.2.e and Q.2.f above, and

(2) The date by which you must have flood insurance in effect.

*R. Loss Settlement*

We will pay the least of the following amounts after application of the deductible:

1. The applicable amount of insurance under this policy;

2. The actual cash value; or

3. The amount it would cost to repair or replace the property with material of like kind and quality within a reasonable time after the loss.

**VIII. Policy Nullification, Cancellation, and Non-Renewal**

*A. Policy Nullification for Fraud, Misrepresentation, or Making False Statements*

1. With respect to all insureds under this policy, this policy is void and has no legal force and effect if at any time, before or after a loss, you or any other insured or your agent have, with respect to this policy or any other NFIP insurance:

a. Concealed or misrepresented any material fact or circumstance;

b. Engaged in fraudulent conduct; or

c. Made false statements.

2. Policies voided under A.1 cannot be renewed or replaced by a new NFIP policy.

3. Policies are void as of the date the acts described in A.1 above were committed.

4. Fines, civil penalties, and imprisonment under applicable Federal laws may also apply to the acts of fraud or concealment described above.

*B. Policy Nullification for Reasons Other Than Fraud*

1. This policy is void from its inception, and has no legal force or effect, if:

a. The property listed on the application is located in a community that was not participating in the NFIP on this policy's inception date and did not join or reenter the program during the policy term and before the loss occurred;

b. The property listed on the application is otherwise not eligible for coverage under the NFIP at the time of the initial application;

c. You never had an insurable interest in the property listed on the application;

d. You provided an agent with an application and payment, but the payment did not clear; or

e. We receive notice from you, prior to the policy effective date, that you have

determined not to take the policy and you are not subject a requirement to obtain and maintain flood insurance pursuant to any statute, regulation, or contract.

2. In such cases, you will be entitled to a full refund of all premium, fees, and surcharges received. However, if a claim was paid for a policy that is void, the claim payment must be returned to FEMA or offset from the premiums to be refunded before the refund will be processed.

*C. Cancellation of the Policy by You*

1. You may cancel this policy in accordance with the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

2. If you cancel this policy, you may be entitled to a full or partial refund of premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

*D. Cancellation of the Policy by Us*

1. Cancellation for Underpayment of Amounts Owed on Policy. This policy will be cancelled, pursuant to VII.D.2, if it is determined that the premium amount you paid is not sufficient to buy any amount of coverage, and you do not pay the additional amount of premium owed to increase the coverage to the originally requested amount within the required time period.

2. Cancellation Due to Lack of an Insurable Interest.

a. If you no longer have an insurable interest in the insured property, we will cancel this policy. You will cease to have an insurable interest if:

(1) For building coverage, the building was sold, destroyed, or removed.

(2) For contents coverage, the contents were sold or transferred ownership, or the contents were completely removed from the described location.

b. If your policy is cancelled for this reason, you may be entitled to a partial refund of premium under the applicable rules and regulations of the NFIP.

3. Cancellation of Duplicate Policies.

a. Your property may not be insured by more than one NFIP policy, and payment for damages to your property will only be made under one policy.

b. If the property is insured by more than one NFIP policy, we will cancel all but one of the policies. The policy, or policies, will be selected for cancellation in accordance with 44 CFR 62.5 and the applicable rules and guidance of the NFIP.

c. If this policy is cancelled pursuant to VIII.D.4.b, you may be entitled to a full or partial refund of premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

4. Cancellation Due to Physical Alteration of Property.

a. If the insured building has been physically altered in such a manner that it is no longer eligible for flood insurance coverage, we will cancel this policy.

b. If your policy is cancelled for this reason, you may be entitled to a partial refund of premium under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

*E. Non-Renewal of the Policy by Us*

Your policy will not be renewed if:

1. The community where your insured property is located is suspended or stops participating in the NFIP;

2. Your building is otherwise ineligible for flood insurance under the Act;

3. You have failed to provide the information we requested for the purpose of rating the policy within the required deadline.

**IX. Liberalization Clause**

If we make a change that broadens your coverage under this edition of our policy, but does not re-quire any additional premium, then that change will automatically apply to your insurance as of the date we implement the change, provided that this implementation date falls within 60 days before or during the policy term stated on the Declarations Page.

**X. What Law Governs**

This policy and all disputes arising from the insurer's policy issuance, policy administration, or the handling of any claim under the policy are governed exclusively by the flood insurance regulations issued by FEMA, the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4001, *et seq.*), and Federal common law.

*In Witness Whereof,* we have signed this policy below and hereby enter into this Insurance Agreement.

Administrator, Federal Insurance and Mitigation Administration

■ 14. Revise Appendix A(3) to Part 61 to read as follows:

## Appendix A(3) to Part 61

**Federal Emergency Management Agency, Federal Insurance and Mitigation Administration**

**Standard Flood Insurance Policy**

**RESIDENTIAL CONDOMINIUM BUILDING ASSOCIATION POLICY**

Please read the policy carefully. The flood insurance provided is subject to limitations, restrictions, and exclusions.

**I. Agreement**

A. This policy covers only a residential condominium building in a regular program community. If the community reverts to emergency program status during the policy term and remains as an emergency program community at time of renewal, this policy cannot be renewed.

B. The Federal Emergency Management Agency (FEMA) provides flood insurance under the terms of the National Flood Insurance Act of 1968 and its amendments, and Title 44 of the Code of Federal Regulations.

C. We will pay you for direct physical loss by or from flood to your insured property if you:

1. Have paid the full amount due (including applicable premiums, surcharges, and fees);

2. Comply with all terms and conditions of this policy; and

3. Have furnished accurate information and statements.

D. We have the right to review the information you give us at any time and revise your policy based on our review.

E. This policy insures only one building. If you own more than one building, coverage will apply to the single building specifically described in the Flood Insurance Application.

F. Subject to the exception in Section I.G below, multiple policies with building coverage cannot be issued to insure a single building to one insured or to different insureds, even if issued through different NFIP insurers. Payment for damages may only be made under a single policy for building damages under Coverage A—Building Property.

G. A Dwelling Form policy with building coverage may be issued to a unit owner in a condominium building that is also insured under a Residential Condominium Building Association Policy (RCBAP). However, no more than $250,000 may be paid in combined benefits for a single unit under the Dwelling Form and the RCBAP. We will only pay for damage once. Items of damage paid for under a RCBAP cannot also be claimed under the Dwelling Form policy.

**II. Definitions**

A. In this policy, ''you'' and ''your'' refer to the named insured(s) shown on the Declarations Page of this policy. The named insured must also include the building owner if building coverage is purchased. Insured(s) includes: Any mortgagee and loss payee named in the Application and Declarations Page, as well as any other mortgagee or loss payee determined to have an existing interest at the time of loss, in the order of precedence. ''We,'' ''us,'' and ''our'' refer to the insurer.

Some definitions are complex because they are provided as they appear in the law or regulations, or result from court cases.

B. *Flood,* as used in this flood insurance policy, means:

1. A general and temporary condition of partial or complete inundation of two or more acres of normally dry land area or of two or more properties (one of which is your property) from:

a. Overflow of inland or tidal waters,

b. Unusual and rapid accumulation or runoff of surface waters from any source,

c. Mudflow.

2. Collapse or subsidence of land along the shore of a lake or similar body of water as a result of erosion or undermining caused by waves or currents of water exceeding anticipated cyclical levels which result in a flood as defined in B.1.a above.

C. The following are the other key definitions we use in this policy:

1. *Act.* The National Flood Insurance Act of 1968 and any amendments to it.

2. *Actual Cash Value.* The cost to replace an insured item of property at the time of loss, less the value of its physical depreciation.

3. *Application.* The statement made and signed by you or your agent in applying for this policy. The application gives information we use to determine the eligibility of the risk, the kind of policy to be issued, and the correct premium payment. The application is part of this flood insurance policy.

4. *Base Flood.* A flood having a one percent chance of being equaled or exceeded in any given year.

5. *Basement.* Any area of a building, including any sunken room or sunken portion of a room, having its floor below ground level on all sides.

6. *Building.*

a. A structure with two or more outside rigid walls and a fully secured roof that is affixed to a permanent site;

b. A manufactured home, also known as a mobile home, is a structure built on a permanent chassis, transported to its site in one or more sections, and affixed to a permanent foundation); or

c. A travel trailer without wheels, built on a chassis and affixed to a permanent foundation, that is regulated under the community's floodplain management and building ordinances or laws.

*Building* does not mean a gas or liquid storage tank, shipping container, or a recreational vehicle, park trailer, or other similar vehicle, except as described in C.6.c above.

7. *Cancellation.* The ending of the insurance coverage provided by this policy before the expiration date.

8. *Condominium.* That form of ownership of one or more buildings in which each unit owner has an undivided interest in common elements.

9. *Condominium Association.* The entity made up of the unit owners responsible for the maintenance and operation of:

a. Common elements owned in undivided shares by unit owners; and

b. Other buildings in which the unit owners have use rights; where membership in the entity is a required condition of ownership.

10. *Condominium Building.* A type of building for which the form of ownership is one in which each unit owner has an undivided interest in common elements of the building.

11. *Declarations Page.* A computer-generated summary of information you provided in your application for insurance. The Declarations Page also describes the term of the policy, limits of coverage, and displays the premium and our name. The Declarations Page is a part of this flood insurance policy.

12. *Deductible.* The fixed amount of an insured loss that is your responsibility and that is incurred by you before any amounts are paid for the insured loss under this policy.

13. *Described Location.* The location where the insured building or personal property are found. The described location is shown on the Declarations Page.

14. *Direct Physical Loss By or From Flood.* Loss or damage to insured property, directly caused by a flood. There must be evidence of physical changes to the property.

15. *Elevated Building.* A building that has no basement and that has its lowest elevated floor raised above ground level by foundation walls, shear walls, posts, piers, pilings, or columns.

16. *Emergency Program.* The initial phase of a community's participation in the National Flood Insurance Program. During this phase, only limited amounts of insurance are available under the Act and the regulations prescribed pursuant to the Act.

17. *Federal Policy Fee.* A flat rate charge you must pay on each new or renewal policy to defray certain administrative expenses incurred in carrying out the National Flood Insurance Program.

18. *Improvements.* Fixtures, alterations, installations, or additions comprising a part of the residential condominium building, including improvements in the units.

19. *Mudflow.* A river of liquid and flowing mud on the surface of normally dry land areas, as when earth is carried by a current of water. Other earth movements, such as landslide, slope failure, or a saturated soil mass moving by liquidity down a slope, are not mudflows.

20. *National Flood Insurance Program (NFIP).* The program of flood insurance coverage and floodplain management administered under the Act and applicable Federal regulations in Title 44 of the Code of Federal Regulations, Subchapter B.

21. *Policy.* The entire written contract between you and us. It includes:

a. This printed form;

b. The application and Declarations Page;

c. Any endorsement(s) that may be issued; and

d. Any renewal certificate indicating that coverage has been instituted for a new policy and new policy term. Only one building, which you specifically described in the application, may be insured under this policy.

22. *Pollutants.* Substances that include, but are not limited to, any solid, liquid, gaseous, or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals, and waste. ''Waste'' includes, but is not limited to, materials to be recycled, reconditioned, or reclaimed.

23. *Post-FIRM Building.* A building for which construction or substantial improvement occurred after December 31, 1974, or on or after the effective date of an initial Flood Insurance Rate Map (FIRM), whichever is later.

24. *Probation Surcharge.* A flat charge you must pay on each new or renewal policy issued covering property in a community the NFIP has placed on probation under the provisions of 44 CFR 59.24.

25. *Regular Program.* The final phase of a community's participation in the National Flood Insurance Program. In this phase, a Flood Insurance Rate Map is in effect and full limits of coverage are available under the Act and the regulations prescribed pursuant to the Act.

26. *Residential Condominium Building.* A building, condominium, containing one or more family units and in which at least 75 percent of the floor area is residential.

27. *Special Flood Hazard Area (SFHA).* An area having special flood or mudflow, and/or flood-related erosion hazards, and shown on a Flood Hazard Boundary Map or Flood Insurance Rate Map as Zone A, AO, A1–A30, AE, A99, AH, AR, AR/A, AR/AE, AR/AH, AR/AO, AR/A1–A30, V1–V30, VE, or V.

28. *Unit.* A single-family residential space in a residential condominium building.

29. *Valued Policy.* A policy in which the insured and the insurer agree on the value of the property insured, that value being payable in the event of a total loss. The Standard Flood Insurance Policy is not a valued policy.

**III. Property Covered**

*A. Coverage A—Building Property*

We insure against direct physical loss by or from flood to:

1. The residential condominium building described on the Declarations Page at the described location, including all units within the building and the improvements within the units.

2. We also insure such building property for a period of 45 days at another location, as set forth in III.C.2.b, Property Removed to Safety.

3. Additions and extensions attached to and in contact with the building by means of a rigid exterior wall, a solid load-bearing interior wall, a stairway, an elevated walkway, or a roof. At your option, additions and extensions connected by any of these methods may be separately insured. Additions and extensions attached to and in contact with the building by means of a common interior wall that is not a solid load-bearing wall are always considered part of the building and cannot be separately insured.

4. The following fixtures, machinery and equipment, including its units, which are insured under Coverage A only:

a. Awnings and canopies;

b. Blinds;

c. Carpet permanently installed over unfinished flooring;

d. Central air conditioners;

e. Elevator equipment;

f. Fire extinguishing apparatus;

g. Fire sprinkler systems;

h. Walk-in freezers;

i. Furnaces;

j. Light fixtures;

k. Outdoor antennas and aerials fastened to buildings;

l. Permanently installed cupboards, bookcases, paneling, and wallpaper;

m. Pumps and machinery for operating pumps;

n. Ventilating equipment;

o. Wall mirrors, permanently installed; and

p. In the units within the building, installed:

(1) Built-in dishwashers;

(2) Built-in microwave ovens;

(3) Garbage disposal units;

(4) Hot water heaters, including solar water heaters;

(5) Kitchen cabinets;

(6) Plumbing fixtures;

(7) Radiators;

(8) Ranges;

(9) Refrigerators; and

(10) Stoves.

5. Materials and supplies to be used for construction, alteration or repair of the insured building while the materials and supplies are stored in a fully enclosed building at the described location or on an adjacent property.

6. A building under construction, alteration, or repair at the described location.

a. If the structure is not yet walled or roofed as described in the definition for building (*see* II.B.6.a.) then coverage applies:

(1) Only while such work is in progress; or

(2) If such work is halted, only for a period of up to 90 continuous days thereafter.

b. However, coverage does not apply until the building is walled and roofed if the lowest floor, including the basement floor, of a non-elevated building or the lowest elevated floor of an elevated building is:

(1) Below the base flood elevation in Zones AH, AE, A1–30, AR, AR/AE, AR/AH, AR/A1–30, AR/A, AR/AO; or

(2) Below the base flood elevation adjusted to include the effect of wave action in Zones VE or V1–30.

The lowest floor level is based on the bottom of the lowest horizontal structural member of the floor in Zones VE or V1–V30 or top of the floor in Zones AH, AE, A1–A30, AR, AR/AE, AR/AH, AR/A1–A30, AR/A, and AR/AO.

7. A manufactured home or a travel trailer, as described in the II.C.6. If the manufactured home is in a special flood hazard area, it must be anchored in the following manner at the time of the loss:

a. By over-the-top or frame ties to ground anchors; or

b. In accordance with the manufacturer's specifications; or

c. In compliance with the community's floodplain management requirements unless it has been continuously insured by the NFIP at the same described location since September 30, 1982.

8. Items of property below the lowest elevated floor of an elevated post-FIRM building located in zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone. Coverage is limited to the following:

a. Any of the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:

(1) Central air conditioners;

(2) Cisterns and the water in them;

(3) Drywall for walls and ceilings in a basement and the cost of labor to nail it, unfinished and unfloated and not taped, to the framing;

(4) Electrical junction and circuit breaker boxes;

(5) Electrical outlets and switches;

(6) Elevators, dumbwaiters, and related equipment, except for related equipment installed below the base flood elevation after September 30, 1987;

(7) Fuel tanks and the fuel in them;

(8) Furnaces and hot water heaters;

(9) Heat pumps;

(10) Nonflammable insulation in a basement;

(11) Pumps and tanks used in solar energy systems;

(12) Stairways and staircases attached to the building, not separated from it by elevated walkways;

(13) Sump pumps;

(14) Water softeners and the chemicals in them, water filters, and faucets installed as an integral part of the plumbing system;

(15) Well water tanks and pumps;

(16) Required utility connections for any item in this list; and

(17) Footings, foundations, posts, pilings, piers, or other foundation walls and anchorage systems required to support a building.

b. Clean-up.

*B. Coverage B—Personal Property*

1. If you have purchased personal property coverage, we insure, subject to B.2 and B.3 below, against direct physical loss by or from flood to personal property that is inside the fully enclosed insured building and is:

a. Owned by the unit owners of the condominium association in common, meaning property in which each unit owner has an undivided ownership interest; or

b. Owned solely by the condominium association and used exclusively in the conduct of the business affairs of the condominium association.

2. We also insure such personal property for 45 days while stored at a temporary location, as set forth in III.C.2.b, Property Removed to Safety.

3. Coverage for personal property includes the following property, subject to B.1. above, which is covered under Coverage B only:

a. Air conditioning units, portable or window type;

b. Carpets, not permanently installed, over unfinished flooring;

c. Carpets over finished flooring;

d. Clothes washers and dryers;

e. ''Cook-out'' grills;

f. Food freezers, other than walk-in, and food in any freezer;

g. Outdoor equipment and furniture stored inside the insured building;

h. Ovens and the like; and

i. Portable microwave ovens and portable dishwashers.

4. Coverage for items of property in a building enclosure below the lowest elevated floor of an elevated post-FIRM building located in zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone, is limited to the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:

a. Air conditioning units, portable or window type;

b. Clothes washers and dryers; and

c. Food freezers, other than walk-in, and food in any freezer.

5. Special Limits. We will pay no more than $2,500 for any one loss to one or more of the following kinds of personal property:

a. Artwork, photographs, collectibles, or memorabilia, including but not limited to, porcelain or other figures, and sports cards;

b. Rare books or autographed items;

c. Jewelry, watches, precious and semi-precious stones, or articles of gold, silver, or platinum;

d. Furs or any article containing fur which represents its principal value.

6. We will pay only for the functional value of antiques.

*C. Coverage C—Other Coverages*

1. Debris Removal.

a. We will pay the expense to remove non-owned debris that is on or in insured property and debris of insured property anywhere.

b. If you or a member of your household perform the removal work, the value of your work will be based on the Federal minimum wage.

c. This coverage does not increase the Coverage A or Coverage B limit of liability.

2. Loss Avoidance Measures.

a. Sandbags, Supplies, and Labor.

(1) We will pay up to $1,000 for costs you incur to protect the insured building from a flood or imminent danger of flood, for the following:

(a) Your reasonable expenses to buy:

(i) Sandbags, including sand to fill them;

(ii) Fill for temporary levees;

(iii) Pumps; and

(iv) Plastic sheeting and lumber used in connection with these items.

(b) The value of work, at the Federal minimum wage, that you perform.

(2) This coverage for Sandbags, Supplies and Labor only applies if damage to insured property by or from flood is imminent and the threat of flood damage is apparent enough to lead a person of common prudence to anticipate flood damage. One of the following must also occur:

(a) A general and temporary condition of flooding in the area near the described location must occur, even if the flood does not reach the building; or

(b) A legally authorized official must issue an evacuation order or other civil order for the community in which the building is located calling for measures to preserve life and property from the peril of flood.

b. Property Removed to Safety.

(1) We will pay up to $1,000 for the reasonable expenses you incur to move insured property to a place other than the described location that contains the property in order to protect it from flood or the imminent danger of flood. Reasonable expenses include the value of work, at the Federal minimum wage, you or a member of your household perform.

(2) If you move insured property to a location other than the described location that contains the property, in order to protect it from flood or the imminent danger of flood, we will cover such property while at that location for a period of 45 consecutive days from the date you begin to move it there.

(3) The personal property that is moved must be placed in a fully enclosed building or otherwise reasonably protected from the elements. Any property removed, including a moveable home described in II.6.b and c, must be placed above ground level or outside of the special flood hazard area

(4) This coverage does not increase the Coverage A or Coverage B limit of liability.

*D. Coverage D—Increased Cost of Compliance*

1. *General.*

This policy pays you to comply with a State or local floodplain management law or ordinance affecting repair or reconstruction of a building suffering flood damage. Compliance activities eligible for payment are: elevation, floodproofing, relocation, or demolition (or any combination of these activities) of your building. Eligible floodproofing activities are limited to:

a. Non-residential buildings.

b. Residential buildings with basements that satisfy FEMA's standards published in

the Code of Federal Regulations [44 CFR 60.6 (b) or (c)].

2. *Limit of Liability.*

We will pay you up to $30,000 under this Coverage D (Increased Cost of Compliance), which only applies to policies with building coverage (Coverage A). Our payment of claims under Coverage D is in addition to the amount of coverage which you selected on the application and which appears on the Declarations Page. But, the maximum you can collect under this policy for both Coverage A—Building Property and Coverage D—Increased Cost of Compliance cannot exceed the maximum permitted under the Act. We do not charge a separate deductible for a claim under Coverage D.

3. *Eligibility.*

a. A building covered under Coverage A (Building Property) sustaining a loss caused by a flood as defined by this policy must:

(1) Be a ''repetitive loss building.'' A repetitive loss building is one that meets the following conditions:

(a) The building is insured by a contract of flood insurance issued under the NFIP.

(b) The building has suffered flood damage on two occasions during a 10-year period which ends on the date of the second loss.

(c) The cost to repair the flood damage, on average, equaled or exceeded 25 percent of the market value of the building at the time of each flood loss.

(d) In addition to the current claim, the NFIP must have paid the previous qualifying claim, and the State or community must have a cumulative, substantial damage provision or repetitive loss provision in its floodplain management law or ordinance being enforced against the building; or

(2) Be a building that has had flood damage in which the cost to repair equals or exceeds 50 percent of the market value of the building at the time of the flood. The State or community must have a substantial damage provision in its floodplain management law or ordinance being enforced against the building.

b. This Coverage D pays you to comply with State or local floodplain management laws or ordinances that meet the minimum standards of the National Flood Insurance Program found in the Code of Federal Regulations at 44 CFR 60.3. We pay for compliance activities that exceed those standards under these conditions:

(1) 3.a.1 above.

(2) Elevation or floodproofing in any risk zone to preliminary or advisory base flood elevations provided by FEMA which the State or local government has adopted and is enforcing for flood-damaged buildings in such areas. (This includes compliance activities in B, C, X, or D zones which are being changed to zones with base flood elevations. This also includes compliance activities in zones where base flood elevations are being increased, and a flood-damaged building must comply with the higher advisory base flood elevation.) Increased Cost of Compliance coverage does not apply to situations in B, C, X, or D zones where the community has derived its own elevations and is enforcing elevation or floodproofing requirements for flood-damaged buildings to elevations derived solely by the community.

(3) Elevation or floodproofing above the base flood elevation to meet State or local ''freeboard'' requirements, *i.e.,* that a building must be elevated above the base flood elevation.

c. Under the minimum NFIP criteria at 44 CFR 60.3(b)(4), States and communities must require the elevation or floodproofing of buildings in unnumbered A zones to the base flood elevation where elevation data is obtained from a Federal, State, or other source. Such compliance activities are also eligible for Coverage D.

d. Coverage D will pay for the incremental cost, after demolition or relocation, of elevating or floodproofing a building during its rebuilding at the same or another site to meet State or local floodplain management laws or ordinances, subject to Exclusion D.5.g below relating to improvements.

e. Coverage D will pay to bring a flood-damaged building into compliance with State or local floodplain management laws or ordinances even if the building had received a variance before the present loss from the applicable floodplain management requirements.

4. *Conditions.*

a. When a building covered under Coverage A—Building Property sustains a loss caused by a flood, our payment for the loss under this Coverage D will be for the increased cost to elevate, floodproof, relocate, or demolish (or any combination of these activities) caused by the enforcement of current State or local floodplain management ordinances or laws. Our payment for eligible demolition activities will be for the cost to demolish and clear the site of the building debris or a portion thereof caused by the enforcement of current State or local floodplain management ordinances or laws. Eligible activities for the cost of clearing the site will include those necessary to discontinue utility service to the site and ensure proper abandonment of on-site utilities.

b. When the building is repaired or rebuilt, it must be intended for the same occupancy as the present building unless otherwise required by current floodplain management ordinances or laws.

5. *Exclusions.*

Under this Coverage D (Increased Cost of Compliance) we will not pay for:

a. The cost to comply with any floodplain management law or ordinance in communities participating in the Emergency Program.

b. The cost associated with enforcement of any ordinance or law that requires any insured or others to test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of pollutants.

c. The loss in value to any insured building due to the requirements of any ordinance or law.

d. The loss in residual value of the undamaged portion of a building demolished as a consequence of enforcement of any State or local floodplain management law or ordinance.

e. Any Increased Cost of Compliance under this Coverage D:

(1) Until the building is elevated, floodproofed, demolished, or relocated on the same or to another premises; and

(2) Unless the building is elevated, floodproofed, demolished, or relocated as soon as reasonably possible after the loss, not to exceed two years.

f. Any code upgrade requirements, *e.g.,* plumbing or electrical wiring, not specifically related to the State or local floodplain management law or ordinance.

g. Any compliance activities needed to bring additions or improvements made after the loss occurred into compliance with State or local floodplain management laws or ordinances.

h. Loss due to any ordinance or law that you were required to comply with before the current loss.

i. Any rebuilding activity to standards that do not meet the NFIP's minimum requirements. This includes any situation where the insured has received from the State or community a variance in connection with the current flood loss to rebuild the property to an elevation below the base flood elevation.

j. Increased Cost of Compliance for a garage or carport.

k. Any building insured under an NFIP Group Flood Insurance Policy.

l. Assessments made by a condominium association on individual condominium unit owners to pay increased costs of repairing commonly owned buildings after a flood in compliance with State or local floodplain management ordinances or laws.

6. *Other Provisions.*

a. Increased Cost of Compliance coverage will not be included in the calculation to determine whether coverage meets the coinsurance requirement for replacement cost coverage under Art. VIII.R. (''Loss Settlement'').

b. All other conditions and provisions of this policy apply.

**IV. Property Not Covered**

We do not insure any of the following:

1. Personal property not inside a building;

2. A building, and personal property in it, located entirely in, on, or over water or seaward of mean high tide if it was constructed or substantially improved after September 30, 1982;

3. Open structures, including a building used as a boathouse or any structure or building into which boats are floated, and personal property located in, on, or over water;

4. Recreational vehicles other than travel trailers described in the Definitions section (see II.C.6.c) whether affixed to a permanent foundation or on wheels;

5. Self-propelled vehicles or machines, including their parts and equipment. However, we do cover self-propelled vehicles or machines not licensed for use on public roads that are:

a. Used mainly to service the described location or

b. Designed and used to assist handicapped persons, while the vehicles or machines are inside a building at the described location;

6. Land, land values, lawns, trees, shrubs, plants, growing crops, or animals;

7. Accounts, bills, coins, currency, deeds, evidences of debt, medals, money, scrip, stored value cards, postage stamps, securities, bullion, manuscripts, or other valuable papers;

8. Underground structures and equipment, including wells, septic tanks, and septic systems;

9. Those portions of walks, walkways, decks, driveways, patios, and other surfaces, all whether protected by a roof or not, located outside the perimeter, exterior walls of the insured building;

10. Containers, including related equipment, such as, but not limited to, tanks containing gases or liquids;

11. Buildings and all their contents if more than 49 percent of the actual cash value of the building is below ground, unless the lowest level is at or above the base flood elevation and is below ground by reason of earth having been used as insulation material in conjunction with energy efficient building techniques;

12. Fences, retaining walls, seawalls, bulkheads, wharves, piers, bridges, and docks;

13. Aircraft or watercraft, or their furnishings and equipment;

14. Hot tubs and spas that are not bathroom fixtures, and swimming pools, and their equipment such as, but not limited to, heaters, filters, pumps, and pipes, wherever located;

15. Property not eligible for flood insurance pursuant to the provisions of the Coastal Barrier Resources Act and the Coastal Barrier Improvements Act of 1990 and amendments to these Acts;

16. Personal property used in connection with any incidental commercial occupancy or use of the building.

**V. Exclusions**

A. We only pay for ''direct physical loss by or from flood,'' which means that we do not pay you for:

1. Loss of revenue or profits;

2. Loss of access to the insured property or described location;

3. Loss of use of the insured property or described location;

4. Loss from interruption of business or production;

5. Any additional living expenses incurred while the insured building is being repaired or is unable to be occupied for any reason;

6. The cost of complying with any ordinance or law requiring or regulating the construction, demolition, remodeling, renovation, or repair of property, including removal of any resulting debris. This exclusion does not apply to any eligible activities we describe in Coverage D—Increased Cost of Compliance; or

7. Any other economic loss you suffer.

B. *Flood in Progress.* If this policy became effective as of the time of a loan closing, as provided by 44 CFR 61.11(b), we will not pay for a loss caused by a flood that is a continuation of a flood that existed prior to coverage becoming effective. In all other circumstances, we will not pay for a loss caused by a flood that is a continuation of a flood that existed on or before the day you submitted the application for coverage under this policy and the correct premium. We will determine the date of application using 44 CFR 611.11(f).

C. We do not insure for loss to property caused directly by earth movement even if the earth movement is caused by flood. Some examples of earth movement that we do not cover are:

1. Earthquake;

2. Landslide;

3. Land subsidence;

4. Sinkholes;

5. Destabilization or movement of land that results from accumulation of water in subsurface land areas; or

6. Gradual erosion.

We do, however, pay for losses from mudflow and land subsidence as a result of erosion that are specifically covered under our definition of flood (*see* II.B.1.c and II.B.2).

D. We do not insure for direct physical loss caused directly or indirectly by:

1. The pressure or weight of ice;

2. Freezing or thawing;

3. Rain, snow, sleet, hail, or water spray;

4. Water, moisture, mildew, or mold damage that results primarily from any condition:

a. Substantially confined to the insured building; or

b. That is within your control including, but not limited to:

(1) Design, structural, or mechanical defects;

(2) Failures, stoppages, or breakage of water or sewer lines, drains, pumps, fixtures, or equipment; or

(3) Failure to inspect and maintain the property after a flood recedes;

5. Water or water-borne material that:

a. Backs up through sewers or drains;

b. Discharges or overflows from a sump, sump pump or related equipment; or

c. Seeps or leaks on or through the insured property;

unless there is a flood in the area and the flood is the proximate cause of the sewer or drain backup, sump pump discharge or overflow, or the seepage of water;

6. The pressure or weight of water unless there is a flood in the area and the flood is the proximate cause of the damage from the pressure or weight of water;

7. Power, heating, or cooling failure unless the failure results from direct physical loss by or from flood to power, heating, or cooling equipment on the described location;

8. Theft, fire, explosion, wind, or windstorm;

9. Anything you or your agents do or conspire to do to cause loss by flood deliberately; or

10. Alteration of the insured property that significantly increases the risk of flooding.

E. We do not insure for loss to any building or personal property located on land leased from the Federal Government, arising from or incident to the flooding of the land by the Federal Government, where the lease expressly holds the Federal Government harmless under flood insurance issued under any Federal Government program.

F. We do not pay for the testing for or monitoring of pollutants unless required by law or ordinance.

**VI. Deductibles**

A. When a loss is insured under this policy, we will pay only that part of the loss that exceeds your deductible amount, subject to the limit of liability that applies. The deductible amount is shown on the Declarations Page.

However, when a building under construction, alteration, or repair does not have at least two rigid exterior walls and a fully secured roof at the time of loss, your deductible amount will be two times the deductible that would otherwise apply to a completed building.

B. In each loss from flood, separate deductibles apply to the building and personal property insured by this policy.

C. No deductible applies to:

1. III.C.2. Loss Avoidance Measures; or

2. III.D. Increased Cost of Compliance.

**VII. Coinsurance**

A. This Coinsurance Section applies only to coverage on the building.

B. We will impose a penalty on loss payment unless the amount of insurance applicable to the damaged building is:

1. At least 80 percent of its replacement cost; or

2. The maximum amount of insurance available for that building under the NFIP, whichever is less.

C. If the actual amount of insurance on the building is less than the required amount in accordance with the terms of VII.B above, then loss payment is determined as follows (subject to all other relevant conditions in this policy, including those pertaining to valuation, adjustment, settlement, and payment of loss):

1. Divide the actual amount of insurance carried on the building by the required amount of insurance.

2. Multiply the amount of loss, before application of the deductible, by the figure determined in C.1 above.

3. Subtract the deductible from the figure determined in C.2 above.

We will pay the amount determined in C.3 above, or the amount of insurance carried, whichever is less. The amount of insurance carried, if in excess of the applicable maximum amount of insurance available under the NFIP, is reduced accordingly.

*Examples*

Example #1 (Inadequate Insurance)
Replacement value of the building—$250,000
Required amount of insurance—$200,000
(80 percent of replacement value of $250,000)
Actual amount of insurance carried—
$180,000
Amount of the loss—$150,000
Deductible—$500
Step 1: 180,000/200,000 = .90
(90 percent of what should be carried.)
Step 2: 150,000 × .90 = 135,000
Step 3: 135,000 500 = 134,500

We will pay no more than $134,500. The remaining $15,500 is not covered due to the coinsurance penalty ($15,000) and application of the deductible ($500).

Example #2 (Adequate Insurance)
Replacement value of the building—$500,000
Required amount of insurance—$400,000
(80 percent of replacement value of $500,000)

Actual amount of insurance carried—
$400,000
Amount of the loss—$200,000
Deductible—$500

In this example there is no coinsurance penalty, because the actual amount of insurance carried meets the required amount. We will pay no more than $199,500 ($200,000 amount of loss minus the $500 deductible).

D. In calculating the full replacement cost of a building:

1. The replacement cost value of any covered building property will be included;

2. The replacement cost value of any building property not covered under this policy will not be included; and

3. Only the replacement cost value of improvements installed by the condominium association will be included.

**VIII. General Conditions**

*A. Pair and Set Clause*

In case of loss to an article that is part of a pair or set, we will have the option of paying you:

1. An amount equal to the cost of replacing the lost, damaged, or destroyed article, minus its depreciation, or

2. The amount that represents the fair proportion of the total value of the pair or set that the lost, damaged, or destroyed article bears to the pair or set.

*B. Other Insurance*

1. If a loss insured by this policy is also insured by other insurance that includes flood coverage not issued under the Act, we will not pay more than the amount of insurance that you are entitled to for lost, damaged, or destroyed property insured under this policy subject to the following:

a. We will pay only the proportion of the loss that the amount of insurance that applies under this policy bears to the total amount of insurance covering the loss, unless VIII.B.1.b or c immediately below applies.

b. If the other policy has a provision stating that it is excess insurance, this policy will be primary.

c. This policy will be primary (but subject to its own deductible) up to the deductible in the other flood policy (except another policy as described in VIII.B.1.b. above). When the other deductible amount is reached, this policy will participate in the same proportion that the amount of insurance under this policy bears to the total amount of both policies, for the remainder of the loss.

2. If there is a National Flood Insurance Program flood insurance policy in the name of a unit owner that covers the same loss as this policy, then this policy will be primary.

*C. Amendments, Waivers, Assignment*

This policy cannot be changed, nor can any of its provisions be waived, without the express written consent of the Federal Insurance Administrator. No action we take under the terms of this policy constitutes a waiver of any of our rights. You may assign this policy in writing when you transfer title of your property to someone else except under these conditions:

1. When this policy insures only personal property; or

2. When this policy insures a building under construction.

*D. Insufficient Premium or Rating Information*

1. Applicability. The following provisions apply to all instances where the premium paid on this policy is insufficient or where the rating information is insufficient, such as where an Elevation Certificate is not provided.

2. Reforming the Policy with Reduced Coverage. Except as otherwise provided in VIII.D.1 and VIII.D.4, if the premium we received from you was not sufficient to buy the kinds and amounts of coverage you requested, we will provide only the kinds and amounts of coverage that can be purchased for the premium payment we received.

a. For the purpose of determining whether your premium payment is sufficient to buy the kinds and amounts of coverage you requested, we will first deduct the costs of all applicable fees and surcharges.

b. If the amount paid, after deducting the costs of all applicable fees and surcharges, is not sufficient to buy any amount of coverage, your payment will be refunded. Unless the policy is reformed to increase the coverage amount to the amount originally requested pursuant to VIII.E.3, this policy will be cancelled, and no claims will be paid under this policy.

c. Coverage limits on the reformed policy will be based upon the amount of premium submitted per type of coverage, but will not exceed the amount originally requested.

3. Discovery of Insufficient Premium or Rating Information. If we discover that your premium payment was not sufficient to buy the requested amount of coverage, the policy will be reformed as described in VIII.D.2. You have the option of increasing the amount of coverage resulting from this reformation to the amount you requested as follows:

a. Insufficient Premium. If we discover that your premium payment was not sufficient to buy the requested amount of coverage, we will send you, and any mortgagee or trustee known to us, a bill for the required additional premium for the current policy term (or that portion of the current policy term following any endorsement changing the amount of coverage). If it is discovered that the initial amount charged to you for any fees or surcharges is incorrect, the difference will be added or deducted, as applicable, to the total amount in this bill.

(1) If you or the mortgagee or trustee pay the additional amount due within 30 days from the date of our bill, we will reform the policy to increase the amount of coverage to the originally requested amount, effective to the beginning of the current policy term (or subsequent date of any endorsement changing the amount of coverage).

(2) If you or the mortgagee or trustee do not pay the additional amount due within 30 days of the date of our bill, any flood insurance claim will be settled based on the reduced amount of coverage.

(3) As applicable, you have the option of paying all or part of the amount due out of a claim payment based on the originally requested amount of coverage.

b. Insufficient Rating Information. If we determine that the rating information we have is insufficient and prevents us from calculating the additional premium, we will ask you to send the required information. You must submit the information within 60 days of our request.

(1) If we receive the information within 60 days of our request, we will determine the amount of additional premium for the current policy term and follow the procedure in VIII.D.3.a above.

(2) If we do not receive the information within 60 days of our request, no claims will be paid until the requested information is provided. Coverage will be limited to the amount of coverage that can be purchased for the payments we received, as determined when the requested information is provided.

4. Coverage Increases. If we do not receive the amount requested in VIII.D.3.a or VIII.D.4.a, or the additional information requested in VIII.D.3.b or VIII.D.4.b by the date it is due, the amount of coverage under this policy can only be increased by endorsement subject to the appropriate waiting period. However, no coverage increases will be allowed until you have provided the information requested in VIII.D.3.b or VIII.D.4.b.

5. Falsifying Information. However, if we find that you or your agent intentionally did not tell us, or falsified, any important fact or circumstance or did anything fraudulent relating to this insurance, the provisions of IX.A apply.

*E. Policy Renewal*

1. This policy will expire at 12:01 a.m. on the last day of the policy term.

2. We must receive the payment of the appropriate renewal premium within 30 days of the expiration date.

3. If we find, however, that we did not place your renewal notice into the U.S. Postal Service, or if we did mail it, we made a mistake, *e.g.,* we used an incorrect, incomplete, or illegible address, which delayed its delivery to you before the due date for the renewal premium, then we will follow these procedures:

a. If you or your agent notified us, not later than one year after the date on which the payment of the renewal premium was due, of non-receipt of a renewal notice before the due date for the renewal premium, and we determine that the circumstances in the preceding paragraph apply, we will mail a second bill providing a revised due date, which will be 30 days after the date on which the bill is mailed.

b. If we do not receive the premium requested in the second bill by the revised due date, then we will not renew the policy. In that case, the policy will remain as an expired policy as of the expiration date shown on the Declarations Page.

c. In connection with the renewal of this policy, we may ask you during the policy term to recertify, on a Recertification Questionnaire that we will provide you, the rating information used to rate your most recent application for or renewal of insurance.

*F. Conditions Suspending or Restricting Insurance*

We are not liable for loss that occurs while there is a hazard that is increased by any means within your control or knowledge.

*G. Requirements in Case of Loss*

In case of a flood loss to insured property, you must:

1. Give prompt written notice to us;

2. As soon as reasonably possible, separate the damaged and undamaged property, putting it in the best possible order so that we may examine it;

3. Prepare an inventory of damaged property showing the quantity, description, actual cash value, and amount of loss. Attach all bills, receipts, and related documents;

4. Within 60 days after the loss, send us a proof of loss, which is your statement of the amount you are claiming under the policy signed and sworn to by you, and which furnishes us with the following information:

a. The date and time of loss;

b. A brief explanation of how the loss happened;

c. Your interest (for example, ''owner'') and the interest, if any, of others in the damaged property;

d. Details of any other insurance that may cover the loss;

e. Changes in title or occupancy of the insured property during the term of the policy;

f. Specifications of damaged buildings and detailed repair estimates;

g. Names of mortgagees or anyone else having a lien, charge, or claim against the insured property;

h. Details about who occupied any insured building at the time of loss and for what purpose; and

i. The inventory of damaged personal property described in G.3 above.

5. In completing the proof of loss, you must use your own judgment concerning the amount of loss and justify that amount.

6. You must cooperate with the adjuster or representative in the investigation of the claim.

7. The insurance adjuster whom we hire to investigate your claim may furnish you with a proof of loss form, and she or he may help you complete it. However, this is a matter of courtesy only, and you must still send us a proof of loss within 60 days after the loss even if the adjuster does not furnish the form or help you complete it.

8. We have not authorized the adjuster to approve or disapprove claims or to tell you whether we will approve your claim.

9. At our option, we may accept the adjuster's report of the loss instead of your proof of loss. The adjuster's report will include information about your loss and the damages you sustained. You must sign the adjuster's report. At our option, we may require you to swear to the report.

*H. Our Options After a Loss*

Options we may, in our sole discretion, exercise after loss include the following:

1. At such reasonable times and places that we may designate, you must:

a. Show us or our representative the damaged property;

b. Submit to examination under oath, while not in the presence of another insured, and sign the same; and

c. Permit us to examine and make extracts and copies of:

(1) Any policies of property insurance insuring you against loss and the deed establishing your ownership of the insured real property;

(2) Condominium association documents including the Declarations of the condominium, its Articles of Association or Incorporation, Bylaws, and rules and regulations; and

(3) All books of accounts, bills, invoices and other vouchers, or certified copies pertaining to the damaged property if the originals are lost.

2. We may request, in writing, that you furnish us with a complete inventory of the lost, damaged, or destroyed property, including:

a. Quantities and costs;

b. Actual cash values or replacement cost (whichever is appropriate);

c. Amounts of loss claimed;

d. Any written plans and specifications for repair of the damaged property that you can reasonably make available to us; and

e. Evidence that prior flood damage has been repaired.

3. If we give you written notice within 30 days after we receive your signed, sworn proof of loss, we may:

a. Repair, rebuild, or replace any part of the lost, damaged, or destroyed property with material or property of like kind and quality or its functional equivalent; and

b. Take all or any part of the damaged property at the value that we agree upon or its appraised value.

*I. No Benefit to Bailee*

No person or organization, other than you, having custody of insured property will benefit from this insurance.

*J. Loss Payment*

1. We will adjust all losses with you. We will pay you unless some other person or entity is named in the policy or is legally entitled to receive payment. Loss will be payable 60 days after we receive your proof of loss (or within 90 days after the insurance adjuster files the adjuster's report signed and sworn to by you in lieu of a proof of loss) and:

a. We reach an agreement with you;

b. There is an entry of a final judgment; or

c. There is a filing of an appraisal award with us, as provided in VIII.M.

2. If we reject your proof of loss in whole or in part you may:

a. Accept our denial of your claim;

b. Exercise your rights under this policy; or

c. File an amended proof of loss as long as it is filed within 60 days of the date of the loss.

*K. Abandonment*

You may not abandon damaged or undamaged insured property to us.

*L. Salvage*

We may permit you to keep damaged insured property after a loss, and we will reduce the amount of the loss proceeds payable to you under the policy by the value of the salvage.

*M. Appraisal*

If you and we fail to agree on the actual cash value or, if applicable, replacement cost of the damaged property so as to determine the amount of loss, then either may demand an appraisal of the loss. In this event, you and we will each choose a competent and impartial appraiser within 20 days after receiving a written request from the other. The two appraisers will choose an umpire. If they cannot agree upon an umpire within 15 days, you or we may request that the choice be made by a judge of a court of record in the state where the insured property is located. The appraisers will separately state the actual cash value, the replacement cost, and the amount of loss to each item. If the appraisers submit a written report of an agreement to us, the amount agreed upon will be the amount of loss. If they fail to agree, they will submit their differences to the umpire. A decision agreed to by any two will set the amount of actual cash value and loss, or if it applies, the replacement cost and loss.

Each party will:

1. Pay its own appraiser; and

2. Bear the other expenses of the appraisal and umpire equally.

*N. Mortgage Clause*

1. The word ''mortgagee'' includes trustee.

2. Any loss payable under Coverage A—Building Property will be paid to any mortgagee of whom we have actual notice, as well as any other mortgagee or loss payee determined to exist at the time of loss, and you, as interests appear. If more than one mortgagee is named, the order of payment will be the same as the order of precedence of the mortgages.

3. If we deny your claim, that denial will not apply to a valid claim of the mortgagee, if the mortgagee:

a. Notifies us of any change in the ownership or occupancy, or substantial change in risk of which the mortgagee is aware;

b. Pays any premium due under this policy on demand if you have neglected to pay the premium; and

c. Submits a signed, sworn proof of loss within 60 days after receiving notice from us of your failure to do so.

4. All terms of this policy apply to the mortgagee.

5. The mortgagee has the right to receive loss payment even if the mortgagee has started foreclosure or similar action on the building.

6. If we decide to cancel or not renew this policy, it will continue in effect for the benefit of the mortgagee only for 30 days after we notify the mortgagee of the cancellation or non-renewal.

7. If we pay the mortgagee for any loss and deny payment to you, we are subrogated to all the rights of the mortgagee granted under the mortgage on the property. Subrogation will not impair the right of the mortgagee to recover the full amount of the mortgagee's claim.

*O. Suit Against Us*

You may not sue us to recover money under this policy unless you have complied with all the requirements of the policy. If you do sue, you must start the suit within one year of the date of the written denial of all or part of the claim, and you must file the suit in the United States District Court of the district in which the insured property was located at the time of loss. This requirement applies to any claim that you may have under this policy and to any dispute that you may have arising out of the handling of any claim under the policy.

*P. Subrogation*

Whenever we make a payment for a loss under this policy, we are subrogated to your right to recover for that loss from any other person. That means that your right to recover for a loss that was partly or totally caused by someone else is automatically transferred to us, to the extent that we have paid you for the loss. We may require you to acknowledge this transfer in writing. After the loss, you may not give up our right to recover this money or do anything that would prevent us from recovering it. If you make any claim against any person who caused your loss and recover any money, you must pay us back first before you may keep any of that money.

*Q. Continuous Lake Flood*

1. If an insured building has been flooded by rising lake waters continuously for 90 days or more and it appears reasonably certain that a continuation of this flooding will result in an insured loss to the insured building equal to or greater than the building policy limits plus the deductible or the maximum payable under the policy for any one building loss, we will pay you the lesser of these two amounts without waiting for the further damage to occur if you sign a release agreeing:

a. To make no further claim under this policy;

b. Not to seek renewal of this policy;

c. Not to apply for any flood insurance under the Act for property at the described location;

d. Not to seek a premium refund for current or prior terms.

If the policy term ends before the insured building has been flooded continuously for 90 days, the provisions of this paragraph Q.1 will apply when the insured building suffers a covered loss before the policy term ends.

2. If your insured building is subject to continuous lake flooding from a closed basin lake, you may elect to file a claim under either paragraph Q.1 above or this paragraph Q.2 (A ''closed basin lake'' is a natural lake from which water leaves primarily through evaporation and whose surface area now exceeds or has exceeded one square mile at any time in the recorded past. Most of the nation's closed basin lakes are in the western half of the United States where annual evaporation exceeds annual precipitation and where lake levels and surface areas are subject to considerable fluctuation due to wide variations in the climate. These lakes may overtop their basins on rare occasions.) Under this paragraph Q.2, we will pay your claim as if the building is a total loss even though it has not been continuously inundated for 90 days, subject to the following conditions:

a. Lake floodwaters must damage or imminently threaten to damage your building.

b. Before approval of your claim, you must:

(1) Agree to a claim payment that reflects your buying back the salvage on a negotiated basis; and

(2) Grant the conservation easement contained in FEMA's ''Policy Guidance for Closed Basin Lakes,'' to be recorded in the office of the local recorder of deeds. FEMA, in consultation with the community in which the property is located, will identify on a map an area or areas of special consideration (ASC) in which there is a potential for flood damage from continuous lake flooding. FEMA will give the community the agreed-upon map showing the ASC. This easement will only apply to that portion of the property in the ASC. It will allow certain agricultural and recreational uses of the land. The only structures that it will allow on any portion of the property within the ASC are certain simple agricultural and recreational structures. If any of these allowable structures are insurable buildings under the NFIP and are insured under the NFIP, they will not be eligible for the benefits of this paragraph Q.2. If a U.S. Army Corps of Engineers certified flood control project or otherwise certified flood control project later protects the property, FEMA will, upon request, amend the ASC to remove areas protected by those projects. The restrictions of the easement will then no longer apply to any portion of the property removed from the ASC; and

(3) Comply with paragraphs Q.1.a through Q.1.d above.

c. Within 90 days of approval of your claim, you must move your building to a new location outside the ASC. FEMA will give you an additional 30 days to move if you show there is sufficient reason to extend the time.

d. Before the final payment of your claim, you must acquire an elevation certificate and a floodplain development permit from the local floodplain administrator for the new location of your building.

e. Before the approval of your claim, the community having jurisdiction over your building must:

(1) Adopt a permanent land use ordinance, or a temporary moratorium for a period not to exceed 6 months to be followed immediately by a permanent land use ordinance, that is consistent with the provisions specified in the easement required in paragraph Q.2.b above;

(2) Agree to declare and report any violations of this ordinance to FEMA so that under Section 1316 of the National Flood Insurance Act of 1968, as amended, flood insurance to the building can be denied; and

(3) Agree to maintain as deed-restricted, for purposes compatible with open space or agricultural or recreational use only, any affected property the community acquires an interest in. These deed restrictions must be consistent with the provisions of paragraph Q.2.b above, except that even if a certified project protects the property, the land use restrictions continue to apply if the property was acquired under the Hazard Mitigation Grant Program or the Flood Mitigation Assistance Program. If a non-profit land trust organization receives the property as a donation, that organization must maintain the property as deed-restricted, consistent with the provisions of paragraph Q.2.b above.

f. Before the approval of your claim, the affected State must take all action set forth in FEMA's ''Policy Guidance for Closed Basin Lakes.''

g. You must have NFIP flood insurance coverage continuously in effect from a date established by FEMA until you file a claim under this paragraph Q.2. If a subsequent owner buys NFIP insurance that goes into effect within 60 days of the date of transfer of title, any gap in coverage during that 60-day period will not be a violation of this continuous coverage requirement. For the purpose of honoring a claim under this paragraph Q.2, we will not consider to be in effect any increased coverage that became effective after the date established by FEMA. The exception to this is any increased coverage in the amount suggested by your insurer as an inflation adjustment.

h. This paragraph Q.2 will be in effect for a community when the FEMA Regional Administrator for the affected region provides to the community, in writing, the following:

(1) Confirmation that the community and the State are in compliance with the conditions in paragraphs Q2.e and Q.2.f above, and

(2) The date by which you must have flood insurance in effect.

*R. Loss Settlement*

1. Introduction

This policy provides three methods of settling losses: Replacement Cost, Special Loss Settlement, and Actual Cash Value. Each method is used for a different type of property, as explained in a–c below.

a. Replacement Cost Loss, Settlement described in R.2 below applies to buildings other than manufactured homes or travel trailers.

b. Special Loss Settlement, described in R.3 below applies to a residential condominium building that is a travel trailer or a manufactured home.

c. Actual Cash Value loss settlement applies to all other property covered under this policy, as outlined in R.4. below.

2. Replacement Cost Loss Settlement

a. We will pay to repair or replace a damaged or destroyed building, after application of the deductible and without deduction for depreciation, but not more than the least of the following amounts:

(1) The amount of insurance in this policy that applies to the building;

(2) The replacement cost of that part of the building damaged, with materials of like kind and quality, and for like occupancy and use; or

(3) The necessary amount actually spent to repair or replace the damaged part of the building for like occupancy and use.

b. We will not be liable for any loss on a Replacement Cost Coverage basis unless and

until actual repair or replacement of the damaged building or parts thereof, is completed.

c. If a building is rebuilt at a location other than the described location, we will pay no more than it would have cost to repair or rebuild at the described location, subject to all other terms of Replacement Cost Loss Settlement.

3. Special Loss Settlement

a. The following loss settlement conditions apply to a residential condominium building that is:

(1) A manufactured home or travel trailer, as defined in II.C.6.b and c, and

(2) at least 16 feet wide when fully assembled and has at least 600 square feet within its perimeter walls when fully assembled.

b. If such a building is totally destroyed or damaged to such an extent that, in our judgment, it is not economically feasible to repair, at least to its pre-damaged condition, we will, at our discretion, pay the least of the following amounts:

(1) The lesser of the replacement cost of the manufactured home or travel trailer or 1.5 times the actual cash value; or

(2) The Building Limit of liability shown on your Declarations Page.

c. If such a manufactured home or travel trailer is partially damaged and, in our judgment, it is economically feasible to repair it to its pre-damaged condition, we will settle the loss according to the Replacement Cost Loss Settlement conditions in R.2 above.

4. Actual Cash Value Loss Settlement

a. The types of property noted below are subject to actual cash value loss settlement:

(1) Personal property;

(2) Insured property abandoned after a loss and that remains as debris at the described location;

(3) Outside antennas and aerials, awning, and other outdoor equipment;

(4) Carpeting and pads;

(5) Appliances; and

(6) A manufactured home or mobile home or a travel trailer as defined in II.C.6.b or c that does not meet the conditions for special loss settlement in R.3 above.

b. We will pay the least of the following amounts:

(1) The applicable amount of insurance under this policy;

(2) The actual cash value, as defined in II.C.2; or

(3) The amount it would cost to repair or replace the property with material of like kind and quality within a reasonable time after the loss.

**IX. Policy Nullification, Cancellation, and Non-Renewal**

*A. Policy Nullification for Fraud, Misrepresentation, or Making False Statements*

1. With respect to all insureds under this policy, this policy is void and has no legal force and effect if at any time, before or after a loss, you or any other insured or your agent have, with respect to this policy or any other NFIP insurance:

a. Concealed or misrepresented any material fact or circumstance;

b. Engaged in fraudulent conduct; or

c. Made false statements.

2. Policies voided under A.1 cannot be renewed or replaced by a new NFIP policy.

3. Policies are void as of the date the acts described in A.1.above were committed.

4. Fines, civil penalties, and imprisonment under applicable Federal laws may also apply to the acts of fraud or concealment described above.

*B. Policy Nullification for Reasons Other Than Fraud*

1. This policy is void from its inception, and has no legal force or effect, if:

a. The property listed on the application is located in a community that was not participating in the NFIP on this policy's inception date and did not join or reenter the program during the policy term and before the loss occurred;

b. The property listed on the application is otherwise not eligible for coverage under the NFIP at the time of the initial application;

c. You never had an insurable interest in the property listed on the application;

d. You provided an agent with an application and payment, but the payment did not clear; or

e. We receive notice from you, prior to the policy effective date, that you have determined not to take the policy and you are not subject a requirement to obtain and maintain flood insurance pursuant to any statute, regulation, or contract.

2. In such cases, you will be entitled to a full refund of all premium, fees, and surcharges received. However, if a claim was paid for a policy that is void, the claim payment must be returned to FEMA or offset from the premiums to be refunded before the refund will be processed.

*C. Cancellation of the Policy by You*

1. You may cancel this policy in accordance with the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

2. If you cancel this policy, you may be entitled to a full or partial refund of premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

*D. Cancellation of the Policy by Us*

1. Cancellation for Underpayment of Amounts Owed on This Policy. This policy will be cancelled, pursuant to VIII.D.2, if it is determined that the premium amount you paid is not sufficient to buy any amount of coverage, and you do not pay the additional amount of premium owed to increase the coverage to the originally requested amount within the required time period.

2. Cancellation Due to Lack of an Insurable Interest.

a. If you no longer have an insurable interest in the insured property, we will cancel this policy. You will cease to have an insurable interest if:

(1) For building coverage, the building was sold, destroyed, or removed.

(2) For contents coverage, the contents were sold or transferred ownership, or the contents were completely removed from the described location.

b. If your policy is cancelled for this reason, you may be entitled to a partial refund of premium under the applicable rules and regulations of the NFIP.

3. Cancellation of Duplicate Policies.

a. Except as allowed under Article I.F, your property may not be insured by more than one NFIP policy, and payment for damages to your property will only be made under one policy.

b. Except as allowed under Article I.G, if the property is insured by more than one NFIP policy, we will cancel all but one of the policies. The policy, or policies, will be selected for cancellation in accordance with 44 CFR 62.5 and the applicable rules and guidance of the NFIP.

c. If this policy is cancelled pursuant to VIII.D.3.a, you may be entitled to a full or partial refund of premium, surcharges, or fees under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

4. Cancellation Due to Physical Alteration of Property.

a. If the insured building has been physically altered in such a manner that it is no longer eligible for flood insurance coverage, we will cancel this policy.

b. If your policy is cancelled for this reason, you may be entitled to a partial refund of premium under the terms and conditions of this policy and the applicable rules and regulations of the NFIP.

*E. Non-Renewal of the Policy by Us*

Your policy will not be renewed if:

1. The community where your insured property is located is suspended or stops participating in the NFIP;

2. Your building is otherwise ineligible for flood insurance under the Act;

3. You have failed to provide the information we requested for the purpose of rating the policy within the required deadline.

**X. Liberalization Clause**

If we make a change that broadens your coverage under this edition of our policy, but does not require any additional premium, then that change will automatically apply to your insurance as of the date we implement the change, provided that this implementation date falls within 60 days before or during the policy term stated on the Declarations Page.

**XI. What Law Governs**

This policy and all disputes arising from the insurer's policy issuance, policy administration, or the handling of any claim under the policy are governed exclusively by the flood insurance regulations issued by FEMA, the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4001, *et seq.*), and Federal common law.

*In Witness Whereof,* we have signed this policy below and hereby enter into this Insurance Agreement.

Administrator, Federal Insurance and Mitigation Administration

## PART 62—SALE OF INSURANCE AND ADJUSTMENT OF CLAIMS

■ 15. Revise the authority citation for Part 62 to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.;* 6 U.S.C. 101 *et seq.*

■ 16. Revise § 62.3 to read as follows:

### § 62.3 Servicing Agent.

(a) Pursuant to sections 1345 and 1346 of the Act, the Federal Insurance Administrator may enter into an agreement with a servicing agent to authorize it to assist in issuing flood insurance policies under the Program in communities designated by the Federal Insurance Administrator and to accept responsibility for delivery of policies and payment of claims for losses as prescribed by and at the discretion of the Federal Insurance Administrator.

(b) The servicing agent will arrange for the issuance of flood insurance to any person qualifying for such coverage under parts 61 and 64 of this subchapter who submits an application to the servicing agent in accordance with the terms and conditions of the contract between the Agency and the servicing agent.

■ 17. Revise § 62.5 to read as follows:

### § 62.5 Nullifications, Cancellations, and Premium Refunds.

(a) Nullification.

(1) Property Ineligible at Time of Application. FEMA will void a policy for a property that was not eligible for coverage at the time of the initial application from the commencement of the policy. FEMA must pay the policyholder a refund of all premium, fees, and surcharges paid from the date of commencement of the policy, but no more than 5 years prior to the date of date of receipt of verifiable evidence that the property was ineligible for coverage at the time of the initial application. If FEMA paid a claim for an ineligible property, the policyholder must return the claim payment to FEMA, or offset the payment from the premiums to be refunded, before FEMA will process the refund.

(2) Property Later Becomes Ineligible. FEMA may not renew a policy for a property that was eligible for coverage at the time of the initial application, but later became ineligible for coverage. In such instances, the FEMA must nullify the policy from the first renewal date after the property became ineligible. FEMA must refund all premium, fees, and surcharges paid from the first renewal date after the property became ineligible, but no more than 5 years prior to the date of receipt of verifiable evidence that the property was eligible for coverage at the time of the initial application, but later became ineligible for coverage. If FEMA paid a claim for a property after it became ineligible for coverage, the policyholder must return the claim payment to FEMA or FEMA must offset the amount of claim payment from the premiums to be refunded before FEMA may process the refund.

(3) Nullification Prior to Policy Effective Date. If FEMA nullifies a policy prior to the policy effective date, that policy will be void from the commencement of the nullified policy term. In such case, FEMA will refund all premium, fees, and surcharges paid for the current policy term only. If FEMA paid a claim for a policy that was improperly issued, the policyholder must return the claim payment to FEMA or FEMA must offset the amount of claim payment from the premiums to be refunded before the NFIP may process the refund.

(b) Cancellation Due to Lack of an Insurable Interest. If the policyholder had an insurable interest, but no longer has an insurable interest, in the insured property, FEMA must cancel the policy on the insured property. If FEMA cancels a policy for this reason, FEMA must refund the policyholder a pro rata share of the premium from the date the policyholder lost an insurable interest in the property, but no more than 5 years prior to the date of the cancellation request. FEMA must pay the policyholder a refund of all fees or surcharges for any full policy term during which the policyholder had no insurable interest in the insured property, but no more than 5 years prior to the date of the cancellation request. A policyholder ceases to have an insurable interest if:

(1) For building coverage, the building was sold, destroyed, or removed.

(2) For contents coverage, the contents were sold or transferred ownership, or the contents were completely removed from the described location.

(c) No Insurance Coverage Requirement. A policyholder may cancel a policy if the policyholder was subject to a requirement by a lender, loss payee, or other Federal agency to obtain and maintain flood insurance pursuant to statute, regulation, or contract, but there is no longer such a requirement. The policyholder will receive a refund of a pro rata share of the premium for the current policy term only, calculated from the date of the cancellation request, but will not receive a refund of any fees or surcharges.

(d) Establishment of a Common Expiration Date. A policyholder may purchase a new policy and cancel an existing policy in order to establish a common expiration date between flood insurance coverage and other coverage. The policyholder will receive a refund of a pro rata share of the premium calculated from the effective date of the new policy to the end date of the previous policy. The policyholder will not receive a refund of any fees or surcharges. In order to rewrite and cancel the policy, the following conditions must apply:

(1) The new policy must be written with the same company for the same or higher amount of coverage. If the policy is written for a higher amount or different type of coverage, the waiting period in § 61.11 will apply.

(2) The other insurance coverage for which the common expiration date is being established must be for coverage on the same building that is insured by the flood policy being cancelled and rewritten.

(3) The coverage for the new policy must be effective prior to the cancelling the existing policy.

(e) Cancelation or Nullification of Duplicate NFIP Policies.

(1) Generally.

(i) Except as described in 44 CFR 62.5(e)(2), if an insured property is covered by more than one NFIP policy not in accordance with applicable regulations and the Standard Flood Insurance Policy, FEMA must nullify the policy with the later effective date. The policy with the earlier effective date will continue. The policyholder will receive a pro rata refund of all premium for the nullified policy from the effective date of the nullified policy, but no more than 5 years prior to the date of receipt of verifiable evidence that the insured property is covered by more than one NFIP policy. The policyholder will receive a refund of all fees or surcharges for any full policy term during which the policyholder was covered by more than one policy, but no more than 5 years prior to the date of receipt of verifiable evidence that the insured property is covered by more than one NFIP policy.

(ii) If both polices have the same policy effective date, the policyholder may choose which policy will remain in effect, and the policyholder will receive a refund of all premium, fees, and surcharges for the cancelled policy from the effective date of the cancelled policy, but no more than 5 years prior to the date of receipt of verifiable evidence that the insured property is covered by more than one NFIP policy.

(2) Exceptions. In the following cases, the policyholder may maintain the policy with the later policy effective

date while cancelling the policy with the earlier policy effective date:

(i) Earlier Policy Expired—The policy with the earlier effective date has expired for more than 30 days. In such cases, the policyholder will receive a refund of a pro rata share of the premium, calculated from the effective date of the policy with the later effective date to the end date of the policy with the earlier effective date, but no more than 5 years prior to the date of cancellation. The policyholder will also receive a refund of all fees and surcharges for any full policy terms during which the insured property is covered by both policies, but no more than 5 years prior to the date of the cancellation request.

(ii) Group Flood Insurance Policy (GFIP)—The policy with the earlier policy effective date is a Group Flood Insurance Policy. In such cases, there will be no refund of any premium, fees, or surcharges.

(iii) Cancellations to Establish a Common Expiration Date—The policy with the earlier effective date is cancelled to establish a common policy expiration date pursuant to paragraph (d) of this section. In such cases, refunds will be provided in accordance with paragraph (d) of this section.

(iv) Force-Placed Policy—The policy with the earlier effective date was force placed pursuant to 42 U.S.C. 4012a using the NFIP's Mortgage Portfolio Protection Program. In such cases, the policyholder will receive a refund of the pro rata share of the premium calculated from the policy effective date of the new policy to the expiration date of the cancelled policy. There will be no refund of any fees or surcharges.

(v) Condominium Unit Covered by a Dwelling Form Policy and an RCBAP—The policy with the earlier effective date is a Dwelling Form Policy with building coverage on a condominium unit that is also covered by a Residential Condominium Building Association Policy (RCBAP) that is issued at the statutory maximum coverage limit for buildings. In such cases, the policyholder will receive a refund of a pro rata share of the premium for the building coverage issued under the Dwelling Form policy, as calculated from the effective date of the RCBAP policy to the end date of the Dwelling Form policy. The policyholder will also receive a refund of all fees and surcharges for any full policy terms during which the condominium unit is covered by both a Dwelling Form policy and an RCBAP in which the coverage equals the statutory maximum coverage limits for buildings, but no more than 5 years prior to the date of the cancellation request.

(f) Other Cancellations and Nullifications. Except as indicated below, FEMA will not refund premiums, assessments, fees, or surcharges if FEMA cancels a policy for any of the following reasons:

(1) Fraud. FEMA will cancel a policy for fraud committed by the policyholder or the agent. FEMA may cancel a policy for misrepresentation of a material fact by the policyholder or agent. Such cancellations will take effect as of the date of the fraudulent act or material misrepresentation of fact.

(2) Administrative Cancellation. FEMA may cancel and rewrite a policy to correct an administrative error, such as when the policy is written with the wrong policy effective date. In such cases, FEMA will apply any premium, assessments, fees, or surcharges to the new policy. FEMA will refund any excess premium, fees, surcharges, or assessments paid.

(3) Nullification for Properties Ineligible Due to Physical Alteration of Property. A policy insuring a building or its contents, or both, may be cancelled if the building has been physically altered in such a manner that the building and its contents are no longer eligible for flood insurance coverage. The policyholder will receive a refund of a pro rata share of the premium for the current policy term only, but the policyholder will not receive a refund of any fees or surcharges.

■ 18. Revise § 62.6 to read as follows:

**§ 62.6 Brokers and Agents Writing NFIP Policies through the NFIP Direct Servicing Agent.**

(a) A broker or agent selling policies of flood insurance placed with the NFIP at the offices of its servicing agent must be duly licensed by the state insurance regulatory authority in the state in which the property is located.

(b) The earned commission which will be paid to any property or casualty insurance agent or broker, with respect to each policy or renewal the agent duly procures on behalf of the insured, in connection with policies of flood insurance placed with the NFIP at the offices of its servicing agent, but not with respect to policies of flood insurance issued pursuant to Subpart C of this Part, will not be less than $10 and is computed as follows:

* * * * *

**§ 62.22 [Amended]**

■ 19. In § 62.22, amend paragraph (a) by removing the two instances of the words ''Federal Insurance Administration'' and replacing them with ''Federal Insurance and Mitigation Administration.''

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

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Part III

## Department of Transportation

Federal Transit Administration

FTA Fiscal Year 2018 Apportionments, Allocations, Program Information and Guidance; Notice

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

### FTA Fiscal Year 2018 Apportionments, Allocations, Program Information and Guidance

**AGENCY:** Federal Transit Administration (FTA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice provides priorities for programs in fiscal year (FY) 2018, announces the full-year apportionments and allocations for grant programs, provides contract authority, and describes plans for several competitive programs.

**FOR FURTHER INFORMATION CONTACT:** For general information about this notice contact Kimberly Sledge, Director, Office of Transit Programs, at (202) 366–2053. Please contact the appropriate FTA Regional Office for any specific requests for information or technical assistance. FTA Regional Office contact information is available on FTA's website: *www.transit.dot.gov.* An FTA headquarters contact for each major program area is included in the discussion of that program in the text of this notice. FTA recommends stakeholders subscribe on FTA's website *www.transit.dot.gov* to receive email notifications when new information is available.

**SUPPLEMENTARY INFORMATION:**

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## I. Overview

This document contains important information about FTA programs, statutes (49 U.S.C. 5301, *et seq.*) and policy priorities. In addition, this document provides notice to stakeholders that FTA is apportioning the full Fiscal Year (FY) 2018 authorized contract authority through September 30, 2018 for FTA formula and competitive programs pursuant to Division L-Transportation, Housing and Urban Development, and Related Agencies Appropriations Act (Pub. L. 115–141).

For each FTA program, FTA has provided information on the FY 2018 authorized funding levels, the basis for apportionment or allocation of funds, requirements specific to the program, the period of availability of funds, and other program information. A separate section provides information on pre-award authority as well as other requirements and guidance applicable to FTA programs and grant administration. Finally, the notice includes a reference to tables on FTA's website that show new contract authority apportioned and made available through September 30, 2018.

Information in this document includes references to the existing FTA program guidance and circulars. Some information in FTA's guidance documents and circulars may have been superseded by new provisions in the Fixing America's Surface Transportation (FAST) Act, but these guidance documents and circulars remain a resource for program management in most areas. FTA intends to revise the guidance and circulars, as appropriate.

## II. FY 2018 Funding for FTA Programs

### *A. Funding Based on Division L-Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2018*

Division L-Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2018 (Pub. L. 115–141) (''Consolidated Appropriations Act, 2018'') makes funding available through September 30, 2018. Current funding availability for each program is identified in section IV of this notice and in Table 1 located on FTA's FY 2018 Apportionment web page: *www.transit.dot.gov/funding/apportionments.*

### *B. Oversight Takedown*

49 U.S.C. 5338(f) (all subsequent statutory references are to title 49, United States Code) provides for the following oversight takedowns of FTA programs: 0.5 percent of Metropolitan and Statewide Planning funds, 0.75 percent of Urbanized Area Formula Grant funds, 1 percent of Fixed Guideway Capital Investment Grants funds, 0.5 percent of Formula Grants for the Enhanced Mobility of Seniors and Individuals with Disabilities funds, 0.5 percent of Formula Grants for Rural Areas funds, 1 percent of State of Good Repair Formula Grants funds, 0.75 percent for Grants for Buses and Bus Facilities funds, and 1 percent of Capital and Preventive Maintenance Projects for grants to the Washington Metropolitan Area Transit Authority. The funds are used to provide necessary oversight activities, such as oversight of the construction of any major capital project receiving Federal transit assistance; to conduct State Safety Oversight, drug and alcohol, civil rights, procurement systems, management, planning certification, and financial management

reviews and audits; evaluations and analyses of grantee-specific problems and issues; for salaries and benefits of FTA employees performing certain oversight activities; and to generally provide technical assistance and correct deficiencies identified in compliance reviews and audits.

*C. FY 2018 Formula Apportionments: Data and Methodology*

1. Apportionment Tables

FTA publishes apportionment tables on its website for each program that reflect the funding level in the full-year appropriations act less oversight take-downs, as applicable. Tables displaying the funds available to eligible states, tribes, and urbanized areas have been posted to *http://www.transit.dot.gov/funding/apportionments.* This website contains a page listing the apportionment and allocation tables for FY 2018, links to prior year formula apportionment notices and tables, and the National Transit Database (NTD) and Census data used to calculate the FY 2018 apportionments.

2. National Transit Database (NTD) and Census Data Used in the FY 2018 Apportionments

Consistent with past practices, the calculations for Sections 5307, 5311, including 5311(j) (Tribal Transit), 5329, 5337, and 5339 rely on the most-recent transit service data reported to the NTD, which for FY 2018 is the 2016 report year. In some cases, where an apportionment is based on the age of the system, the age is calculated as of September 30, 2017, the last day before FY 2018 began. Recipients or beneficiaries of either Section 5307 or 5311 funds are required to report to the NTD. Additionally, several transit operators report to the FTA's NTD on a voluntary basis. For the 2016 report year, the NTD includes data from 953 reporters in urbanized areas, 925 of which reported operating transit service. The NTD also includes data from 1,478 providers of rural transit service, which includes 126 Indian Tribes providing transit service.

The 2010 Census data is used to determine population and population density for Sections 5303, 5305, 5307 and 5339 as well as rural population and rural land area for the 5311 program. The formulas for Sections 5307, 5311, and 5311(j) include tiers where funding is allocated based on the number of persons living in poverty, and the Section 5310 formula program allocates funding based on the population of older adults and people with disabilities. The Census Bureau no longer publishes decennial census data on persons living in poverty and persons with disabilities. As a result, since FY 2013, FTA has used the data for these populations available via the Census' American Community Survey (ACS). The NTD and Census data that FTA used to calculate the apportionments associated with this notice can be found on FTA's website: *www.transit.dot.gov/funding/apportionments.*

The FY 2018 apportionments use data on low-income persons, persons with disabilities, and older adults from the 2011–2015 ACS five-year data set, which was published in December 2016. This data represents the most recent five-year ACS estimates that are available as of October 1 for the year being apportioned. As was the case in prior years, data on low-income persons comes from ACS Table B17024, ''Age by Ratio of Income to Poverty in the Last Twelve Months,'' and data on people with disabilities under 65 years old comes from ACS Table S1810, ''Disability Characteristics.'' Data on older adults (over 65 years old) comes from ACS Table B01001, ''Sex by Age.''

## III. FY 2018 Program Highlights and Changes

*A. Streamlining Activities*

This past year FTA has reviewed its existing regulations and guidance and other agency actions to evaluate their continued necessity and determine whether they are crafted effectively to solve current problems. FTA's review was based on the principle that there should be no more requirements than necessary, and those requirements should be straightforward, clear, and designed to minimize burdens. Once issued, these requirements should be reviewed periodically and revised to ensure that they continue to meet the needs for which they originally were designed, remain cost-effective, and remain cost-justified. As a part of this review, FTA also considered input from external stakeholders that was provided in response to the Department's Notice of Review of Policy, Guidance and Regulation (82 FR 26734 (June 8, 2017)) and Notification of Regulatory Review (82 FR 45750 (Oct. 2, 2017)). Because of these reviews and external input, FTA has implemented the following:

1. Risk-Based Federal Financial and Milestone Progress Reporting and Review

Beginning on October 1, 2017, FTA implemented a risk-based policy on how frequently recipients must submit milestone progress reports (MPRs) and Federal Financial Reports (FFRs) for awarded grants. Under the new policy, all grants of $2 million or less that are awarded to recipients located in urbanized areas over 200,000 in population should be reported annually rather than quarterly unless a specific risk is identified for that grant. FTA has identified the awards that meet this criterion and has switched them from a quarterly to an annual reporting cycle. As FTA reviews new draft applications in FY 2018, we will assign a quarterly or an annual reporting cycle for the award based on this criterion. This policy change will reduce the grant reporting burden by approximately 13,000 reports for FTA recipients while allowing FTA to prioritize reviewing MPRs and FFRs for higher risk grants.

2. Real Estate Appraisal and Review Appraisal Submissions

All real property transactions must be undertaken in accordance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (Uniform Act or URA), 42 U.S.C. 4601 *et seq.,* and 49 CFR part 24, the implementing regulation. This includes requirements for appraisals and review appraisals as described in FTA 5010.1E Award Management Requirements. Additionally, Circular 5010.1E requires recipients to provide appraisals and review appraisals to FTA for review and concurrence for acquisitions and dispositions or property condemnation of more than $500,000, or in-kind contributions and land exchanges of any value before federal assistance is expended, or when the value is used as non-federal share. To reduce the burden on FTA recipients, FTA has increased the threshold to $1,000,000 for which appraisals and review appraisals for acquisition, disposition or property condemnations must be submitted to FTA for review. In-kind contributions and land exchanges of any value must still be submitted to FTA for review and concurrence. This change will reduce required submissions to FTA by 20 percent, saving about 50 total weeks of review time. FTA will make page-edits to Circular 5010.1E circular subsequent to this notice to document this change. FTA notes that all appraisals regardless of value must be compliant with 49 CFR 24.103. FTA may choose to review any appraisal or review appraisal used in an FTA assisted award when circumstances warrant or as part of a periodic review. The recipient must maintain documentation that supports valuation decisions in the parcel files.

3. Updates to Triennial Review and State Management Reviews

For FY 2018, FTA has made updates and process changes to its Triennial and State Management Reviews. These changes are based on feedback received from our recipients, review contractors, and colleagues and are also part of FTA's ongoing commitment to improve consistency and transparency in its oversight reviews. We anticipate that these changes will result in a more efficient review process that provides our recipients with a clearer understanding of what is expected during a Triennial or State Management Review, how FTA reviewers determine compliance, and why a finding of deficiency is made.

The Grantee Information Request (GIR) package is now called the Recipient Information Request (RIR) package. The FTA has redesigned the RIR to significantly reduce the level of effort required for completion by the recipient. The updated RIR package consists of:

*Recipient Profile Information:* Basic information about the recipient that FTA uses to better understand the recipient's institutional and operating structure, and to help determine applicability of oversight requirements.

*Recipient Information Request:* A list of documents and answers to specific questions that the FTA needs to begin assessing a recipient's compliance with the basic requirements identified in the Comprehensive Review Guide. The FTA is moving away from the narrative responses required in previous years. Once FTA's contractors begin reviewing the requested documentation, the recipient may be asked to provide answers to additional targeted questions on a case-by-case basis.

*Changes to the Comprehensive Review Guide:*

The FTA undertook a ''back to basics'' exercise with the Triennial and State Management Review Guide, known as the Comprehensive Review Guide, to identify the minimum compliance requirements and the optimal methods for assessing compliance. The key to this effort was ensuring that all questions were directly related to specific, citable, written requirements. This new guide clearly articulates what is expected of recipients and exactly how FTA will determine compliance. The guide can be accessed at *https://www.transit.dot.gov/oversight-policy-areas/fy18-comprehensive-review-guide.*

4. Online Dialogue on Definition of Federal Project

The current definition of a ''Federal'' project is defined in the FAST Act, Public Law 114–94 as, ''any highway project, public transportation capital project, or multimodal project that, if implemented as proposed by the project sponsor, would require approval by any operating administration or secretarial office within the Department of Transportation.'' The FTA is now examining how it defines ''Federal'' project and the effects of that definition on project implementation. To learn more, the FTA is conducting an online dialogue to help identify potential opportunities to expedite investments in transit infrastructure through the exclusion of certain projects or project elements from potentially burdensome Federal requirements. FTA intends to review the relevant thresholds for defining whether a project or project element qualifies as federally funded, which determines whether it is subject to various Federal requirements, reviews, and oversight.

Through this online dialogue, the FTA will pose a series of questions and invite States, transit agencies, transit operators, and other stakeholders to submit comments and responses on this topic.

The online dialogue will be open through August 15, 2018. FTA will provide a link to the online dialogue through email, social media, and its website.

5. Emergency Relief Docket

On February 2, 2018 FTA announced the establishment of an Emergency Relief Docket for calendar year 2018. See *https://www.gpo.gov/fdsys/pkg/FR-2018-02-02/pdf/2018-02083.pdf* for more information. After an emergency or major disaster, if FTA requirements impede a grantee or subgrantee's ability to respond to the emergency or major disaster, a grantee or subgrantee may submit a request for temporary relief from FTA administrative and statutory requirements. A grantee or subgrantee seeking relief must submit a petition for waiver of FTA requirements at *www.regulations.gov* for posting in the docket (FTA–2018–0001). For additional information on the Emergency Relief Docket, please contact the appropriate FTA Regional Office.

6. Cancellation of Circulars

As part of FTA's ongoing review of requirements, FTA has identified several circulars that should be cancelled. Information in these circulars is either no longer applicable or found in other guidance documents.

| Circular No. | Circular name |
|---|---|
| 2710.6 | Section 15 Accounting and Reporting Release Number 1. |
| 2710.7 | Section 15 Accounting and Reporting Release Number 2. |
| 4715.1A | Human Resource Programs (Section 20) Application and Project Management Guidelines. |
| 7008.1A | Financial Capacity Policy. |
| 7020.1 | Cross-Border Leasing Guidelines. |
| 9045.1 | New Freedom Program Guidance and Application Instructions. |
| 9050.1 | The Job Access and Reverse Commute (JARC) Program Guidance and Application Instructions. |

Under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), an agency may waive the normal notice and comment procedure if it finds, for good cause, that it would be impracticable, unnecessary, or contrary to the public interest. Additionally, 5 U.S.C. 553(d) provides that an agency may waive the 30-day delayed effective date upon finding of good cause.

Circulars 2710.6 and 2710.7 are interpretations of the uniform system of accounts and records and reporting system required by Section 15 of the Urban Mass Transportation Act of 1964 (UMTA Act), as amended, that was replaced by the Uniform Systems of Accounts (USOA). FTA finds, for good cause, that notice and comment for cancelling this guidance is unnecessary because the USOA was subject to notice and comment at 81 FR 70260. Further, the delayed effective date is unnecessary because the cancellation was already made effective by the adoption of the USOA.

Circular 4715.1A provides guidance on applying for Federal financial assistance and managing projects awarded under Section 20 of the UMTA Act, which was codified under the FAST Act at 49 U.S.C. 5314. FTA is

cancelling this circular because human resource grants are now covered under Circular 6100.1E, Research, Technical Assistance, and Training Programs: Application Instructions and Program Management Guidelines, which was published in the **Federal Register** (78 FR 47514) on August 13, 2014 with a request for public comment. FTA finds, for good cause, that notice and comment for cancelling this circular is unnecessary because it was replaced by guidance that was subject to notice and comment. Further, the delayed effective date is unnecessary because the cancellation was already made effective by the notice of availability of the Circular 6100.1E at 80 FR 19396.

Circular 7008.1A defines the basis upon which FTA will make the determination of financial capacity of grantees required under 49 U.S.C. 5309 and in reviewing Transportation Improvement Plans (TIPs). Additionally, the circular provides guidance for grantees making the required self-certifications of financial capacity under 49 U.S.C. 5307. FTA is cancelling this circular because these programs are now covered under Circular 9030.1E, Urbanized Area Formula Program: Program Guidance and Application Instructions, which was published on January 16, 2014 (79 FR 2930) and addressed comments received during the development of the circular. FTA finds, for good cause, that notice and comment for cancelling this circular is unnecessary because it was replaced by guidance that was subject to notice and comment. Further, the delayed effective date is unnecessary because the cancellation was already made effective by the publication of the notice of availability in the **Federal Register**.

Circular 7020.1 sets forth cross-border leasing guidelines, which allow grantees to lease FTA-funded transit equipment from a foreign entity. However, the American Jobs Creation Act of 2004 eliminated the tax benefits associated with such transactions, thereby rendering the vast majority of cross-border leases unprofitable. Thus, FTA is cancelling this circular, which is no longer utilized. FTA finds, for good cause, that notice and comment for cancelling this circular is unnecessary because it is outdated and unutilized. Similarly, the delayed effective date is unnecessary because the circular is no longer in use.

Circulars 9045.1 and 9050.1 include guidance and application instructions for the New Freedom Program and the Job Access and Reverse Commute Program. Both programs were repealed by MAP–21. Therefore, FTA is cancelling the corresponding circulars. FTA finds, for good cause, that notice and comment for cancelling these circulars is unnecessary because these programs are no longer authorized. The statutory language does not require interpretation to carry out its intent, and comments cannot alter the guidance given the explicit mandate. Further, the delayed effective date is unnecessary because the cancelation of the circulars was already made effective by statute.

Accordingly, FTA finds good cause under 5 U.S.C. 553(b)(3)(B) and (d)(3) to waive notice and opportunity for comment and the delayed effective date for all cancelled circulars.

*B. Policy Priorities*

As FTA implements its programs, it is particularly focused on the following policy priority areas.

1. Safety

Federal transit law requires States with rail transit systems operating within their jurisdictions to establish a State Safety Oversight (SSO) program that must be certified by the FTA by April 15, 2019 (49 U.S.C. 5329(e)). The FTA is prohibited by law (49 U.S.C. 5329(e)(3)) from obligating any funds to any transit agency within a State that fails to obtain certification by the deadline. The FTA recommends that States submit their complete SSO program certification applications no later than September 30, 2018. For more information on the certification requirements, please visit the FTA website: *www.transit.dot.gov/regulations-and-guidance/safety/transit-safety-oversight-tso.*

2. Positive Train Control (PTC)

On May 31, 2017, FTA and the Federal Railroad Administration (FRA) jointly announced the allocation of $197 million for projects to install positive train control (PTC) systems on commuter railroads and other passenger-rail related facilities. As authorized under Section 3028 of the Fixing America's Surface Transportation (FAST) Act, these funds are available to assist in financing the installation of PTC systems required under 49 U.S.C. 20157. All funding allocated under this program has been obligated ahead of the September 30, 2018 statutory deadline. Costs associated with the installation of PTC are also eligible under FTA's formula programs, including the Urbanized Area Formula Program (49 U.S.C. 5307) and the State of Good Repair Program (49 U.S.C. 5337).

3. Automation

Transit automation is a critical area of emerging technology with the capability to enhance and transform public transportation. FTA is developing a transit automation research initiative as one of the mobility innovation projects to explore the value and challenges of transit automation innovative technologies. FTA is currently exploring the use of automation technologies in transit bus operations. Key research activities include developing a transit automation strategic plan; growing stakeholder partnerships/engagements to increase understanding of transit automation use cases; fielding demonstrations to identify promising solutions; and exploring the human factors associated with adoption of transit automation approaches. Potential benefits of transit bus automation may include: Increased passenger/operator safety; operational efficiencies; expanded transit capacity; fuel efficiencies; service effectiveness; and rider satisfaction. More information on Shared Mobility can be found at: *https://www.transit.dot.gov/regulations-and-guidance/shared-mobility-faqs-eligibility-under-fta-grant-programs.*

4. Value Capture

Current law includes a definition of ''value capture'' to mean ''recovering the increased property value to property located near public transportation resulting from investments in public transportation.'' (49 U.S.C. 5302(24)). Value capture financing strategies include, but are not limited to, land value taxes, tax increment financing, special assessment districts, transportation utility fees, development impact fees, negotiated extractions, transit-oriented development, air rights, and joint development. FTA encourages the use of value capture strategies that contribute to the operation, maintenance, or expansion of public transportation services. Revenue generated by value capture is considered by FTA as local funding and can be used as the local share towards the funding of capital projects and operating costs eligible under Chapter 53 of title 49, United States Code. FTA is updating its program circulars and website to include additional guidance on the use of value capture financing strategies.

5. Transit Asset Management Plans

A transit provider's initial Transit Asset Management (TAM) plan must be completed no later than October 1, 2018. A provider may submit in writing to FTA a request to extend this deadline. FTA must receive a request to extend the deadline before the deadline occurs and will consider all requests on a case-by-case basis. See 49 CFR part

625 for more information about the requirements for TAM plans.

6. Bus Testing (49 U.S.C. 5318)

The Federal Transit Administration (FTA) is required to maintain a bus testing facility to test bus models purchased with Federal funding assistance. Any new model of a vehicle/bus to be used in public transportation revenue service and purchased with FTA funds must be tested at this bus testing facility. Fees for bus testing are shared: FTA funds 80 percent of the fees and the entity having the vehicle tested pays 20 percent of the fees.

In 2016, FTA issued a regulation to implement minimum performance standards, a scoring system, and a pass/fail threshold for new model transit buses procured with FTA financial assistance authorized under 49 U.S.C. Chapter 53 (49 CFR part 655). The standards and scoring system address the following categories: Structural integrity, safety, maintainability, reliability, fuel economy, emissions, noise, and performance. Buses must meet a minimum performance standard in each of these categories to receive an overall passing score and be eligible for purchase using FTA financial assistance. Buses can achieve higher scores with higher performance in each category, and the final rule establishes a numerical scoring system based on a 100-point scale so that buyers can more effectively compare vehicles.

The Consolidated Appropriations Act, 2018 provides $5 million for the operation and maintenance of the bus testing facility authorized under 49 U.S.C. 5318. This is a $2 million increase over previous annual appropriation amounts. Additionally, the Act provides an additional $2 million for certain grantees receiving funds under 49 U.S.C. 5312(h) to operate and maintain a facility to conduct the testing of low or no emission vehicle new bus models using the standards established pursuant to section 5318.

FTA's website has additional information, resources, and a link to sign up for email notices about the Bus Testing Program at: *www.transit.dot.gov/research-innovation/bus-testing.*

*C. FY 2018 Competitive Program Funding*

FTA's competitive grants programs and the FY 2018 authorized funding levels are identified in the chart below. FTA selects projects for funding after issuance of a Notice of Funding Opportunity. Additional information about each competitive program is in Section III of this notice.

| FY 2018 competitive programs | Statute 49 U.S.C. | 2018 authorized funding level (in millions) |
|---|---|---|
| Innovative Coordinated Access and Mobility Grants | FAST Section 3006(b) | $3.25 |
| Tribal Transit | 5311(c)(1)(A) | 5.0 |
| Grants for Buses and Bus Facilities Competitive Program | 5339 | 366.29 |
| Low or No Emission Grants Competitive Program | 5339 | 84.45 |
| Pilot Program TOD Planning | MAP–21 Section 2005(b) | 10.00 |

**Note:** The Grants for Buses and Bus Facilities and Low or No Emission Grants programs received funding in addition to the authorized levels; $161,446,000 and $29,450,000, respectively.

## IV. FY 2018 Program-Specific Information

*A. Metropolitan Planning Program (49 U.S.C. 5303 and 5305(d))*

Section 5305(d) authorizes Federal funding to support a cooperative, continuous, and comprehensive planning program for transportation investment decision-making at the metropolitan area level. The specific requirements of metropolitan transportation planning are set forth in 49 U.S.C. 5303 and further explained in 23 CFR part 450, as incorporated by reference in 49 CFR part 613, Planning Assistance and Standards. The State DOTs are the designated recipients of Metropolitan Planning Programs (MPP) and State Planning and Research Program (SPRP) funds allocated by FTA, which are then sub-allocated to Metropolitan Planning Organizations (MPOs) for planning activities that support the economic vitality of the metropolitan area. The Secretary has the discretion to award MPP and SPRP assistance to States, authorities of States, (MPOs), and local governmental authorities.

Each MPO must establish specific performance targets against system performance measures issued by U.S. DOT), and use these in tracking progress towards attaining critical outcomes. The MPO must coordinate with States and transit providers in setting these targets. MPOs must provide a system performance report that evaluates progress in meeting the performance targets in comparison with the system performance identified in prior reports.

MPP funding must support work resulting in balanced and comprehensive intermodal transportation planning for the movement of people and goods in the metropolitan area. Comprehensive transportation planning is not limited to transit planning or surface transportation planning, but also encompasses the relationships among land use and all transportation modes, without regard to the programmatic source of Federal assistance. MPP funds may be used for studies relating to management, mobility management, planning, operations, capital requirements, economic feasibility, performance-based planning, safety, and transit asset management. Funds may also be used to develop or update the metropolitan planning agreements. Funds may also be used to evaluate previously funded projects or to conduct peer reviews and exchanges of technical data, information, or assistance, among MPOs and other transportation planners. Funds may be also used for planning for multimodal transportation access to transit facilities; system planning: Scenario planning; corridor-level alternative analysis; development of federally required documents; safety, security and emergency transportation planning; coordinated public transit human services transportation planning; and public participation in the transportation planning, including the development of the Public Participation Plan. An exhaustive list of eligible work activities is provided in FTA Circular 8100.1C, Program Guidance for Metropolitan Planning and State Planning and Research Program Grants, dated September 1, 2008.

*For more information or questions on the Metropolitan Planning program, please contact Victor Austin at (202) 366–2996 or victor.austin@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $112,664,897 in FY 2018 to provide financial assistance for metropolitan planning needs under Section 5305.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $112,664,897 is available to the Metropolitan Planning Program (Section 5305(d)) to support metropolitan transportation planning activities set forth in Section 5303. The total amount apportioned for the Metropolitan Planning Program to States for use by MPOs in urbanized areas (UZAs) is $112,101,573 as shown in the table below, after the deduction for oversight (authorized by Section 5338).

METROPOLITAN PLANNING PROGRAM

| | |
|---|---|
| Total Appropriation available | $112,664,897 |
| Oversight Deductions ..... | (563,324) |
| Total Apportioned ..... | 112,101,573 |

3. Basis for Formula Apportionment

Of the amounts authorized in Section 5305, 82.72 percent is made available to the Metropolitan Planning Program. As a subset of the Metropolitan Planning Program funds, FTA apportions eighty percent to the states by statutory formula based on the most recent decennial Census for each State's UZA population. The remaining 20 percent is provided to the States based on an FTA administrative formula to address planning needs in larger, more complex UZAs. The amount published for each State includes this supplemental allocation.

4. Requirements

The States allocate Metropolitan Planning funds to MPOs in UZAs or portions thereof to provide funds for planning projects included in a one or two-year program of planning work activities (the Unified Planning Work Program, or UPWP) that includes multimodal systems planning activities spanning both highway and transit planning topics. Each State has either reaffirmed or developed, in consultation with its MPOs, an allocation formula among MPOs within the State, based on the 2010 Census. The allocation formula among MPOs in each State may be changed annually, but any change requires approval by the FTA Regional Office before grant approval. Program guidance for the Metropolitan Planning Program is found in FTA Circular 8100.1C, *Program Guidance for Metropolitan Planning and State Planning and Research Program Grants,* dated September 1, 2008.

5. Period of Availability

The Metropolitan Planning program funds apportioned in this notice are available for obligation during FY 2018 plus three additional fiscal years. Funds apportioned in FY 2018 must be obligated in grants by September 30, 2021. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2021, will revert to FTA for reapportionment under the Metropolitan Planning Program.

6. Other Program Information

The planning programs provide funding and procedural requirements to metropolitan areas and States for multimodal transportation planning that is cooperative, continuous, and comprehensive, resulting in long-range plans and short-range programs of projects that reflect transportation investment priorities. The planning programs are jointly administered by FTA and the Federal Highway Administration (FHWA), which provides additional funding. Several changes established by the FAST Act to Sections 5303 and 5304 are noted below:

New emphasis is placed on intercity transportation, including intercity buses and intermodal facilities that support intercity transportation, and commuter vanpool providers. The selection and role of the transit representation on MPO policy boards in large urbanized areas is clarified. MPOs in urbanized areas designated as transportation management areas must include officials of agencies that administer or operate major modes of transportation, as well as representatives of public transit operators, on MPO policy boards.

The representative of public transit shall be selected per the bylaws or enabling legislation of the MPO, and the representative of public transit may also serve as a representative of a local municipality on the MPO board. For additional information please reference the Final Rule on Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning (81 FR 34050, May 27, 2016).

The scope of the planning process adds two new planning factors, in addition to the eight pre-existing factors established under prior law. The two new factors are: (1) Improve the resiliency and reliability of the transportation system, and reduce the vulnerability of the existing transportation infrastructure to natural disasters, and (2) enhance travel and tourism. MPOs and State DOTs should provide public ports, intercity bus operators and employer-based commuting programs with a reasonable opportunity to comment on transportation plans. Plans must place greater emphasis on the congestion management process. MPOs that serve a Transportation Management Areas (TMAs) with a population of 1 million or more must prepare a congestion management performance plan, while TMAs with a population less than 1 million may prepare a congestion management plan. MPOs that serve transportation management areas must address congestion management through a process that provides for safe and effective integrated management and operation of the multimodal transportation system based on cooperatively developed metropolitan-wide strategies.

The long-range statewide transportation plan and metropolitan transportation plan must include a description of the performance measures and performance targets. State DOTs and MPOs are also required to provide a system performance report evaluating the condition and performance of the transportation system.

In the Final Rule on Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning (81 FR 34050), FHWA and FTA make the statewide, metropolitan, and nonmetropolitan transportation planning regulations consistent with current statutory requirements. The final rule establishes the following: (1) A new mandate for States and MPOs to take a performance-based approach to planning and programming; (2) a new emphasis on the nonmetropolitan transportation planning process, by requiring States to have a higher level of involvement with nonmetropolitan local officials and providing a process for the creation of Regional Transportation Planning Organizations (RTPOs); (3) implementation of the aforementioned statutory requirement for a structural change to the membership of the larger MPOs; (4) a new framework for voluntary scenario planning; (5) a new authority for the integration of the planning and environmental review processes; and (6) a process for programmatic mitigation plans.

Among the most significant changes is the new mandate for a performance-based planning process: MPOs and State DOTs must establish performance targets that address forthcoming U.S. DOT-issued national performance

measures that are based on the goals outlined in the legislation—safety, infrastructure condition, congestion reduction, system reliability, economic vitality, environmental sustainability, reduced project delivery delays, transit safety, and transit asset management. MPOs also must coordinate their performance targets, to the maximum extent practicable, with performance targets set by FTA grantees under the new performance measure requirements for safety and state of good repair. Transportation Improvement Programs (TIPs) must include a description of the anticipated progress toward achieving the performance targets resulting from implementation of the TIP. After May 27, 2018, a State's and MPO's long-range plans, STIPs, and TIPs must reflect performance targets and plans per the provisions of the final rule.

*B. State Planning and Research Program (49 U.S.C. 5304 and 5305(e))*

This program provides financial assistance to States for statewide transportation planning and other technical assistance activities, including supplementing the technical assistance program provided through the Metropolitan Planning program and planning support for non-urbanized areas. The specific requirements of Statewide transportation planning are set forth in 49 U.S.C. 5304 and further explained in 23 CFR part 450 as referenced in 49 CFR part 613, Planning Assistance and Standards. State DOTs are required to reference performance measures and performance targets within the Statewide Planning process. This funding must support work resulting in balanced and comprehensive intermodal transportation planning for the movement of people and goods and has the same eligibilities as MPP funds.

*For more information or questions on the State Planning and Research program, please contact Victor Austin at (202) 366–2996 or victor.austin@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $23,535,414 in FY 2018, to provide financial assistance for statewide planning and other technical assistance activities under Section 5305. As specified in law, this represents the 17.28 percent of the amounts available for Section 5305 that are allocated to the Statewide Planning and Research program.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $23,535,414 is for the State Planning and Research Program (Section 5305(e)). The total amount apportioned for the State Planning and Research Program (SPRP) is $23,417,737 as shown in the table below, after the deduction for oversight (authorized by Section 5338).

STATEWIDE TRANSPORTATION PLANNING PROGRAM

| | |
|---|---|
| Total Appropriation available | $23,535,414 |
| Oversight Deductions | (117,677) |
| Total Apportioned | 23,417,737 |

States' apportionments for this program are displayed in Table 2.

3. Basis for Formula Apportionment

Of the amount authorized for Section 5305, 17.28 percent is allocated to the State Planning and Research program. FTA apportions funds to States by a statutory formula that is based on the most recent decennial Census data available, specifically, the State's UZA population as compared to the UZA population of all States.

4. Requirements

Funds are provided to States for Statewide transportation planning programs. These funds may be used for a variety of purposes such as planning, technical studies and assistance, performance-based planning, demonstrations, and management training. In addition, a State may authorize a portion of these funds to be used to supplement Metropolitan Planning funds allocated by the State to its UZAs, as the State deems appropriate. Program guidance for the State Planning and Research program is found in FTA Circular 8100.1C, *Program Guidance for Metropolitan Planning and State Planning and Research Program Grants,* dated September 1, 2008.

5. Period of Availability

The State Planning and Research program funds apportioned in this notice are available for obligation during FY 2018 plus three additional fiscal years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2021. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2021 will revert to FTA for reapportionment under the State Planning and Research program.

*C. Urbanized Area Formula Program (49 U.S.C. 5307)*

The Urbanized Area Formula Program provides financial assistance to designated recipients in urbanized areas (UZAs) for capital investments in public transportation systems, planning, job access and reverse commute projects, and, in some cases, operating assistance. FTA apportions funds for this program through a statutory formula. Of the amount authorized for Section 5307 each year, $30 million is set aside for the competitive Passenger Ferry Grant Program (Ferry program), as authorized under 49 U.S.C. 5307(h). The Ferry program offers financial assistance to public ferry systems in urbanized areas for capital projects. Projects are selected annually through a funding competition. Additionally, 0.5 percent will be apportioned to eligible States for State Safety Oversight (SSO) Program grants, and 0.75 percent will be set aside for program oversight. Further information on the 0.5 percent apportionment to States for the State Safety Oversight Program is provided in section IV.M. of this notice.

*For more information or questions on the Urbanized Area Formula Program, contact Tara Clark at (202) 366–2623 or tara.clark@dot.gov. For more information on the Ferry Program, contact Vanessa Williams at (202) 366–4818 or vanessa.williams@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $5,279,690,721 in FY 2018 to provide financial assistance for urbanized areas under Section 5307.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $5,279,690,721 is available for the Urbanized Area Formula program. The total amount apportioned to urbanized areas (UZAs) is $5,228,378,222, which includes the addition of amounts apportioned to UZAs pursuant to the Section 5340 Growing States and High-Density States Formula factors. This amount to UZAs excludes the set-aside of $30 million for the Ferry program, apportionments under the State Safety Oversight Program, and oversight (authorized by Section 5338), as shown in the table below:

URBANIZED AREA FORMULA PROGRAM

| | |
|---|---|
| Total Appropriation available | [a] $4,726,907,174 |
| Oversight Deduction | −35,451,804 |
| State Safety Oversight Program | −23,634,536 |
| Ferry Discretionary Program | −30,000,000 |
| 5340 High Density States | [b] 282,825,570 |
| 5340 Growing States | [b] 214,714,305 |
| Reapportioned Funds | 1,816,904 |

URBANIZED AREA FORMULA PROGRAM—Continued

| | |
|---|---|
| Total Apportioned ..... | 5,137,177,613 |

[a] Includes 1.5 percent set-aside for Small Transit Intensive Cities Formula Table 3 displays the amounts apportioned under the Urbanized Area Formula Program.
[b] Includes technical corrections to fix FY 2017 errors.

3. Basis for Formula Apportionment

FTA apportions Urbanized Area Formula Program funds based on statutory formulas. Congress established four separate formulas to apportion available funding: The Section 5307 Urbanized Area Formula Program formula, the Small Transit Intensive Cities (STIC) formula, the Growing States and High Density States formula, and a formula based on low-income population.

Consistent with prior apportionment notices, Table 3 shows a total Section 5307 apportionment for each UZA, which includes amounts apportioned under each of these formulas. Detailed information about the formulas is provided in Table 4. For technical assistance purposes, the UZAs that receive STIC funds are listed in Table 6. FTA will provide breakouts of the funding allocated to each UZA under these formulas upon request to the FTA Regional Office.

FTA has calculated dollar unit values for the formula factors used in the Urbanized Area Formula Program apportionment calculations. These values represent the amount of money each unit of a factor is worth in this year's apportionment. The unit values change each year, based on all data used to calculate the apportionments, as well as the amount appropriated by Congress for the apportionment. The dollar unit values for FY 2018 are displayed in Table 5. To replicate the basic formula component of a UZA's apportionment, multiply the dollar unit value by the appropriate formula factor (*i.e.,* the population, population x population density), and when applicable, data from the NTD (*i.e.,* route miles, vehicle revenue miles, passenger miles, and operating cost).

a. Section 5307—Urbanized Area Formula

For UZAs between 50,000 and 199,999 in population, the Urbanized Area Formula is primarily based on population and population density. For UZAs with populations of 200,000 or more, the formula is based on population and population density, as well as a combination of bus revenue vehicle miles, bus passenger miles, bus operating costs, fixed guideway vehicle revenue miles, and fixed guideway route miles, either within the UZA or attributable to the UZA. The Urbanized Area Formula is defined in 49 U.S.C. 5336. Consistent with Section 5336(b), FTA has included 27 percent of the fixed guideway directional route miles and vehicle revenue miles from eligible urbanized area transit systems, but which were attributable to rural areas outside of the urbanized areas from which the system receives funds.

b. Small Transit Intensive Cities (STIC) Formula

Under the STIC formula, FTA apportions 1.5 percent of the funds made available for Section 5307 to UZAs that are under 200,000 in population and have public transportation service that operates at a level equal to or above the industry average for UZAs with a population of at least 200,000, but not more than 999,999. STIC funds are apportioned based on six performance categories: Passenger miles traveled per vehicle revenue mile, passenger miles traveled per vehicle revenue hour, vehicle revenue miles per capita, vehicle revenue hours per capita, passenger miles traveled per capita, and passengers per capita. In FY 2019, the STIC set aside will increase from 1.5 percent to 2 percent.

The data used to determine a UZA's eligibility under the STIC formula and to calculate the STIC apportionments was obtained from the NTD for the 2016 reporting year. Because performance data change with each year's NTD reports, the UZAs eligible for STIC funds and the amount each receives may vary each year. UZAs that received funding through the STIC formula for FY 2018 are listed in Table 6.

c. Section 5340—Growing States and High Density States Formula

FTA also apportions funds to qualifying UZAs and States according to the Section 5340 Growing States and High Density States formula, as shown in Table 3. More information on this program and its formula is found in Section IV.P. of this notice.

d. Low-Income Population

Of the amount authorized and appropriated for the Urbanized Area Formula Program in each year, 3.07 percent is apportioned based on low income population. As specified in statute, FTA apportions 75 percent of the available funds to UZAs with a population of 200,000 or more. Funds are apportioned based on the ratio of the number of low income individuals in each UZA to the total number of low income individuals in all urbanized areas of that size. FTA apportions the remainder of the funds (25 percent) to UZAs with populations of less than 200,000, per an equivalent formula. The low-income populations used for this calculation were based on the American Community Survey (ACS) data set for 2011–2015. This information is updated by the Census Bureau annually.

4. Requirements

To comply with or maintain compliance with the Clean Air Act (CAA) or the Americans with Disabilities Act (ADA) of 1990, the maximum Federal share for the Urbanized Area Formula Program, including the Passenger Ferry Program, is 85 percent for the net project cost of acquiring vehicles (including clean-fuel or alternative fuel). The maximum Federal share is 90 percent of the net project cost for acquiring vehicle-related equipment or facilities (including clean-fuel or alternative-fuel vehicle-related equipment or facilities) for complying with or maintaining compliance with the CAA or ADA.

Program guidance for the Urbanized Area Formula Program is found in FTA Circular 9030.1E, Urbanized Area Formula Program: Program Guidance and Application Instructions, dated January 16, 2014, and is supplemented by additional information and changes provided in this notice and that may be posted to the Urbanized Area Formula Grants program web page. FTA is in the process of updating the program circular to incorporate changes resulting from FAST Act amendments to 49 U.S.C. 5307.

5. Period of Availability

Funds made available under the Urbanized Area Formula Program are available for obligation during the year of apportionment plus five additional years. Accordingly, funds apportioned in FY 2018 must be obligated by September 30, 2023. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2023 will revert to FTA for reapportionment under the Urbanized Area Formula Program.

Funds allocated under the Passenger Ferry program follow the same period of availability as Section 5307. Accordingly, funds allocated in FY 2018 must be obligated by September 30, 2023. Any of the funds allocated in FY 2018 that remain unobligated at the close of business on September 30, 2023 will revert to FTA for reallocation under the Passenger Ferry program.

*D. Fixed Guideway Capital Investment Grants Program (49 U.S.C. 5309)*

The Capital Investment Grants (CIG) Program includes four types of eligible projects: New Starts projects, Small Starts projects, Core Capacity Improvement projects, and Programs of Inter-related Projects. Funding is provided for construction of: (1) New fixed guideway systems or extensions to existing fixed guideway systems such as rapid rail (heavy rail), commuter rail, light rail, trolleybus (using overhead catenary), cable car, passenger ferries, and bus rapid transit operating on an exclusive transit lane for the majority of the corridor length during peak periods that also includes features that emulate the services provided by rail fixed guideway, including defined stations, traffic signal priority for public transit vehicles, and short headway bi-directional service for a substantial part of weekdays and weekends; (2) corridor-based bus rapid transit service that does not operate on an exclusive transit lane but includes features that emulate the services provided by rail fixed guideway, including defined stations, traffic signal priority for public transit vehicles, and short headway bi-directional services for a substantial part of weekdays; (3) projects that expand the capacity by at least 10 percent in an existing fixed guideway corridor that is at capacity today or will be in five years; and (4) programs of two or more interrelated projects as described above that have logical connectivity with one another and will all begin construction in a reasonable timeframe.

*For more information about the Capital Investment Grant program contact Elizabeth Day, Office of Capital Project Development, at (202) 366–5159 or elizabeth.day@dot.gov. For information about published allocations contact Eric Hu, Office of Transit Programs, at (202) 366–0870 or eric.hu@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $2,301,785,760 in FY 2018, to provide financial assistance under Section 5309.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $2,650,010,000 is available to the Fixed Guideway Capital Investment Grants Program. The Consolidated Appropriations Act, 2018 requires of the amounts made available, $2,252,508,586 to be obligated by December 31, 2019. The funds are allocated in the following manner: $1,506,910,000 for New Starts projects; $715,700,000 for Core Capacity projects; $400,900,000 for Small Starts projects; and $26,500,000 for Oversight. These amounts are based on allocating the $2.64 billion in new budget authority and $5.05 million from recovered and unobligated Section 5309 Bus and Bus Facilities funds that were appropriated from FY 2000 thru FY 2005. The total amount available for projects is $2,623,509,990 as shown in the table below, after the deduction for oversight (authorized by Section 5338).

FIXED GUIDEWAY CAPITAL INVESTMENT GRANTS PROGRAM

| | |
|---|---|
| Total Appropriation available | $2,650,010,000 |
| Oversight Deduction | (26,500,000) |
| Total Apportioned * | 2,623,510,000 |

* Of the total amount apportioned, $2,252,508,586 shall be obligated by December 31, 2019.

3. Basis for Allocation

Funds are allocated on a competitive basis and subject to program evaluation.

4. Requirements

Projects become candidates for funding under the Capital Investment Grant Program by successfully completing steps in the process defined in Section 5309 and obtaining a satisfactory rating under the statutorily-defined criteria. For New Starts and Core Capacity Improvement projects, the steps in the process include project development, engineering, and construction. For Small Starts projects, the steps in the process include project development and construction. For programs of interrelated projects, the steps in the process depend on the combination of project types included.

5. Period of Availability

The Fixed Guideway Capital Investment Grant program funds apportioned in this notice are available for obligation during FY 2018 plus three additional fiscal years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2021, except $2,252,508,586 that must be obligated by December 31, 2019. All funds must be disbursed by the recipient by September 30, 2026.

*E. Formula Grants for the Enhanced Mobility of Seniors and Individuals With Disabilities Program (49 U.S.C. 5310)*

The Section 5310 Enhanced Mobility of Seniors and Individuals with Disabilities Program provides formula funding to states and urbanized areas for meeting the transportation needs of older adults and people with disabilities when the public transportation service provided is unavailable, insufficient, or inappropriate to meet these needs. The program aims to improve mobility for seniors and individuals with disabilities by removing barriers to transportation service and expanding transportation mobility options. The Pilot Program for Innovative Coordinated Access and Mobility Program (Pilot Program)—was established by Section 3006(b) of the FAST Act. The purpose of the program is to assist in financing innovative projects for the transportation disadvantaged that improve the coordination of transportation services and non-emergency medical transportation (NEMT) services, including, for example, the deployment of coordination technology, and projects that create or increase access to community One-Call/One-Click Centers.

*For more information or questions on the Enhanced Mobility of Seniors and Individuals with Disabilities program, please contact Kelly Tyler at (202) 366–3102 or kelly.tyler@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $273,840,764 in FY 2018 to provide formula funding to states for meeting the transportation needs of older adults and people with disabilities. The law also authorizes $3.25 million for the competitive Pilot Program.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $127,772,132 is available for projects under the Section 5310 formula program after the oversight deduction as shown in the table below.

FORMULA GRANTS FOR THE ENHANCED MOBILITY OF SENIORS AND INDIVIDUALS WITH DISABILITIES PROGRAM

| | |
|---|---|
| Total Appropriation available | $273,840,764 |
| Oversight Deduction | (1,369,204) |
| Total Apportioned (Formula) | 272,471,560 |
| Innovative Coordinated Access and Mobility Pilot Program | 3,250,000 |
| Total Apportioned | 275,721,560 |

3. Basis for Formula Apportionment

Sixty percent of the funds are apportioned among designated recipients for urbanized areas with a population of 200,000 or more individuals. Twenty percent of the funds are apportioned among the States for urbanized areas with a population of at least 50,000 but less than 200,000.

Twenty percent of the funds are apportioned among the States for rural areas, defined as areas with a population less than 50,000. Census Data on Older Adults and People with Disabilities is used for the Section 5310 program apportionments. FY 2018 Apportionments Table 8 displays the amounts apportioned under the Enhanced Mobility of Seniors and Individuals with Disabilities Program.

Under the Section 5310 formula, funds are allocated using Census data on older adults (*i.e.,* persons 65 and older) and people with disabilities. However, beginning in 2010, the Census Bureau stopped collecting this demographic information as part of its decennial census. Data on seniors and people with disabilities is now only available from the American Community Survey (ACS), which is conducted and published on a rolling basis. FTA's FY 2018 Section 5310 apportionments incorporate ACS data published in December 2016. Data on seniors comes from the ACS 20111–2015 five-year data set, Table B01001, ''Sex by Age.'' Data on persons with disabilities comes from the ACS 2011 2015 five-year data set, Table S.1810, ''Disability Characteristics.''

4. Requirements

At least 55 percent of program funds must be used on traditional Section 5310 projects such as buses and vans; wheelchair lifts, ramps, and securement devices; or transit-related information technology systems including scheduling/routing/one-call systems. Mobility management programs are also defined as capital projects for purposes of this provision. The acquisition of transportation services under a contract, lease, or other arrangement is also eligible; both the capital and operating costs associated with contracted service are eligible capital expenses for purposes of this provision. The capital eligibility of acquisition of services is limited to the Section 5310 program. The remaining 45 percent of a recipient's 5310 funds may be used for capital expenses or operating assistance.

a. Eligible Recipients

Eligible recipients include States for rural and small urban areas and designated recipients chosen by the Governor of the State for large urban areas; or a State or local governmental entity that operates a public transportation service. For urbanized areas less than 200,000 in population and in the rural areas, the State is the designated recipient for Section 5310. Current Section 5310 designations remain in effect until changed by the Governor of a State by officially notifying the appropriate FTA Regional Administrator of re-designation. A State or local governmental entity that operates a public transportation service may be a direct recipient for Section 5310 funds.

For urbanized areas over 200,000 in population, the recipient charged with administering the Section 5310 Program must be officially designated in accordance with the planning process, by the Governor of a State, responsible local officials, and publicly owned operators of public transportation prior to grant award (See the definition of designated recipient, 49 U.S.C. 5302(4)). Designated recipients are responsible for administering the program. Eligible subrecipients include State or local governmental authorities, private nonprofit agencies, and operators of public transportation that receive a grant indirectly through a recipient. For the 55 percent of funds that must be used for capital projects, eligible subrecipients include private nonprofit organizations as well as State or local governmental authorities that are either approved by the State to coordinate services for seniors and people with disabilities, or which certify to the Governor that no nonprofit organizations are readily available in the area to provide the service.

b. Local Match

Capital assistance is provided at 80 percent Federal share; 20 percent local share. Operating assistance requires a 50 percent local match. Funds provided under other Federal programs (other than those of the DOT, except for the Federal Lands Transportation Program) may be used as local match for funds provided under Section 5310, and revenue from service contracts may be used as local match.

c. Planning and Consultation

The coordinated planning provision requires that all projects be included in the local coordinated human service-public transportation plan. The plan must be developed and adopted with representation from seniors, individuals with disabilities, representatives of public, private, nonprofit transportation and human services providers, and other members of the public.

d. State and Project Management Plans

States, designated recipients, and State or local governmental entities that operate a public transportation service that are responsible for implementing the Section 5310 program are required to document their approach to managing the program. The Management Plans serve as the basis for FTA management reviews of the program, and provide public information on the administration of the programs.

e. Program of Projects (POP)

Designated recipients are required to develop a Program of Projects (POP) with the grant application and submit it to the FTA Regional Office. The POP should be developed with respect to the coordinated plan, long range plan, and the transportation improvement plan. For additional guidance in developing the required POP, see Chapter IV of the FTA Circular 9070.1G, *Enhanced Mobility of Seniors and Individuals with Disabilities Program Guidance and Application Instructions,* dated July 7, 2014.

5. Period of Availability

The Enhanced Mobility of Seniors and Individuals with Disabilities program funds apportioned in this notice are available for obligation during FY 2018 plus two additional fiscal years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2020. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2020, will revert to FTA for reapportionment among the States and urbanized areas.

6. Other Program Information

A State may transfer apportioned funds between small urbanized areas and rural areas if it can certify that the needs are being met in the area to which the funds were originally apportioned. The State can transfer the funds (rural and small urbanized area) to any area within the state if a statewide program for Section 5310 is established. Section 5310 funds may not be transferred to other FTA programs. However, Section 5310 funds apportioned to large urbanized areas may not be transferred to other areas. Section 5310 program recipients may partner with meal delivery programs such as the Older Americans Act (OAA)-funded meal programs (to find local programs, visit: *www.Eldercare.gov*) and the USDA Summer Food Service Program *http://www.fns.usda.gov/sfsp/summer-food-service-program-sfsp.* Transit service providers receiving 5310 funds may coordinate and assist in providing meal delivery services on a regular basis if this does not conflict with the provision of transit services.

Program Guidance is found in FTA Circular 9070.1G, *Enhanced Mobility of Seniors and Individuals with Disabilities Program Guidance and Application Instructions,* dated July 7,

2014. Section 3006(b) of the FAST Act created a new competitive pilot program for innovative coordinated access and mobility that is discussed above. The Federal share is 80 percent for capital projects. Local Match of 20 percent can come from other Federal (non-DOT) funds.

*F. Formula Grants for Rural Areas Program (49 U.S.C. 5311)*

The Formula Grants for Rural Areas program provides formula funding to States and Indian tribes for supporting public transportation in areas with a population of less than 50,000. Funding may be used for capital, operating, planning, job access and reverse commute projects, and State administration expenses. Eligible sub-recipients include State and local governmental authorities, Indian Tribes, private non-profit organizations, and private intercity bus companies. Indian Tribes are also eligible direct recipients under the Formula Grants for Rural Areas program, both for funds apportioned to the States and for projects apportioned or selected to be funded with funds set aside from the Tribal Transit Program.

*For more information about the Formula Grants for Rural Areas program, please contact Élan Flippin at (202) 366–3800 or elan.flippin@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $577,721,886 in FY 2018 to provide financial assistance for rural areas under the Formula Grants for Rural Areas program, including funds for Section 5340 Growing States.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $577,721,886 is for the Rural Area Programs. The total amount apportioned to the program is $659,737,385 as shown in the table below, after the additional appropriation of $85,243,672 for the Section 5340 Growing States and oversight deduction (authorized by Section 5338).

GRANTS FOR RURAL AREAS FORMULA PROGRAM

| | |
|---|---|
| Total Appropriation available | $577,721,886 |
| Oversight Deduction | (3,228,173) |
| 5340 Growing States | 85,243,672 |
| Total Apportioned | 659,737,385 |

3. Basis for Formula Apportionment

FTA apportions the Formula Grants for Rural Areas program funds to states by a statutory formula using the latest available U.S. decennial census data. Most of the Formula Grants for Formula Grants for Rural Areas program funds (83.15 percent) are apportioned based on land area and population factors. In the first tier, no state may receive more than 5 percent of the amount apportioned based on land area. The remaining funds (16.85 percent) are apportioned based on land area, vehicle revenue miles, and low-income individual factors. In the second tier, no state may receive more than 5 percent of the amount apportioned based on land area, or more than 5 percent of the amounts apportioned for vehicle revenue miles. In addition to funds made available under Section 5311, FTA adds amounts apportioned based on rural population per the growing states formula factors of 49 U.S.C. 5340 to the amounts apportioned to the states under the Section 5311 formula. Before FTA apportions Section 5311 funds to the states, FTA subtracts funding from the total available amounts for the Appalachian Development Transportation Assistance Program, the Tribal Transit Program, the Rural Transportation Assistance Program (RTAP), and FTA oversight activities.

Data from the National Transit Database (NTD) 2016 Report Year was used for this apportionment, including data from directly-reporting Indian tribes. Data from public transportation systems that reported as urbanized area systems, but that was not attributable to an urbanized area, was also included. The Formula Grants for Rural Areas program includes three takedowns: The Appalachian Development Public Transportation Assistance Program; the Rural Transit Assistance Program (RTAP); and the Tribal Transit Program. These separate programs are described in the sections that follow.

4. Requirements

The Formula Grants for Rural Areas program provides funding for capital, operating, planning, job access and reverse commute projects, and administration expenses for public transit service in rural areas under 50,000 in population. The planning activities undertaken with Formula Grants for Rural Areas program funds are in addition to those awarded to the State under Section 5305 and must be used specifically for the needs of rural areas.

a. Intercity Bus Transportation

Each State must spend no less than 15 percent of its annual Formula Grants for Rural Areas program apportionment for the development and support of intercity bus transportation, unless it can certify, after consultation with affected intercity bus service providers, that the intercity bus service needs of the State are adequately met. FTA encourages consultation with other stakeholders, such as communities affected by loss of intercity service. The cost of an unsubsidized portion of privately provided intercity bus service that connects feeder service, including all operating and capital costs of such service whether offset by revenue from such service may be used as in-kind local match for the intercity bus projects. FTA is updating the Formula Grants for Rural Areas program circular to include this change.

b. State Administration

States may elect to use up to 10 percent of their apportionment at 100 percent Federal share to administer the Formula Grants for Rural Areas program and provide technical assistance to subrecipients. Technical assistance includes project planning, program and management development, public transportation coordination activities, and research the State considers appropriate to promote effective delivery of public transportation to rural areas.

c. Other Requirements

The Federal share for capital assistance is 80 percent and for operating assistance is 50 percent, except that States eligible for the sliding scale match under FHWA programs may use that match ratio for Formula Grants for Rural Areas program capital projects and 62.5 percent of the sliding scale capital match ratio for operating projects.

Each State prepares an annual program of projects, which must provide for fair and equitable distribution of funds within the States, including Indian reservations, and must provide for maximum feasible coordination with transportation services assisted by other Federal sources.

Additional program guidance for the Formula Grants for Rural Areas program is found in FTA Circular 9040.1G, *Formula Grants for Rural Areas: Program Guidance and Application Instructions,* dated November 24, 2014, and is supplemented by additional information that may be posted to FTA's web page.

5. Period of Availability

The Formula Grants for Rural Areas program funds apportioned in this notice are available for obligation during FY 2018 plus two additional fiscal years. Accordingly, funds apportioned

in FY 2018 must be obligated in grants by September 30, 2020. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2020, will revert to FTA for reapportionment under the Formula Grants for Rural Areas program.

6. Other Program Information

Revenue from the sale of advertising and concessions may be used as local match.

*G. Rural Transportation Assistance Program (49 U.S.C. 5311(b)(3))*

This program provides funding to assist in the design and implementation of training and technical assistance projects, research, and other support services tailored to meet the needs of transit operators in rural areas.

*For more information about Rural Transportation Assistance Program (RTAP), please contact Élan Flippin at (202) 366–3800 or elan.flippin@dot.gov.*

1. Authorized Amounts

There is a two percent takedown from the funds made available for RTAP. Of the two percent takedown, 15 percent is reserved for the National RTAP program. The remainder is available for allocation to the States.

Federal Transit Law authorizes $12,912,692 in FY 2018 to provide technical assistance.

2. FY 2018 Funding Availability

Under the Consolidated Appropriations Act, 2018 $12,912,692 is available for the RTAP Program. The total amount apportioned for RTAP is $10,975,788 as shown in the table below, after the deduction for National RTAP.

RURAL TRANSIT ASSISTANCE PROGRAM (RTAP)

| | |
|---|---|
| Total Appropriation available | $12,912,692 |
| National RTAP ..... | (1,936,904) |
| Total Apportioned ..... | 10,975,788 |

3. Basis for Formula Apportionment

FTA allocates RTAP funds to the States by an administrative formula. First, FTA allocates $65,000 to each State ($10,000 to each territory), and then allocates the balance based on rural population in the 2010 census.

4. Requirements

Eligible RTAP expenses include the design and implementation of training and technical assistance projects, research, and other support services tailored to meet the needs of transit operators in rural areas. States may use the funds to undertake research, training, technical assistance, and other support services to meet the needs of transit operators in rural areas. These funds are to be used in conjunction with a State's administration of the Formula Grants for Rural Areas program, but also may support the rural components of the Section 5310 program.

5. Period of Availability

The RTAP funds apportioned in this notice are available for obligation during FY 2018 plus two additional fiscal years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2020.

6. Other Program Information

The National RTAP project is administered by cooperative agreement and re-competed at five-year intervals. In July of 2014, FTA awarded a cooperative agreement to the Neponset Valley Transportation Management Association to administer the National RTAP Program. The National RTAP projects are guided by a project review board that consists of managers of rural transit systems and State DOT RTAP programs. National RTAP resources also support the biennial Transportation Research Board National Conference on Rural Public and Intercity Bus Transportation and other research and technical assistance projects of a national scope.

*H. Appalachian Development Public Transportation Assistance Program (49 U.S.C. 5311(c)(2))*

This program is a take-down under the Formula Grants for Rural Areas program to provide additional funding to support public transportation in the Appalachian region. There are sixteen eligible States that receive an allocation under this provision. The State allocations are shown in the Formula Grants for Rural Areas program table posted on FTA's website on the FY 2018 Apportionments page.

*For more information about the Appalachian Development Public Transportation Assistance Program, please contact Élan Flippin at (202) 366–3800 or elan.flippin@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $20 million in each of FY 2016 through FY 2020 as a take-down under the Formula Grants for Rural Areas program to support public transportation in the Appalachian region.

2. FY 2018 Funding Availability

Under the Consolidated Appropriations Act, 2018, $20 million is available.

APPALACHIAN DEVELOPMENT PUBLIC TRANSPORTATION ASSISTANCE PROGRAM

| | |
|---|---|
| Total Appropriation available | $20,000,000 |
| Total Apportioned ..... | 20,000,000 |

3. Basis for Formula Apportionment

FTA apportions the funds using percentages established under Section 9.5(b) of the Appalachian Regional Commission Code (subtitle IV of title 40). Allocations are based in general on each State's remaining estimated need to complete eligible sections of the Appalachian Development Highway System as determined from the latest percentages of available cost estimates for completion of the System. Such cost estimates are produced at approximate five-year intervals. Allocations contain upper and lower limits in amounts determined by the Commission and are made in accordance with legislative instructions.

4. Requirements

Funds apportioned under this program may be used for purposes consistent with the Formula Grants for Rural Areas program to support public transportation in the Appalachian region. Funds can be applied for in the State's annual Formula Grants for Rural Areas program grant.

Appalachian program funds that cannot be used for operating may be used for a highway project under certain circumstances. States should contact their regional office if they intend to request a transfer. Additional information about the requirements for this section can be found in Chapter VII of FTA Circular 9040.1G, *Formula Grants for Rural Areas: Program Guidance and Application Instructions,* dated November 24, 2014.

5. Period of Availability

The Appalachian program funds apportioned in this notice are available for obligation during FY 2018 plus two additional fiscal years, consistent with that established for the Formula Grants for Rural Areas program.

*I. Formula Grants for Public Transportation on Indian Reservations Program (49 U.S.C. 5311(j))*

The Public Transportation on Indian Reservations Program, or Tribal Transit Program (TTP), totals $35 million, of

which $30 million is for a formula program and $5 million is for a competitive grant program. It is funded as a takedown from funds made available for the Formula Grants for Rural Areas program. Formula factors include vehicle revenue miles and the number of low-income individuals residing on tribal lands (defined as American Indian Areas, Alaska Native Areas, and Hawaiian Home Lands). Eligible direct recipients are Federally recognized Indian tribes and Alaskan Native Villages providing public transportation in rural areas. The TTP funds are allocated for grants to eligible recipients for any purpose eligible under Formula Grants for Rural Areas program, which includes capital, operating, planning, and job access and reverse commute projects.

*For more information about the Tribal Transit Program contact Douglas Moore, Office of Transit Programs at (202) 366–0876 or douglas.moore@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $35 million in FY 2018 ($30 million for formula and $5 million for the competitive program) to provide assistance to the tribes. Under the Consolidated Appropriations Act, 2018, $30 million is available through September 30, 2018 for the formula program and $5 million for the competitive program.

2. FY 2018 Funding Availability

In FY 2018, $30 million is for the formula program as shown below.

FORMULA GRANTS FOR PUBLIC TRANSPORTATION ON INDIAN RESERVATIONS PROGRAM

| | |
|---|---|
| Total Appropriation available | $30,000,000 |
| Total Apportioned ..... | 30,000,000 |

PUBLIC TRANSPORTATION ON INDIAN RESERVATIONS PROGRAM COMPETITIVE GRANTS

| | |
|---|---|
| Total Appropriation available | $5,000,000 |
| Total Apportioned ..... | 5,000,000 |

3. Basis for Formula Apportionment

Funding is allocated by formula and distributed to eligible Indian tribes providing public transportation on tribal lands. The formula apportionment shown in Table 10 is based on a statutory formula which includes three tiers. Tiers 1 and 2 are based on data reported to NTD by Indian tribes; Tier 3 is based on 2010–2014 American Community Survey data. The three tiers for the formula are: Tier 1—50 percent based on vehicle revenue miles reported to the NTD; Tier 2—25 percent provided in equal shares to Indian tribes reporting at least 200,000 vehicle revenue miles to the NTD; Tier 3—25 percent based on Indian tribes providing public transportation on tribal lands (American Indian Areas, Alaska Native Areas, and Hawaiian Home Lands) on which more than 1,000 low income individuals reside. If more than one eligible tribe provides public transportation services on tribal lands in a single Tribal Statistical Area, and the tribes cannot determine how to allocate Tier 3 funds, FTA will allocate the funds based on the relative portion of transit (as defined by unlinked passenger trips) operated by each tribe, as reported to the National Transit Database.

4. Requirements

Formula funds apportioned under this program can be used for purposes consistent with the Formula Grants for Rural Areas program to support public transportation on Indian Reservations in rural areas. Funds allocated under the competitive program must be used consistent with the tribe's proposal and the allocation notice published in the **Federal Register**, which is used to announce the selected projects. Eligible recipients under both the competitive and formula program include federally-recognized Indian tribes or Alaska native villages, groups, or communities as identified by the U.S. Department of the Interior Bureau of Indian Affairs (BIA). A tribe must have the legal, financial and technical capabilities to receive and administer Federal funds.

Section 5335 requires NTD reporting for all recipients of Section 5311 funds. This reporting requirement continues to apply to the Tribal Transit Program. Tribes that provide public transportation in rural areas are reminded to report annually so they are included in the TTP formula apportionments. To be considered in the FY 2018 formula apportionments, tribes should have submitted their reports to the NTD no later than April 30, 2016; voluntary reporting to the NTD is also encouraged. Additionally, to be considered for the FY 2019 formula apportionment funds, tribes need to submit their reports to the NTD no later than April 30, 2017. Tribes needing assistance with reporting to the NTD should contact the NTD Helpline at 1–888–252–0936 or *NTDHelp@dot.gov.*

5. Period of Availability

The TTP program funds apportioned in this notice are available for obligation during FY 2018 plus two additional fiscal years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2020. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2020, will revert to FTA for reapportionment under the TTP program.

6. Other Program Information

Section 207 of title 23, United States Code establishes a Tribal Transportation Self-Governance Program (Self Governance Program). The Self Governance Program will establish specific criteria for determining eligibility for a tribe to participate in the program. A Negotiated Rulemaking to implement this program in consultation with tribal representatives and other interested stakeholders is under development.

The funds set aside for the TTP are not meant to replace or reduce funds that Indian tribes receive from States through the Formula Grants for Rural Areas program but are to be used to enhance public transportation on Indian reservations and transit serving tribal communities. Funds allocated to Indian tribes by the States may be included in the State's Formula Grants for Rural Areas program application or maybe awarded by FTA in a grant directly to the Indian tribe. FTA encourages Indian tribes intending to apply to FTA as direct recipients to contact the appropriate FTA Regional Office at the earliest opportunity.

All TTP grantees must comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal requirements in carrying out the project supported by the FTA grant. To assist tribes with understanding these requirements, FTA regularly conducts Tribal Transit Technical Assistance Workshops. FTA has also expanded its technical assistance to tribes receiving funds under this program. In FY 2015, FTA implemented the Tribal Transit Technical Assistance Assessments initiative. Through these assessments, FTA collaborates with tribal transit leaders to review processes and identify areas in need of improvement and then assist with solutions to address these needs—all in a supportive and mutually beneficial manner. These assessments include discussions of compliance areas pursuant to the Master Agreement, a site visit, promising practices reviews, and technical assistance from FTA and its contractors. FTA will post information about upcoming workshops to its website and will disseminate information about the reviews through

its Regional offices. FTA has regional tribal transit liaisons in each of the FTA Regional Offices that are available to assist tribes with applying for and managing FTA grants. Tribes are encouraged to work directly with their regional tribal transit liaison.

*J. Public Transportation Innovation (49 U.S.C. 5312)*

Public Transportation Innovation is FTA's research program with the overarching statutory goal to improve public transportation. The law specifies research focus areas, including providing more effective and efficient public transportation service; mobility management; system capacity; advanced vehicle design; asset maintenance; construction and project management; environment and energy efficiency; and safety improvements. FTA may make grants, enter contracts, cooperative agreements, and other agreements to carry out the research, development, demonstration, and deployment projects, including research and technology of national significance to public transportation.

Within this section are three distinct programs: (a) A Research, Development, Demonstration, Deployment, & Evaluation program (49 U.S.C. 5312(b-e)); (b) a Low or No Emission Vehicle Component Assessment Program (LoNo-CAP) (49 U.S.C. 5312(h)); and (c) a Transit Cooperative Research Program (49 U.S.C. 5312(i)). Eligible recipients can be departments, agencies, and governmental agencies, including Federal Laboratories; state and local entities; providers of public transportation; private or non-profit organizations; institutions of higher education; and technical community colleges—each program area has specific requirements relating to the type of organization that may receive a grant or enter an agreement.

The types of research eligible for funding are broad, and include opportunities to enhance public transportation operational effectiveness and efficiency; improve services; leverage new types of vehicle technologies; utilize transformative technologies to improve public transportation; field new mobility models; and support increased safety.

*For more information about the Public Transportation Innovation program, contact Edwin Rodriguez, Office of Research, Demonstration and Innovation at (202) 366–0671 or edwin.rodriguez@dot.gov.*

*For more information on the LoNo-CAP program, please contact Sam Yimer at (202) 366–1321 or samuel.yimer@dot.gov or visit: https://www.transit.dot.gov/research-innovation/lonocap.*

1. Authorized Amounts

Federal transit law authorizes $28 million in contract authority for FY 2018 for the Public Transportation Innovation program and an $20 million subject to congressional additional appropriations.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $28,000,000 is for the Public Transportation Innovation program. The total amounts apportioned to each subcomponent of the program is shown below in the table.

PUBLIC TRANSPORTATION INNOVATION PROGRAM

| | |
|---|---|
| Research, Development, Demonstration, Deployment, & Evaluation | $20,000,000 |
| Low or No Emission Vehicle Component Testing | 3,000,000 |
| Transit Cooperative Research Program (TCRP) | 5,000,000 |
| Total Apportioned | 28,000,000 |

3. Basis for Allocation

Public Transportation Innovation funds are allocated according to the authorized purposes and amounts described above, and then remaining amounts are subject to competitive allocations where not specifically authorized. The Secretary may make grants and enter contracts, cooperative agreements, and other agreements for research, development, demonstration, and deployment projects, and evaluation of research and technology of national significance to public transportation, that the Secretary determines will improve public transportation. For FY 2018, FTA intends to fund projects and activities consistent with its research priorities of mobility innovation, infrastructure, and safety. Projects may be selected through Notices of Funding Opportunity (NOFO), or Requests for Proposals (RFPs), or sole-sourced. FTA awards to a diverse set of recipients and issues different types of research agreements, including grants, cooperative agreements, contracts, or interagency agreements. Potential recipients can register to receive notification of funding availability under this program on *Grants.gov*.

FTA awards an annual cooperative agreement to the National Academies of Science to administer the TCRP. FTA solicited proposals for the LoNo-CAP in Fall 2016. Awards were made to Auburn University and The Ohio State University in September 2017 for $1.5 million each. Both facilities expect to begin testing in the late December 2018/January 2019 timeframe.

Per the statute, FTA only considered proposals from ''institutions of higher education'' as defined in section 1002 of title 20, U.S.C., the Higher Education Act of 1965. Eligible institution(s) of higher education must have capacity to carry out transportation-related advanced component testing and evaluation, with laboratories capable of testing and evaluation, and direct access to or a partnership with a testing facility capable of emulating real-world circumstances to test low or no emission components.

LoNo-CAP differs from the Bus Testing Program (Section 5318) in that LoNo-CAP testing is voluntary with a 50/50 shared fee structure (FTA pays 50 percent of the testing fees, the entity requesting the testing pays 50 percent of the fees). Additionally, LoNo-CAP will only test components, and it will not assign passing or failing scores. The LONO component testing performed under LoNo-CAP complements the Section 5318 Bus Testing Program, under which FTA will continue to test complete buses as a condition of eligibility for FTA grant funding. Eligible activities under LoNo-CAP include testing and assessing voluntarily submitted LoNo components for transit buses, publishing the results of these LoNo component assessments, and preparing an annual report to Congress summarizing the results of the component assessments. For more information on the LoNo-CAP program, visit *https://www.transit.dot.gov/research-innovation/lonocap.*

Requirements

Eligible expenses include activities involving (a) research, innovation, development, demonstration, deployment, evaluation; (b) low or no emission vehicle component testing; and (c) transit cooperative research.

The Federal share of the cost of a project carried out under FTA's Research, Innovation, Development, Deployment, and Demonstration program shall not exceed 80 percent; the remaining 20 percent of the costs can be met with in-kind resources. In some cases, FTA may require a higher non-Federal share if FTA determines a recipient would obtain a clear and direct financial benefit from the project, or if the non-Federal share is an evaluation factor under a competitive selection process.

However, for the LoNo-CAP, the Government share is 50 percent; the remaining 50 percent of the costs will be paid by amounts recovered through the fees established by the testing facilities. There is no match requirement for the TCRP.

Application instructions and program management guidelines are set forth in FTA Circular C 6100.1E, Technology Development and Deployment, ''Research, Technical Assistance and Training Program: Application Instructions and Program Management Guidelines'' dated May 11, 2015.

All research recipients are required to work with FTA to develop approved Statements of Work. FTA will be updating the Circular for the Research Program.

4. Period of Availability

FTA establishes the period in which the funds must be obligated to each project. If the funds are not obligated within that period of time, they revert to FTA for reallocation under the program.

5. Other Program Information

FTA publishes an annual Research Report on projects, evaluations, and benefits of its research portfolio. The FY2017 report can be accessed on FTA's website at *https://www.transit.dot.gov/research-innovation/fta-reports-and-publications.* Section 6019(b) of the FAST Act establishes new requirements for annual modal research plans in 49 U.S.C. 6501.

For the new LoNo-CAP (5312(h)), FTA solicited proposals in Fall 2016, finalized selections, and made two awards in 2017. LoNo-CAP differs from the Bus Testing Program (Section 5318) in that LoNo-CAP testing is voluntary; it will only test components, and it will not assign passing or failing scores. The LoNo component testing performed under LoNo-CAP complements the Section 5318 Bus Testing Program, under which FTA will continue to test complete buses as a condition of eligibility for FTA grant funding. Eligible activities under LoNo-CAP include testing and assessing voluntarily submitted Lo-No components for transit buses, publishing the results of these LoNo component assessments, and preparing an annual report to Congress summarizing the results of the component assessments.

TCRP is a cooperative effort of three organizations: FTA; the National Academies, acting through the Transportation Research Board (TRB); and the Transit Development Corporation, Inc. (TDC), a nonprofit educational and research organization established by the American Public Transportation Association (APTA). FTA funds the TCRP through a cooperative agreement. The TCRP is governed by an independent board, the TCRP Oversight and Project Selection (TOPS) Committee. The TOPS Committee sets priorities to decide what research studies will be undertaken and annually selects projects. The FY 2018 selected projects can be found at *http://onlinepubs.trb.org/onlinepubs/tcrp/docs/TCRP_AnnounceFY2018.pdf.*

*For more information about TCRP, please contact Faith Hall at (202) 366–9055 or faith.hall@dot.gov.*

Pursuant to the Small Business Innovation Development Act, a portion of the 5312 funds must be set aside for the Department's Small Business Innovation Research Program (SBIR) to address high priority research that will demonstrate innovative, economic, accurate, and durable technologies, devices, applications, or solutions to significantly improve current transit-related service, including transit vehicle operation, safety, infrastructure and environmental sustainability, mobility, rider experience, or broadband communication. Information on current and past SBIR projects can be found on the DOT SBIR website: *https://www.volpe.dot.gov/work-with-us/small-business-innovation-research.*

*K. Technical Assistance and Workforce Development (49 U.S.C. 5314)*

The Technical Assistance and Workforce Development program, 49 U.S.C. 5314, has three types of programs: Technical assistance and standards development; human resources and training; and the National Transit Institute. FTA funds projects across these areas to achieve statutory goals to assist the public transportation industry to more effectively and efficiently provide public transportation service; development standards and best practices; provide specific technical assistance in several areas, including complying with the Americans with Disabilities Act and human services transportation coordination as well as meeting the transportation needs of older adults. Key focus areas for human resources and training are employment training; outreach to aid in recruiting public transportation workers, especially to increase employment for certain targeted groups; frontline workforce development; and advanced training for new and emerging technology areas such as low and no emission bus maintenance. The National Transit Institute's goal is to develop and conduct training and educational programs for Federal, State, and local transportation employees and others engaged in public transportation work.

*For more information or questions about the Technical Assistance and Workforce Development programs, please contact Edwin Rodriguez, Office of Research, Demonstration, and Innovation at (202) 366–0671 or edwin.rodriguez@dot.gov.*

1. Authorized Amounts

Federal Transit law authorizes $9 million in contract authority for the Technical Assistance and Workforce Development Program and an additional $5 million subject to congressional appropriations.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $14 million is for the Technical Assistance and Workforce Development program as shown in the table below.

TECHNICAL ASSISTANCE AND WORKFORCE DEVELOPMENT

| | |
|---|---|
| Total Appropriation available | $14,000,000 |
| Total Appropriated ..... | 14,000,000 |

3. Basis for Allocation

Under the Technical Assistance and Workforce Development Program, funds are available for the NTI and to support the FTA and USDOT strategic plan for technical assistance, standards development, and workforce development. Projects may be selected through sole source, Notices of Funding Opportunity (NOFO) or Requests for Proposals (RFPs). Potential recipients can register to receive notification of funding availability under this program on *Grants.gov.* Once selected, FTA enters cooperative agreements, grants, contracts, or other agreements to award funds and manage the projects carried out under this section.

4. Requirements

Eligible expenses include activities involving: (a) Technical assistance; (b) standards development; and (c) human resources and training, including workforce development programs and activities. Eligible technical assistance activities may include activities to support: (a) Compliance with the ADA; (b) compliance with coordinating planning and human services transportation; (c) meeting the transportation needs of elderly individuals; (d) increasing transit ridership in coordination with MPOs and other entities, particularly around

transit-oriented development; (e) addressing transportation equity with regard to the effect that transportation planning, investment, and operations have for low-income and minority individuals; (f) facilitating best practices to promote bus driver safety; (g) compliance with Buy America requirements and pre- and post-award audits; (h) assisting with the development and deployment of low and no emission vehicles or components for vehicles; (i) and other technical assistance activities that are necessary to advance the interests of public transportation.

Eligible standards development activities include the development of voluntary and consensus-based standards and best practices by the industry including those needed for safety, fare collection, intelligent transportation systems, accessibility, procurement, security, asset management, operations, maintenance, vehicle propulsion, communications, and vehicle electronics.

Eligible human resources and training activities include (a) employment training programs; (b) outreach programs to increase employment for veterans, females, individuals with disabilities, and minorities in public transportation; (c) research on public transportation personnel and training needs; (d) training and assistance for veteran and minority business opportunities; and (e) consensus-based national training standards and certifications in partnership with industry stakeholders. FTA funding directly allocated for these eligible purposes must be done through a competitive frontline workforce development program as required by Section 5314. Should FTA allocate funds for these purposes, it will advertise the available funding in a Notice of Funding Opportunity (NOFO) on *Grants.gov* and on its website. In the meantime, recipients of funds under Sections 5307, 5337, and 5339 may use 0.5 percent of their available funds to pay for workforce development activities (up to an 80 percent Federal share). There is a separate eligibility to use 0.5 percent of available funds under the sections above for training at the National Transit Institute.

The Government's share of the cost of a project carried out using a grant under this section shall not exceed 80 percent. However, for the human resources and training, including the Innovative Public Transportation Frontline Workforce Development Program, the Government's share cannot exceed 50 percent. The Federal share for other types of awards will be stated in the agreement. In some cases, FTA may require a higher non-Federal share if FTA determines a recipient would obtain a clear and direct financial benefit from the project, or if the non-Federal share is an evaluation factor under a competitive selection process.

The non-Government share of the cost of a project carried out under these sections (Technical Assistance and Standards and Technical Assistance and Training) may be derived from in-kind contributions as defined in the most current version of FTA Circular 5010, ''Award Management Guidelines'' found on FTA's Circular web page at *http://www.fta.dot.gov/circulars.* Application instructions and program management guidelines are set forth in FTA Circular 6100.1E, ''Research, Technical Assistance and Training Programs: Application Instructions and Program Management Guidelines'' dated May 11, 2015.

All recipients of Section 5314 funds are required to work with FTA to develop approved statements of work. There is no match requirement for the National Transit Institute.

5. Period of Availability

FTA establishes the period in which the funds must be obligated to each project. If the funds are not obligated within that time, they revert to FTA for reallocation under the program. However, the $5 million of general funds for technical assistance and training funds appropriated by congress in the consolidated appropriations Act, 2018 must be obligated by September 30, 2018 or no longer available and returned to the U.S. Treasury.

6. Other Program Information

FTA publishes an annual report to Congress on the technical assistance and standards activities that receive assistance under this section. Additionally, FTA must report annually on the Frontline Workforce Development Program. FTA reports can be found on FTA's web page at *www.transit.dot.gov.*

*L. Public Transportation Emergency Relief Program (49 U.S.C. 5324)*

FTA's Emergency Relief (ER) Program is authorized to provide funding for public transportation expenses incurred because of an emergency or major disaster. The Further Additional Supplemental Appropriations for Disaster Relief Requirements Act, 2018 (Division B, Subdivision 1 of Pub. L. 115–123) provides $330 million for this program for transit systems affected by Hurricanes Harvey, Irma, and Maria in 2017. FTA will provide more information about the allocation of these funds under a separate **Federal Register** notice.

Funds appropriated for this program are used to assist in responding to a publicly declared emergency or disaster. Eligible expenses include emergency operating expenses, such as evacuations, rescue operations, and expenses incurred to protect assets in advance of a disaster, as well as capital projects to protect, repair, reconstruct, or replace equipment and facilities of a public transportation system that the Secretary determines is in danger of suffering serious damage or has suffered serious damage because of an emergency. Additionally, transit agencies in the affected areas may request relief from certain FTA administrative and regulatory requirements for costs incurred in support of evacuations, rescue efforts, and the efficient shut down and resumption of transit services during and after the storm. Requests for relief from these requirements may be submitted to FTA's Emergency Relief Docket at *https://www.regulations.gov/.* The docket number for calendar year 2018 is FTA–2018–0001.

FTA also encourages transit agencies in affected areas to become familiar with FTA's Emergency Relief Program Manual, available at *transit.dot.gov/emergencyrelief.* When funding is made available by Congress through FTA's Emergency Relief Program, or at FEMA's direction, FTA will work with agencies to assess the impacts of the storm, including emergency operations and any potential damages to transit rolling stock or facilities.

Recipients of FTA funding affected by a declared emergency or disaster are also authorized to use funds apportioned under Sections 5307 and 5311 for emergency purposes under the provisions of FTA's Emergency Relief Program. Recipients are advised that formula funds disbursed to a grantee for emergency purposes will not be replaced or restored if funding is subsequently made available through FTA under the ER Program or by the Federal Emergency Management Agency (FEMA).

In the event of a disaster affecting a public transportation system, the affected recipient should contact its FTA Regional Office as soon as practicable to determine whether Emergency Relief Program funds are available, and to notify FTA that it plans to seek reimbursement for emergency operations and/or repairs that have already taken place or are in process. If Emergency Relief funds are unavailable, the recipient may seek reimbursement

from FEMA. Properly documented costs for which the grantee has not received reimbursement from FEMA may later be reimbursed by grants made either from Emergency Relief Program funding (if appropriated) or from Sections 5307 and 5311 program funding, once the eligible recipient formally applies to FTA for reimbursement and FTA determines that the expenses are eligible for emergency relief.

More information on the Emergency Relief Program and FTA's response to Hurricane Sandy is available on the FTA website at *https://www.transit.dot.gov/funding/grant-programs/emergency-relief-program/emergency-relief-program. For more information or questions on this program, please contact John Bodnar at (202) 366–9091 or john.bodnar@dot.gov.*

*M. State Safety Oversight Formula Program (49 U.S.C. 5329)*

The State Safety Oversight Formula Program provides funding to support States with rail fixed guideway public transportation systems (rail transit systems) to develop and carry out State Safety Oversight (SSO) Programs consistent with the requirements of 49 U.S.C. 5329. Federal transit law requires States with rail transit systems operating within their jurisdictions to establish a State Safety Oversight (SSO) program that must be certified by the Federal Transit Administration (FTA) by April 15, 2019. The FTA is prohibited by law from awarding any funds to any transit agency within a State that fails to obtain certification by the deadline. The FTA recommends that States submit their complete SSO program certification applications no later than September 30, 2018. For more information on the certification requirements, please visit the FTA Web: *www.transit.dot.gov/regulations-and-guidance/safety/transit-safety-oversight-tso.*

*For more information or questions on the Public Transportation Safety program, please contact Maria Wright at (202) 366–5922 or maria1.wright@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $23,634,536 in FY 2018 to provide funding to support States in developing and carrying out the SSO Program.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $23,634,536 is available for the State Safety Oversight (SSO) Formula program as shown in the table below.

STATE SAFETY OVERSIGHT FORMULA PROGRAM

| | |
|---|---|
| Total Appropriation available | $23,634,536 |
| Total Appropriated ..... | 23,634,536 |

3. Basis for Formula Apportionment

FTA will continue to allocate funds to the States by an administrative formula, which is detailed in the **Federal Register** notice apportioning SSO Formula Grant Program FY 2013 and FY 2014 funds (Mar. 10, 2014). Grant funds for the SSO program are apportioned to eligible States using a three-tier formula based on statutory requirements, which apportion sixty percent (60 percent) of available funds based on rail transit system passenger miles (PMT), vehicle revenue miles (VRM), and directional route miles (DRM), twenty percent (20 percent) of available funds equally to each eligible State, and twenty percent (20 percent) based on the number of rail transit systems in each state.

4. Requirements

FTA requires each applicant to demonstrate in its grant application that its proposed grant activities will develop, lead to, or carry out a State Safety Oversight program that meets the requirements under 49 U.S.C. 5329(e). Grant funds may be used for program operational and administrative expenses, including employee training activities. Please see the **Federal Register** notice which apportioned SSO Formula Grant Program FY 2013 and FY 2014 funds (79 FR 13380, Mar. 10, 2014) for more information.

5. Period of Availability

SSO Formula Grant Program funds are available for the year of apportionment plus two additional years. Any FY 2018 funds that remain unobligated at the close of business on September 30, 2020 will revert to FTA for reapportionment under the SSO Formula Grant Program.

6. Other Program Information

Section 5329 authorizes FTA to temporarily assume oversight of a rail transit safety system, under certain circumstances. FTA also has the authority to issue restrictions and prohibitions to address unsafe conditions or practices. On August 11, 2016, FTA published a final rule to set procedures for FTA's administration of the Public Transportation Safety Program. The final rule provides procedures whereby FTA may: (1) Require a recipient to use Chapter 53 funds to correct safety violations identified by the Administrator or a State Safety Oversight Agency before such funds are used for any other purpose, or (2) withhold up to 25 percent of funds apportioned under 49 U.S.C. 5307 from a recipient when the Administrator has evidence that the recipient has engaged in a pattern or practice of serious safety violations, or has otherwise refused to comply with the Public Transportation Safety Program, or any regulation or directive issued under those laws for which the Administrator exercises enforcement authority for safety.

*N. State of Good Repair Program (49 U.S.C. 5337)*

The State of Good Repair Program provides financial assistance to designated recipients in Urbanized Areas (UZAs) with fixed guideway and high intensity motorbus systems for capital investments that maintain, rehabilitate, and replace aging transit assets and bring fixed guideway and high intensity motorbus systems into a state of good repair. FTA apportions funds for this program through a statutory formula using data reported to the National Transit Database (NTD).

*For more information or questions on the State of Good Repair program, please contact Eric Hu at (202) 366–0870 or eric.hu@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $2,593,703,558 in FY 2018 for the State of Good Repair Program.

2. FY 2018 Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $2,993,703,558 is for the State of Good Repair Program. This amount includes additional funds appropriated in the amount of $400 million. The total amount apportioned is $2,963,766,522 after the deduction for oversight as shown in the table below.

STATE OF GOOD REPAIR PROGRAM

| | |
|---|---|
| Total Appropriation available ..... | $2,993,703,558 |
| Oversight Deduction ..... | (29,937,036) |
| Total Apportioned ..... | 2,963,766,522 |

3. Basis for Formula Apportionment

FTA apportions State of Good Repair Program funds per a statutory formula. Funds are apportioned to urbanized areas with fixed guideway or high intensity motorbus systems that have been in operation for at least seven years. This means that only segments of fixed guideway and high intensity motorbus systems that entered revenue service on or before September 30, 2010

are included in the formula, as identified in the NTD. Funds apportioned to urbanized areas with fixed guideway are determined by two equal elements: (1) A fixed proportion, based on the proportion an urbanized area would have received in FY 2011 to the total amount apportioned to all urbanized areas in the FY 2011 Fixed Guideway Modernization program using the fixed guideway definition defined in prior law; and (2) a variable proportion, based on the proportion of vehicle revenue miles and directional route miles attributed to an urbanized area relative to all urbanized areas, with revenue miles weighted for 60 percent of this element and directional miles weighted for 40 percent of this element. Funds apportioned to urbanized areas with motorbus systems are 60 percent based on revenue miles and 40 percent based on route miles that attributed to an urbanized area relative to all urbanized areas. The fixed guideway tier is apportioned 97.15 percent of the total appropriation, and the remaining 2.85 percent is apportioned to the high-intensity motorbus tier.

4. Requirements

In addition to the program guidance found in the FTA Circular 5300.1, ''State of Good Repair Grants Program: Guidance and application Instructions,'' all recipients must comply with the regulation at 49 CFR part 625, issued under the authority of Section 5326 for the Transit Asset Management plan (TAM).

5. Period of Availability

The State of Good Repair Program funds apportioned in this notice are available for obligation during FY 2018 plus three additional years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2021. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2021 will revert to FTA for reappointment under the State of Good Repair Program.

6. Other Program Information

In July 2016, FTA published a Final Rule (49 CFR part 625) for Transit Asset Management (81 FR 48890, July 26, 2016). Grantees must have a TAM plan in place by October 1, 2018. Beginning in FY 2019 all projects funded under the State of Good Repair Program must appear in the investment prioritization of the grantee's TAM plan.

*O. Grants for Buses and Bus Facilities Program (49 U.S.C. 5339)*

The Grants for Buses and Bus Facilities Program provides financial assistance to states, local governmental entities that operate fixed route bus service, and designated recipients for capital investments in public transportation systems to replace, rehabilitate, lease, and purchase buses and related equipment and to construct bus-related facilities, including technological changes or innovations to modify low or no emission vehicles or facilities. Funding is provided through Section 5339(a) formula allocations and Section 5339(b) competitive grants. A sub-program, the Section 5339(c) Low- or No-Emission Vehicle Program, provides competitive grants for bus and bus facility projects that support low and zero-emission vehicles.

*For more information or questions on the Grants for Buses and Bus Facilities Formula Program, please contact John Bodnar at (202) 366–9091 or john.bodnar@dot.gov. For information or questions regarding the competitive Buses and Bus Facilities Infrastructure Investment Program please contact Mark G. Bathrick at (202) 366–9955 or mark.bathrick@dot.gov. For information or questions regarding the competitive Low or No Emissions Grant Program, contact Tara Clark at (202) 366–2623 or tara.clark@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes, $445,519,476 for the formula program, $246,514,000 for the Bus competitive program, and $55,000,000 for the Low or No Emissions program in FY 2018 to provide financial assistance for the Grants for Buses and Bus Facilities Program.

2. Funding Availability

In FY 2018 under the Consolidated Appropriations Act, 2018, $654,623,476 is available for the Grants for Buses and Bus Facilities Formula Program, $84,450,000 for the Low or No Emission Grants (competitive) Program, and $407,960,000 for the Grants for Buses and Bus Facilities (competitive) Program. These amounts represent additional funds appropriated in the amount of $209,104,000; $29,450,000; and $161,446,000, respectively. The amounts apportioned after the 0.75 percent take-down for oversight are shown in the table below.

| Grants for Buses and Bus Facilities (Formula) | |
|---|---|
| Total Appropriation (Formula) available | $654,623,476 |
| Oversight Deduction | (4,909,676) |
| Total Apportioned (Formula) | $649,713,800 |
| **Grants for Buses and Bus Facilities (Low or No Emission (Competitive))** | |
| Total Appropriation (Low or No Emission) available | $84,450,000 |
| Total to be Allocated (Low or No Emission) | $84,450,000 |
| **Grants for Buses and Bus Facilities (Bus Competitive)** | |
| Total Appropriation (Bus Competitive) available | 492,410,000 |
| Oversight Deduction | (3,693,075) |
| Low or No Emission Grants (Competitive) | (84,450,000) |
| Allocation to Projects under FY 2017 Competition (April 5, 2018) | (37,973,775) |
| Total to be Allocated (Bus Competition) | $366,293,150 |

3. Basis for Formula Apportionment

Section 5339(a) Buses and Bus Facilities Program formula funds are apportioned to States, territories, and designated recipients based on a statutory formula. Under the National Distribution, each State is allocated $3.5 million and each territory is allocated $1 million for use anywhere in the State or territory for fiscal years 2018. The remainder of the available funding is then apportioned to UZAs based on population, vehicle revenue miles, and passenger miles using the same apportionment formula and allocation process as the Urbanized Area Formula Program. Funds for UZAs under 200,000 in population are apportioned to the State for allocation to eligible recipients within such areas of the State at the Governor's discretion. Funds for UZAs with populations of 200,000 or more are apportioned directly to one or more designated recipient(s) within each UZA for allocation to eligible projects and recipients within the UZA.

FTA allocates funds under the competitive Section 5339(b) and 5339(c) programs on an annual basis based on a notice of funding opportunity, which contains detailed guidance on applicant eligibility, project eligibility, evaluation criteria, and application requirements.

4. Requirements

Eligible recipients for Section 5339(a) formula grants include: (1) designated recipients that allocate funds to fixed route bus operators, and (2) States and local governmental entities that operate fixed route bus service. Eligible subrecipients include public agencies or private nonprofit organizations engaged

in public transportation, including those providing services open to a segment of the general public as defined by age, disability, or low income. The definition of eligible recipients applies to funding apportioned in previous fiscal years that remain available for obligation. The requirements of the Urbanized Area Formula Program apply to recipients of Section 5339 funds within an urbanized area. The requirements of Formula Grants for Rural Areas program apply to recipients of Section 5339 funds within rural areas.

Under prior law, only designated recipients were eligible direct recipients of Section 5339(a) funds. Given that State and local government entities that operate fixed route service are now eligible direct recipients of Section 5339(a) funds, FTA does not require designated recipients to maintain program management plans (PMPs) if they do not manage any sub-awards of Section 5339 funds.

For additional program requirements, refer to FTA Circular 5100, ''Buses and Bus Facilities Formula Program: Guidance and Application Instructions.''

5. Period of Availability

The Bus and Bus Facilities Program formula funds apportioned in this notice are available for obligation during FY 2018 plus three additional years. Accordingly, funds apportioned in FY 2018 must be obligated in grants by September 30, 2021. Any FY 2018 apportioned funds that remain unobligated at the close of business on September 30, 2021 will revert to FTA for reapportionment under the Buses and Bus Facilities Formula Program. Competitive program funds authorized under Sections 5339(b) and 5339(c) follow the same period of availability and reapportionment policy.

6. Other Program Information

Although it does not provide additional funding, as authorized under Section 5339(a)(9), FTA has established a pilot program to allow designated recipients in urbanized areas between 200,000 and 1 million in population to elect to pool their Buses and Bus Facilities Program formula allocations with other designated recipients within their respective states. The purpose of this provision is to allow for the transfer of formula funding within a State in a manner that supports the transit asset management plans of the participating designated recipients. A State that intends to participate in this pilot program beginning in FY 2019 (October 1, 2018) must submit a request to establish a State Pool to its FTA Regional Office by August 31, 2018. The request must identify the urbanized areas that will participate in the pool for FY 2019, and must include a letter from each urbanized area's participating designated recipient, and from any affected eligible recipients of Section 5339(a) funds within the urbanized area, indicating their intention to participate in this pooling provision for FY 2019. An urbanized area that participates in a State Pool must contribute its entire Section 5339(a) apportionment for the fiscal years in which it participates in the pool. For a multi-state area, designated recipient for a multistate area may participate in only one State Pool. FY 2019 is the last year that a State may establish a State Pool. For FY 2019, the request must specify the proposed distribution of the pooled funding and must provide a detailed explanation of how this distribution will support the transit asset management plans of each participating designated recipient, including any eligible recipients to which the designated recipient will allocate funding. Upon approval, FTA will make the requested amounts of program funding available to the urbanized areas as directed in the request. A State that elects to participate in this pilot program will be required to develop an allocation plan for the period of fiscal years 2019 and 2020 that ensures that a designated recipient participating in the State's pool receives under the program an amount of funds that equals the amount of funds that would have otherwise been available to the designated recipient for that period pursuant to the formulas provided. The amounts in the State Pool will be apportioned separately from funds apportioned to the State under the Governor's Apportionment for urbanized areas under 200,000 in population, and will be made available directly by FTA to the participating urbanized areas, as directed in the approved allocation plan. An allocation plan may be revised for future fiscal years, if it remains compliant with the requirement to ensure equity over the period the pool is in effect. Approved requests to establish a State Pool for the specified UZAs will remain in effect until cancelled at the request of the State or one or more designated recipients. If a State or designated recipient elects to end its participation in this pooling provision in any future fiscal year, FTA will adjust the formula allocations so that the total amount that each affected urbanized area has received over the fiscal years in which it participated, plus the following apportionment, equals the amount it would have received over this period had it not participated in the State pool. Adjustments will be made using the formula apportionment factors used for each of the affected fiscal years. After the pools are determined, FTA will publish a supplementary table showing the participating UZAs, the State total, and the amounts for each UZA for FY 2019. In future years, the States must provide the amounts determined by August 31 (in an updated allocation plan), so that FTA can publish the breakdowns and make the funds available in the Apportionment Notice.

*P. Growing States and High Density States Formula Factors (49 U.S.C. 5340)*

Federal transit law authorizes the use of formula factors to distribute additional funds to the Section 5307 Urbanized Area Formula program and Section 5311 Formula Grants for Rural Areas program programs for growing states and high density states. FTA will continue to publish single urbanized and rural apportionments that show the total amount for Section 5307 and 5311 programs that includes Section 5340 apportionments for these programs.

*For more information or questions on this program, please contact Tara Clark at (202) 366–2623 or tara.clark@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes $552,783,547 for apportionment in FY 2018 for the Growing States and High Density States Formula factors.

2. FY 2018 Funding Availability

Under the Consolidated Appropriations Act, 2018, $582,783,547 is for the Growing States and High Density States formula. This amount represents additional appropriated funds in the amount of $30 million.

GROWING STATES AND HIGH DENSITY STATES FORMULA FACTORS

| | |
|---|---|
| Growing States | $286,132,747 |
| High Density States | 296,650,800 |
| Total Apportioned | 582,783,547 |

3. Basis for Formula Apportionment

Under the Growing States portion of the Section 5340 formula, FTA projects each State's 2025 population by comparing each State's apportionment year population (as determined by the Census Bureau) to the State's 2010 Census population and extrapolating to 2025 based on each State's rate of population growth between 2010 and the apportionment year. Each State receives a share of Growing States funds

based on its projected 2025 population relative to the nationwide projected 2025 population.

Once each State's share is calculated, funds attributable to that State are divided into an urbanized area allocation and a non-urbanized area allocation on the basis of the percentage of each State's 2010 Census population that resides in urbanized and non-urbanized areas. Urbanized Areas receive portions of their State's urbanized area allocation based on the 2010 Census population in that urbanized area relative to the total 2010 Census population in all urbanized areas in the State. These amounts are added to the Urbanized Area's Section 5307 apportionment.

The States' rural area allocation is added to the allocation that each State receives under the Formula Grants for Rural Areas program.

The High Density States portion of the Section 5340 formula are allocated to urbanized areas in States with a population density equal to or greater than 370 persons per square mile. Based on this threshold and 2010 Census data, the States that qualify are Maryland, Delaware, Massachusetts, Connecticut, Rhode Island, New York and New Jersey. The amount of funds provided to each of these seven States is allocated on the basis of the population density of the individual State relative to the population density of all seven States. Once funds are allocated to each State, funds are then allocated to urbanized areas within the States based on an individual urbanized area's population relative to the population of all urbanized areas in that State.

*Q. Washington Metropolitan Area Transit Authority Grants*

Section 601 of the Passenger Rail Investment and Improvement Act of 2008 (PRIIA) authorized an aggregate amount of $1.5 billion to be available in increments over 10 fiscal years beginning in fiscal year 2009 to assist the Washington Metropolitan Transit Authority (WMATA) in implementing its Capital Improvement Program and preventive maintenance projects.

*For more information or questions on the Washington Metropolitan Area Transit Authority Grants program, please contact Eric Hu at (202) 366–0870 or eric.hu@dot.gov or Corey Walker at (202) 219–3562 or corey.walker@dot.gov.*

1. Authorized Amounts

Section 601 of PRIIA authorizes $150,000,000 in FY 2018.

2. FY 2107 Funding Availability

Under the Consolidated Appropriations Act, 2018, $150,000,000 is available. The total amount available is $ 148,500,000 after the deduction for oversight as shown in the table below.

WASHINGTON METROPOLITAN AREA TRANSIT AUTHORITY GRANTS

| | |
|---|---|
| Total Appropriation available | $150,000,000 |
| Oversight Deduction ..... | (1,500,000) |
| Total Apportioned ..... | 148,500,000 |

3. Basis for Allocation

The funding is authorized under Section 601, Authorization for Capital and Preventive Maintenance Projects for Washington Metropolitan Area Transit Authority, of the Passenger Rail Investment and Improvement Act of 2008, (Pub. L. 110–432) Division B, Title VI.

4. Requirements

Grants may be provided for capital and preventive maintenance expenditures for WMATA after it has been determined that WMATA has placed the highest priority on investments that will improve the safety of the system, including, but not limited, to fixing the track signal system, replacing 1000 series railcars, installing guarded turnouts, buying equipment for wayside worker protection, and installing rollback protection on cars that are not equipped with the safety feature. FTA will communicate further program requirements directly to WMATA. The maximum Federal share for each project shall be for 50 percent of the net project cost of the project, and matching funds shall be provided in cash from sources other than Federal funds or revenues from the operation of public transportation systems.

5. Period of Availability

Funds appropriated for WMATA under Section 601 PRIIA shall remain available until expended.

## V. FTA Policy and Procedures for FY 2018 Grants

*A. Automatic Pre-Award Authority To Incur Project Costs*

1. Caution to New Grantees

While FTA provides pre-award authority to incur expenses before grant award for formula programs, it recommends that first-time grant recipients NOT utilize this automatic pre-award authority without verifying with the appropriate FTA Regional Office that all pre-requisite requirements have been met. Commonly, a new grantee may misunderstand pre-award authority conditions and be unaware of all of the applicable FTA requirements that must be met in order to be reimbursed for project expenditures incurred in advance of grant award. FTA programs have specific statutory requirements that are often different from those for other Federal grant programs with which new grantees may be familiar. If funds are expended for an ineligible project or activity, or for an eligible activity but at an inappropriate time (*e.g.,* prior to NEPA completion), FTA will be unable to reimburse the project sponsor and, in certain cases, the entire project may be rendered ineligible for FTA assistance.

2. Policy

FTA provides pre-award authority to incur expenses before grant award for certain program areas described below. This pre-award authority allows grantees to incur certain project costs before grant approval and retain the eligibility of those costs for subsequent reimbursement after grant approval. The grantee assumes all risk and is responsible for ensuring that all conditions are met to retain eligibility. This pre-award spending authority permits an eligible grantee to incur costs on an eligible transit capital, operating, planning, or administrative project without prejudice to possible future Federal participation in the cost of the project. In this notice, FTA provides pre-award authority through the authorization period of the FAST Act (October 1, 2015 through September 30, 2020) for capital assistance under all formula programs, so long as the conditions described below are met. FTA provides pre-award authority for planning and operating assistance under the formula programs without regard to the period of the authorization. All pre-award authority is subject to conditions and triggers stated below:

a. Operating, Planning, or Administrative Assistance

FTA does not impose additional conditions on pre-award authority for operating, planning, or administrative assistance under the formula grant programs. Grantees may be reimbursed for expenses incurred before grant award so long as funds have been expended in accordance with all Federal requirements, would have been allowable if incurred after the date of award, and the grantee is otherwise eligible to receive the funding. In addition to cross-cutting Federal grant

requirements, program specific requirements must be met. For example, a State of Good Repair Formula Grants project on or after October 1, 2018 must be included in the grantee's certified TAM Plan, a planning project must be included in a Unified Planning Work Program (UPWP); a Section 5310 project be included in a coordinated public transit-human services transportation plan (coordinated plan) and selected by the designated recipient before incurring expenses and expenditures on State Administration expenses under State Administered programs must be consistent with the State Management Plan (as defined in FTA Circular 9040.1G, Chapter 6). Designated recipients for Section 5310 have pre-award authority for the ten percent of the apportionment they may use for program administration.

b. Transit Capital Projects

For transit capital projects, the date that costs may be incurred varies depending on the type of activity and its potential to have a significant impact on the human and natural environment as described under conditions in section 3 below. Before an applicant may incur costs when pre-award authority has not been granted, it must first obtain a written Letter of No Prejudice (LONP) from FTA. To obtain an LONP, a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA regional office, as described in section 4 below.

c. Public Transportation Innovation, Technical Assistance and Workforce Development

Unless provided for in an announcement of project selections, pre-award authority does not apply to Public Transportation Innovation projects or Section 5314 Technical Assistance and Workforce Development projects. Before an applicant may incur costs for activities under these programs, it must first obtain a written Letter of No Prejudice (LONP) from FTA. To obtain an LONP, a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA headquarters office. Information about LONP procedures may be obtained from the appropriate headquarters office.

3. Conditions

The conditions under which pre-award authority may be utilized are specified below:

*a.* Pre-award authority is not a legal or implied commitment that the subject project will be approved for FTA assistance or that FTA will obligate Federal funds. Furthermore, it is not a legal or implied commitment that all items undertaken by the applicant will be eligible for inclusion in the project.

*b.* All FTA statutory, procedural, and contractual requirements must be met.

*c.* No action will be taken by the grantee that prejudices the legal and administrative findings that the Federal Transit Administration must make in order to approve a project.

*d.* Local funds expended by the grantee after the date of the pre-award authority will be eligible for credit toward local match or reimbursement if FTA later makes a grant or grant amendment for the project. Local funds expended by the grantee before the date of the pre-award authority will not be eligible for credit toward local match or reimbursement. Furthermore, the expenditure of local funds or the undertaking of certain activities that would compromise FTA's ability to comply with Federal environmental laws (*e.g.,* project implementation activities such as land acquisition, demolition, or construction before the date of pre-award authority) may render the project ineligible for FTA funding.

*e.* The Federal amount of any future FTA assistance awarded to the grantee for the project will be determined based on the overall scope of activities and the prevailing statutory provisions with respect to the Federal/local match ratio at the time the funds are obligated.

*f.* For funds to which the pre-award authority applies, the authority expires with the lapsing of the fiscal year funds.

*g.* When a grant for the project is subsequently awarded, the grant and the Federal Financial Report in TrAMS must indicate the use of pre-award authority.

*h.* Environmental Requirements.

All Federal environmental grant requirements must be met at the appropriate time for the project to remain eligible for Federal funding. Designated recipients may incur costs for design and environmental review activities for all projects from the date of the authorization of formula funds or the date of the announcement of the competitive allocations of funds for the project.

For projects that qualify for a categorical exclusion (CE) pursuant to 23 CFR 771.118(c), designated recipients may start activities and incur costs for property acquisition, demolition, construction, and acquisition of vehicles, equipment, or construction materials from the date of the authorization of formula funds or the date of the announcement of the competitive allocation of funds for the project. FTA recommends that a grant applicant considering a (CE) pursuant to 23 CFR 771.118(c) contact FTA's Regional Office for assistance in determining the appropriate environmental review process and level of documentation necessary before incurring costs for property acquisition, demolition, construction, and acquisition of vehicles, equipment, or construction materials. If FTA subsequently finds that a project does not qualify for this CE, it will be ineligible for FTA assistance. FTA encourages grant applicants to contact FTA's Regional Office before exercising pre-award authority for projects to which it believes a CE at 23 CFR 771.118(c)(8), (9), (10), (12), or (13) applies.

For all other non-Capital Investment Grant projects that do not qualify for a CE under 23 CFR 771.118(c), grant applicants may take action and incur costs for property acquisition, demolition, construction, and acquisition of vehicles, equipment, or construction materials from the date that FTA completes the environmental review process required by NEPA and its implementing regulations, 23 U.S.C. 139, and other environmental laws by its issuance of a Section 771.118(d) categorical exclusion determination, a Finding of No Significant Impact (FONSI), or a Record of Decision (ROD).

*i.* Planning and other requirements.

Formula funds must be authorized or appropriated and earmarked project allocations published or announced before pre-award authority can be considered.

The requirement that a project be included in a locally-adopted Metropolitan Transportation Plan, the metropolitan transportation improvement program and federally-approved statewide transportation improvement program (23 CFR part 450) must be satisfied before the grantee may advance the project beyond planning and preliminary design with non-federal funds under pre-award authority. If the project is located within an EPA-designated non-attainment or maintenance area for air quality, the conformity requirements of the Clean Air Act, 40 CFR part 93, must also be met before the project may be advanced into implementation-related activities under pre-award authority triggered by the completion of the NEPA process. For a planning project to have pre-award authority, the planning project must be included in a MPO-approved Unified Planning Work Program (UPWP) that has been coordinated with the State.

*j.* Federal procurement procedures, as well as the whole range of applicable Federal requirements (*e.g.,* Buy America, Davis-Bacon Act, and Disadvantaged Business Enterprise) must be followed for projects in which Federal funding will be sought in the future. Failure to follow any such requirements could make the project ineligible for Federal funding. In short, this increased administrative flexibility requires a grantee to make certain that no Federal requirements are circumvented through the use of pre-award authority.

*k.* All program specific requirements must be met. For example, projects under Section 5310 must comply with specific program requirements, including coordinated planning.

Before incurring costs, grantees are strongly encouraged to consult with the appropriate FTA Regional office regarding the eligibility of the project for future FTA funds and for questions on environmental requirements, or any other Federal requirements that must be met.

4. Pre-Award Authority for the Fixed Guideway Capital Investment Grants Program

Projects proposed for Section 5309 Capital Investment Grant (CIG) program funds are required to follow a multi-step, multi-year process defined in law. For New Starts and Core Capacity projects, this process includes three phases: project development (PD), engineering, and construction. For Small Starts projects, this process includes two phases: PD and construction. After receiving a letter from the project sponsor requesting entry into the PD phase, FTA must respond in writing within 45 days whether the information was sufficient for entry. If FTA's correspondence indicates the information was sufficient and the New Starts, Small Starts or Core Capacity project enters PD, FTA extends pre-award authority to the project sponsor to incur costs for PD activities. PD activities include the work necessary to complete the environmental review process and as much engineering and design activities as the project sponsor believes are necessary to support the environmental review process. Upon completion of the environmental review process with a ROD, FONSI, or CE determination by FTA for a New Starts, Small Starts, or Core Capacity Improvement project, FTA extends pre-award authority to project sponsors to incur costs for as much engineering and design as needed to develop a reasonable cost estimate and financial plan for the project, utility relocation, and real property acquisition and associated relocations for any property acquisitions not already accomplished as a separate project for hardship or protective purposes or right-of-way under 49 U.S.C. 5323(q).

For Small Starts projects, upon completion of the environmental review process and confirmation from FTA that the overall project rating is at least a Medium, FTA extends pre-award authority for vehicle purchases. Upon receipt of a letter notifying a New Starts or Core Capacity project sponsor of the project's approval into the engineering phase, FTA extends pre-award authority for vehicle purchases as well as any remaining engineering and design, demolition, and procurement of long lead items for which market conditions play a significant role in the acquisition price. The long lead items include, but are not limited to, procurement of rails, ties, and other specialized equipment, and commodities.

Please contact the FTA Regional Office for a determination of activities not listed here, but which meet the intent described above. FTA provides this pre-award authority in recognition of the long-lead time and complexity involved with purchasing vehicles as well as their relationship to the ''critical path'' project schedule. FTA cautions grantees that do not currently operate the type of vehicle proposed in the project about exercising this pre-award authority. FTA encourages these sponsors to wait until later in the process when project plans are more fully developed. FTA reminds project sponsors that the procurement of vehicles must comply with all Federal requirements, including, but not limited to, competitive procurement practices, the Americans with Disabilities Act, Disadvantaged Business Enterprise program requirements and Buy America. FTA encourages project sponsors to discuss the procurement of vehicles with FTA in regard to Federal requirements before exercising pre-award authority. Because there is not a formal engineering phase for Small Starts projects, FTA does not extend pre-award authority for demolition and procurement of long lead items. Instead, this work must await receipt of a construction grant award or an expedited grant agreement.

a. Real Property Acquisition

As noticed above, FTA extends pre-award authority for the acquisition of real property and real property rights for fixed Guideway Capital Investment Grant projects (New or Small Starts or Core Capacity) upon completion of the environmental review process for that project. The environmental review process is completed when FTA signs an environmental Record of Decision (ROD) or Finding of No Significant Impact (FONSI), or makes a Categorical Exclusion (CE) determination. With the limitations and caveats described below, real estate acquisition may commence, at the project sponsor's risk. For FTA-assisted projects, any acquisition of real property or real property rights must be conducted in accordance with the requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act (URA) and its implementing regulations, 49 CFR part 24. This pre-award authority is strictly limited to costs incurred: (i) To acquire real property and real property rights in accordance with the URA regulation; and (ii) to provide relocation assistance in accordance with the URA regulation. This pre-award authority is limited to the acquisition of real property and real property rights that are explicitly identified in the final environmental impact statement (FEIS), environmental assessment (EA), or CE document, as needed for the selected alternative that is the subject of the FTA-signed ROD or FONSI, or CE determination. This pre-award authority regarding property acquisition that is granted at the completion of the environmental review process does not cover site preparation, demolition, or any other activity that is not strictly necessary to comply with the URA, with one exception—namely when a building that has been acquired, has been emptied of its occupants, and awaits demolition poses a potential fire safety hazard or other hazard to the community in which it is located, or is susceptible to reoccupation by vagrants. Demolition of the building is also covered by this pre-award authority upon FTA's written agreement that the adverse condition exists. Pre-award authority for property acquisition is also provided when FTA makes a CE determination for a protective buy or hardship acquisition in accordance with 23 CFR 771.117(d)(12). Pre-award authority for property acquisition is also provided when FTA completes the environmental review process for the acquisition of right-of-way as a separate project in accordance with 49 U.S.C. 5323(q). When a tiered environmental review in accordance with 23 CFR 771.111(g) is used, pre-award authority is NOT provided upon completion of the first-tier environmental document except when the Tier-1 ROD or FONSI signed by FTA explicitly provides such pre-award authority for a particular identified acquisition. Project sponsors should use pre-award authority for real

property acquisition relocation assistance with a clear understanding that it does not constitute a funding commitment by FTA. FTA provides pre-award authority upon completion of the environmental review process for real property acquisition and relocation assistance to maximize the time available to project sponsors to move people out of their homes and places of business, in accordance with the requirements of the URA, but also with maximum sensitivity to the circumstances of the people so affected.

b. Reimbursement of Costs Incurred Under Pre-Award Authority

Although FTA provides pre-award authority for property acquisition, long lead items, demolition, utility relocation, and vehicle purchases upon completion of the environmental review process, FTA does not award Federal funding for these activities conducted under pre-award authority until the project receives a Capital Investment Grants program construction grant. This is to ensure that Federal funds are not risked on a project whose advancement into construction is not yet assured.

c. National Environmental Policy Act (NEPA) Activities

NEPA requires that certain projects proposed for FTA funding assistance be subjected to a public and interagency review of the need for the project, its environmental and community impacts, and alternatives to avoid and reduce adverse impacts. Projects of more limited scope also need a level of environmental review (to determine whether there are significant environmental impacts) or confirmation that a categorical exclusion (CE) applies. FTA's regulation titled ''Environmental Impact and Related Procedures,'' at 23 CFR part 771 states that the costs incurred by a grant applicant for the preparation of environmental documents requested by FTA are eligible for FTA financial assistance (23 CFR 771.105(e)). Accordingly, FTA extends pre-award authority for costs incurred to comply with NEPA regulations and to conduct NEPA-related activities, effective as of the earlier of the following two dates: (1) The date of the Federal approval of the relevant STIP or STIP amendment that includes the project or any phase of the project, or that includes a project grouping under 23 CFR 450.216(j) that includes the project; or (2) the date that FTA approves the project into the project development phase of the CIG program. The grant applicant must notify the FTA Regional Office to initiate the Federal environmental review process in accordance with the ''Dear Colleague'' letter from the FTA Administrator dated February 24, 2011. NEPA-related activities include, but are not limited to, public involvement activities, historic preservation reviews, Section 4(f) evaluations, wetlands evaluations, endangered species consultations, and biological assessments. This pre-award authority is strictly limited to costs incurred to conduct the NEPA process and associated engineering, and to prepare environmental, historic preservation and related documents. When a New Starts, Small Starts, or Core Capacity project is granted pre-award authority for the environmental review process, the reimbursement for NEPA activities conducted under pre-award authority may be sought at any time through Section 5307 (Urbanized Area Formula Program) or the flexible highway programs (STP and CMAQ). Reimbursement from the Section 5309 CIG program for NEPA activities conducted under pre-award authority is provided only for expenses incurred after entry into the project development phase and only once a construction grant agreement is signed. As with any pre-award authority, FTA reimbursement for costs incurred is not guaranteed.

d. Other Activities Requiring Letter of No Prejudice (LONP)

Except as discussed in paragraphs i through iii above, a CIG project sponsor must obtain a written LONP from FTA before incurring costs for any activity not covered by pre-award authority. To obtain an LONP, an applicant must submit a written request accompanied by adequate information and justification to the appropriate FTA Regional Office, as described in B below.

*B. Letter of No Prejudice (LONP) Policy*

1. Policy

LONP authority allows an applicant to incur costs on a project utilizing non-Federal resources, with the understanding that the costs incurred subsequent to the issuance of the LONP may be reimbursable as eligible expenses or eligible for credit toward the local match should FTA approve the project at a later date. LONPs are applicable to projects and project activities not covered by automatic pre-award authority. The majority of LONPs will be for Section 5309 Capital Investment Grants program projects undertaking activities not covered under automatic pre-award authority. LONPs may be issued for formula funds beyond the life of the current authorization or FTA's extension of automatic pre-award authority; however, the LONP is limited to a five-year period, unless otherwise authorized in the LONP. Receipt of Federal funding under any program is not implied or guaranteed by an LONP.

2. Conditions and Federal Requirements

The conditions and requirements for pre-award authority specified in section V.4.ii and V.4.iii above apply to all LONPs. Because project implementation activities may not be initiated before completion of the environmental review process, FTA will not issue an LONP for such activities until the environmental review process has been completed with a ROD, FONSI, or CE determination.

3. Request for LONP

Before incurring costs for project activities not covered by automatic pre-award authority, the project sponsor must first submit a written request for an LONP, accompanied by adequate information and justification, to the appropriate regional office and obtain written approval from FTA. FTA approval of an LONP is determined on a case-by-case basis. Federal funding under the Fixed Guideway Capital Investment Grants program is not implied or guaranteed by an LONP. Specifically, when requesting an LONP, the applicant shall provide the following items:

*a.* Description of the activities to be covered by the LONP.

*b.* Justification for advancing the identified activities. The justification should include an accurate assessment of the consequences to the project scope, schedule, and budget should the LONP not be approved.

*c.* Allocated level of risk and contingency for the activity requested.

*C. FY 2018 Annual List of Certifications and Assurances*

The FY 2018 Certifications and Assurances and Master Agreement must be used for all grants and cooperative agreements awarded in FY 2018. All recipients with active projects are required to sign the FY 2018 Certifications and Assurances within 90 days of publication.

*D. Civil Rights Requirements*

1. Civil Rights Overview

Recipients must carry out provisions of the Americans with Disabilities act (ADA) of 1990, Section 504 of the Rehabilitation Act of 1973, as amended, and the U.S. DOT's implementing regulations at 49 CFR parts 27, 37, 38, and 39. FTA's ADA Circular (4710.1) provides guidance for carrying out the

regulatory requirements of the ADA. In addition, recipients must regularly prepare and submit civil rights program plans and reports to establish voluntary compliance and document policies and practices in the areas of Title VI, DBE and EEO. The current status of civil rights programs can be found on each recipient's Civil Rights Information page of TrAMS. New program plans and program updates can be submitted there as well. Prior to submitting an application for funding, recipients should consult with FTA Circulars and guidance and submit the following programs, as applicable:

*a.* Title VI of the Civil Rights Act of 1964: The U.S. DOT's Title VI implementing regulations are found in 49 CFR part 21. FTA's Title VI Circular (4702.1B) provides guidance for carrying out the regulatory requirements.

*b.* Disadvantaged Business Enterprise (DBE) program and triennial goal: The U.S. DOT's DBE implementing regulations are found in 49 CFR part 26 and provide guidance for carrying out the regulatory requirements and developing the triennial DBE goal.

*c.* Title VII of the Civil Rights Act of 1964, Equal Employment Opportunity (EEO): The U.S. DOT's EEO implementing regulations are found in 49 CFR part 21. FTA's EEO Circular (4704.1A) provides guidance for carrying out the regulatory requirements.

2. Title VI of the Civil Rights Act of 1964

Recipients in urbanized areas of 200,000 or more in population and with 50 or more fixed-route vehicles in peak service must conduct a service equity analysis for all service changes that meet the recipient's definition of ''major service change'' prior to implementing the service change. A service equity analysis is also required for all New Start, Small Start, or other new fixed guideway capital projects, and must be completed six months prior to implementing revenue service. Recipients also must conduct a fare equity analysis for all fare increases or decreases prior to implementing a fare change and for changes to fare media, such as a transition to a cashless fare system. Recipients that do not meet the abovementioned threshold of 200,000 or more in population and 50 fixed route vehicles in peak service (*i.e.,* small transit providers) are not required to conduct a service or fare equity analysis but should review their policies and practices to ensure their service and fare changes do not result in disparate impacts on the basis of race, color, or national origin. For guidance, see Title VI Circular 4702.1B at *https://www.transit.dot.gov/title6.* Should you have any questions, please contact your Regional Civil Rights Officer.

3. Disadvantaged Business Enterprise Program—Transit Vehicle Manufacturers

Recipients exercising pre-award authority are expected to comply with the Disadvantaged Business Enterprise (DBE) regulations. The Department of Transportation's DBE program helps small businesses owned by socially and economically disadvantaged individuals to compete in the marketplace, and is designed to support the people who create jobs—our nation's entrepreneurs. When procuring vehicles, 49 CFR 26.49(a) requires that transit vehicle manufacturers ''must establish and submit for FTA's approval an annual overall percentage goal'' and ''may make the certification required by this section if you have submitted the goal this section requires and FTA has approved it or not disapproved it.''

Recipients are advised that it is not sufficient to accept a certification stating that ''FTA has not disapproved'' of a TVMs DBE goal. Rather, Recipients must ensure that the TVM has submitted a goal to FTA and FTA has either approved it or not disapproved it. A recipient may request from FTA verification that a TVM has submitted a DBE goal to FTA for its review. Please email your Regional Civil Rights Officer regarding your request and FTA will respond via email within five business days. Furthermore, to assist with TVM certification compliance, FTA maintains a web posting of all certified TVMs located at *https://www.transit.dot.gov/TVM.*

Finally, FTA takes the position that failure by a Recipient to verify a TVM's eligibility to bid on an FTA-assisted contract prior to award cannot be cured after award of the contract and will likely result in FTA declining to provide Federal funding for the vehicle procurement.

Furthermore, recipients are also reminded of the requirement in 49 CFR 26.49(a)(4), which states that ''FTA recipients are required to submit within 30 days of making an award, the name of the successful bidder, and the total dollar value of the contract in the manner prescribed in the grant agreement.'' Recipients are to report to FTA all vehicle purchases, post-production alterations, and retrofit procurements within the 30 days of award. Vehicles purchased solely for personal use and/or purchased ''off the lot'' do not need to be reported.

*E. Consolidated Planning Grants*

FTA and FHWA planning funds under both the Metropolitan Planning and State Planning and Research Programs can be consolidated into a single consolidated planning grant, awarded by either FTA or FHWA. The Consolidated Planning Grants (CPG) eliminate the need to monitor individual fund sources, if several have been used, and ensures that the oldest funds will always be used first.

Under the CPG, States can report metropolitan planning program expenditures (to comply with the Uniformed Guidance 2 CFR 200, subpart F) for both FTA and FHWA under the Catalogue of Federal Domestic Assistance number for FTA's Metropolitan Planning Program (20.505). Additionally, for States with an FHWA Metropolitan Planning (PL) fund-matching ratio greater than 80 percent, the State can waive the 20 percent local share requirement, with FTA's concurrence, to allow FTA funds used for metropolitan planning in a CPG to be granted at the higher FHWA rate. For some States, this Federal match rate can exceed 90 percent.

States interested in transferring planning funds between FTA and FHWA should contact the FTA Regional Office or FHWA Division Office for more detailed procedures. The FHWA Order 4551.1 dated August 12, 2013, on ''Funding Transfers to Other Agencies and Among Title 23 Programs'' provides guidance and more detailed information.

*For further information on CPGs, contact Ann Souvandara, Office of Budget and Policy, FTA, at (202) 366–0649 or ann.souvandara@dot.gov.*

*F. Grant Application Procedures*

All applications for FTA funds should be submitted to the appropriate FTA Regional Office. All applications are filed electronically. FTA continues to award and manage grants and cooperative agreements using the Transit Award Management System (TrAMS). Information on accessing and using TrAMS, including a list of FTA points of contact for the system, can be found on FTA's website at *http://www.transit.dot.gov/TrAMS.*

FTA regional staff are responsible for working with grantees to review and process grant applications. For an application to be considered complete and ready for FTA to assign a Federal Award Identification Number (FAIN), enabling submission in TrAMS, and submission to the Department of Labor (when applicable), the following requirements must be met:

*1.* Recipient has registered in the System for Award Management (SAM) and its registration is current. If your agency is not registered or needs to ensure it is current, visit the SAM website at (*https://www.sam.gov*).

*2.* Recipient's contact information, including Dun and Bradstreet Data Universal Numbering System (DUNS), is correct and up-to-date. If requested by phone (1–866–705–5711), DUNS is provided immediately. If your organization does not have a DUNS, please visit the Dun & Bradstreet website at *http://fedgov.dnb.com/webform* to obtain the number.

*3.* Recipient has properly submitted its annual certifications and assurances.

*4.* Recipient's Civil Rights submissions are current.

After October 1, 2018, the grantee has a Transit Asset Management plan in place that meets the requirements of 49 CFR part 625, or is covered by a compliant Group Plan.

*5.* Documentation is on file to support recipient's status as either a designated recipient (for the program and area) or a direct recipient.

*6.* Funding is available, including any flexible funds included in the budget, and split letters or suballocation letters on file (where applicable) to support amount being applied for in grant application.

*7.* The project is listed in a currently approved Transportation Improvement Program (TIP); Statewide Transportation Improvement Program (STIP), or Unified Planning Work Program (UPWP).

*8.* All eligibility issues are resolved.

*9.* Required environmental findings are made.

*10.* The application contains a well-defined scope of work, including at least one project with accompanying project narratives, budget scope and activity line item information, Federal and non-Federal funding amounts, and milestones.

*11.* Major Capital Projects as defined by 49 CFR part 633 ''Project Management Oversight'' must document FTA has reviewed the project management plan and provided approval.

*12.* Milestone information is complete, or FTA determines that milestone information can be finalized before the grant is ready for award. FTA will also review status of other open grants' reports to confirm financial and milestone information is current on other open grants and projects.

Before FTA can award grants for competitive projects and activities, notification must be provided to the House and Senate authorizing and appropriations committees. Other important issues that impact FTA grant processing activities are discussed below.

*a. System for Award Management (SAM) Registration and Dun and Bradstreet Universal Numbering System (DUNS) Number.*

Each applicant or recipient of Federal Funds is required to: (1) Be registered in SAM before submitting its application; (2) have a valid DUNS number; and (3) continue to maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by the Federal Transit Administration (FTA). FTA will not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time the FTA is ready to make a Federal award, FTA may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

The System for Award Management (SAM) *https://www.sam.gov/portal/SAM/* is the Official U.S. Government system that consolidated the capabilities of many systems. There is no fee to register or use this site. Entities may register and update their information at no cost directly from the above site. SAM registration (formerly CCR registration) needs to be renewed at least annually.

*b. Award Budgets—Scope Codes and Activity Line Items (ALI) Codes; Financial Purpose Codes.*

FTA uses the Scope and Activity Line Item (ALI) Codes in the award budgets to track disbursements, monitor program trends, report to Congress, and to respond to requests from the Inspector General and the Government Accountability Office (GAO), as well as to manage grants. The accuracy of the data is dependent on the careful and correct use of codes.

c. Designated and Direct Recipients Documentation

For its formula programs, FTA primarily apportions funds to the designated recipient in the large UZAs (areas over 200,000), or for areas under 200,000 (small UZAs and rural areas), it apportions the funds to the Governor, or its designee (*e.g.,* State DOT). Depending on the program and as described in the individual program sections found in Section IV of this notice, further suballocation of funds may be permitted to eligible recipients who may then apply directly to FTA for the funding (direct recipients), so long as the required documentation is on file.

For the programs in which FTA may make grants to eligible direct recipients, other than the designated recipient(s), recipients are reminded that documentation must be on file to support: (1) The status of the recipient either as a designated recipient or direct recipient; and (2) the allocation of funds to the direct recipient.

Documentation to support existing designated recipients for the UZA must also be on file at the time of the first application in FY 2018. Further, split letters and/or suballocation letters (Governor's Apportionment letters), must also be on file to support grant applications from direct recipients. Once suballocation letters for FY 2018 funding are finalized they should be uploaded into TrAMS.

The Direct Recipient is required to upload to TrAMS a copy of the suballocation letter (Letter) indicating their allocation of funding [for the appropriate fund program] when the applicant transmits their application for initial review. The letter must be signed by the Designated Recipient, or as applicable in accordance with their planning requirements. If there are two Designated Recipients, both entities must sign the Letter. The Letter must: (1) Indicate the allocations to the respective Direct Recipients listed in the letter; (2) incorporate language above the signatories to reflect this agreement; and (3) make clear that the Direct Recipient will assume any/all responsibility associated with the award for the funds. When drafting the letter, Designated Recipients may use the template language below:

''As identified in this Letter, the Designated Recipient(s) authorize the reassignment/reallocation of [enter fund source; *e.g.* Section 5307 funds] to the Direct Recipient(s) named herein. The undersigned agree to the amounts allocated/reassigned to each direct Recipient. Each Direct Recipient is responsible for its application to the Federal Transit Administration to receive such funds and assumes the responsibilities associated with any award for these funds.''

2. Payments

Once a grant has been awarded and executed, requests for payment can be processed. To process payments, FTA uses ECHO-Web, an internet accessible system that provides grantees the capability to submit payment requests on-line, as well as receive user-IDs and passwords via email. New applicants should contact the appropriate FTA

Regional Office to obtain and submit the registration package necessary for set-up under ECHO-Web.

3. Oversight

FTA is responsible for conducting oversight activities to help ensure that grants recipients use FTA Federal financial assistance in a manner consistent with its intended purpose and in compliance with regulatory and statutory requirements. FTA conducts periodic oversight reviews to assess grantee compliance with applicable Federal requirements. Each Urbanized Area Formula Program recipient is reviewed every three years, (also known as FTA's Triennial Review); and States and state-wide public transportation agencies are reviewed periodically to assess the management practices and program implementation of FTA state-wide programs (*e.g.,* Planning, Rural Areas, Enhanced Mobility of Seniors and Individuals with Disabilities Programs). Other more detailed reviews are scheduled based on an annual grantee oversight assessment. Important objectives of FTA's oversight program include, but are not limited to: Determining grantee compliance with Federal requirements; identifying technical assistance needs, and delivering technical assistance to meet those needs; spotting emerging issues with grantees in a forward-looking fashion; recognizing when there is a need for more in-depth reviews in the areas of procurement, financial management, and civil rights; and identifying grantees with recurring or systemic issues.

4. Technical Assistance

As noted throughout the notice, FTA continues to rely on several of the existing program circulars for general program guidance. FTA is continuing to update the program circulars, with an opportunity for notice and comment (where warranted), to reflect amendments to chapter 53 of title 49, U.S.C. made by the FAST Act. In the meantime, if you have any questions, please do not hesitate to contact FTA. FTA headquarters and regional staff will be pleased to answer your questions and provide any technical assistance you may need to apply for FTA program funds and manage the grants you receive. At its discretion, FTA may also use program oversight consultants to provide technical assistance to grantees on a case by case basis. This notice and the program guidance circulars previously identified in this document may be accessed via the FTA website at *www.fta.dot.gov.*

*G. Grant Management*

1. Grant Reporting

Recipients of FTA funds are reminded that all FTA grantees are required to report on their grants. It is critical to ensure reports demonstrate that reasonable progress is being made on projects. At a minimum, all awards require a Federal Financial Report (FFR) and a Milestone Progress Report (MPR) on an annual basis. Some reports are required quarterly depending on the recipient and the type of projects funded under the grant and FTA's risk-based reporting policy that went into effect on October 1, 2017. The requirements for these reports and other reporting requirements can be found in the latest version of FTA Circular 5010. FTA staff, auditors, and contractors rely on the information provided in the FFR and MPR to review and report on the status of both financial and project-level activities contained in the grant. It is critical that recipients provide accurate and complete information in these reports and submit them by the required due date. Failure to report and/or demonstrate reasonable progress on projects can result in suspension or premature close-out of a grant.

2. Inactive Grants and Grant Closeout

In FY 2018 FTA will continue to focus on identifying and working with recipients to close inactive grants. If appropriate, FTA will act to close out and deobligate funds from these grants if reasonable progress is not made. The efficient use of funds will further FTA's fulfillment of its mission to provide efficient and effective public transportation systems for the nation. As inactive grants continue to be an audit finding within the DOT, FTA must act to ensure its grants do not prevent the DOT from receiving a ''clean audit'' opinion on its annual financial statements.

In October 2017, FTA identified a list of grants that were awarded on or prior to September 30, 2014 and have had no funds disbursed since September 30, 2016 or have never had a disbursement. FTA Regional Offices will be contacting grant recipients with grants that meet these criteria to notify them that FTA intends to close the grant and deobligate any remaining funds unless the grantee can provide information that demonstrates that the projects funded by the grant remain active and the grantee has a realistic schedule to expedite completion of the projects funded in the grant.

In addition, FTA will work to identify any grants that may be subject to Grants Oversight and New Efficiency (GONE) Act reporting in October 2018. The GONE Act requires Federal agencies to report active awards whose period of performance end date is two or more years prior to the end of the fiscal year. For FY 2018, this means any active award with a period of performance end date on September 30, 2016 or prior. FTA plans to work with recipients whose awards are in this category to close the awards or modify the award to extend the period of performance, as necessary.

Issued in Washington, DC.

**K. Jane Williams,**

*Acting Administrator.*

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Part IV

## Nuclear Regulatory Commission

10 CFR Parts 30, 32, and 35

Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments; Final Rules

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Parts 30, 32, and 35**

**[NRC–2008–0175]**

**RIN 3150–AI63**

## Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations related to the medical use of byproduct material. The final rule will amend the NRC regulations related to the medical use of byproduct material. This rule amends the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. This rule also amends the training and experience (T&E) requirements to remove from multiple sections the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State; and address a request filed in a petition for rulemaking (PRM), PRM–35–20, to exempt certain board-certified individuals from certain T&E requirements (*i.e.,* ''grandfather'' these individuals). Additionally, this rule amends the requirements for measuring molybdenum contamination; adds a new requirement for the reporting of failed technetium and rubidium generators; and allows licensees to name associate radiation safety officers (ARSOs) on a medical license.

**DATES:** This final rule is effective on January 14, 2019.

**ADDRESSES:** Please refer to Docket ID NRC–2008–0175 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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0175. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *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:** Kimyata Morgan-Butler, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–0733, email: *Kimyata.Morgan-Butler@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### Executive Summary

#### *A. Need for the Regulatory Action and Legal Authority*

The NRC is amending its regulations related to the medical use of byproduct material. These regulations were last amended in their entirety in 2002. Over the last 14 years, stakeholders and members of the medical community have identified certain issues in implementing these regulations. As a result, the NRC is updating its regulations to address technological advances and changes in medical procedures. The amended rule would also enhance patient safety. The NRC is revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR) under the legal authority granted to the NRC by the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

#### *B. Major Provisions*

- The final rule establishes separate requirements for identifying and reporting MEs involving permanent implant brachytherapy. These new regulations require reporting of an event in which there is actual or potential harm to a patient resulting from an ME. Additionally, licensees are required to develop, implement, and maintain procedures for determining if an ME has occurred, including procedures for verifying certain aspects of a permanent implant brachytherapy treatment within 60 days from the date the treatment was performed. Note that the terms ''ME,'' ''ME definition,'' ''ME criteria,'' and ''ME reporting criteria'' are used interchangeably in the Executive Summary and the Discussion sections of this document.
- Training and experience requirements are amended in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC has determined that certification by a specialty board, coupled with meeting the recentness of training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the T&E requirements and has the requisite current knowledge and, therefore, additional attestation by a preceptor is unnecessary. Individuals who are not board certified will still need to obtain a written attestation; however, the language of the attestation is modified. Additionally, residency program directors will be allowed to provide these written attestations. Note that the terms ''written attestation,'' ''attestation,'' ''preceptor statement,'' and ''preceptor attestation'' are used interchangeably in the Executive Summary and the Discussion sections of this document.
- The rule addresses the issues raised in a petition for rulemaking (PRM–35–20) that was submitted to the NRC in 2006. The petition requested that experienced board-certified Radiation Safety Officers (RSOs) and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempt from the specific T&E requirements in §§ 35.50 and 35.51, respectively. In effect, they will be ''grandfathered'' for these training requirements for the modalities that they practiced as of October 24, 2005. This petition is discussed in detail in Section II., Petition for Rulemaking, PRM–35–20, of this document.
- The requirements for measuring the molybdenum-99 (Mo-99) concentration for elutions of Mo-99/Technetium-99m (Tc-99m) generators are changed and requirements are added for reporting and notification of a generator eluate exceeding permissible Mo-99, strontium-82 (Sr-82), or strontium-85 (Sr-85) concentrations. The occurrence of generator eluate exceeding permissible concentrations is also referred to as ''breakthrough.'' The current requirement to measure the Mo-99 concentration after the first eluate is changed to require that the Mo-99 concentration be measured in each eluate. This requirement is changed in

response to several breakthrough incidents reported to the NRC.

• Additionally, licensees will be allowed to appoint a qualified individual with expertise in certain uses of byproduct material to be named on a license to serve as an ARSO. This will make it easier for an individual to become an RSO on other medical licenses and will increase the number of individuals who are available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs.

*C. Costs and Benefits*

The NRC has not established a quantitative cutoff for defining an economically significant regulatory action for the purposes of the Congressional Review Act. The NRC assumes ''significant'' impact if the ratio of annualized costs to estimated annual gross revenues for a licensee exceeds 1 percent. The final rule will have an estimated $7.8 million implementation cost for the medical community. This cost will be spread over the 7,418 impacted licensees for an average implementation cost of approximately $1,100 per licensee. The NRC assumes that all affected licensees have annual revenues greater than $110,000. Therefore, the estimated cost impacts do not exceed the 1 percent criterion for ''significant'' impacts, and the final rule is not considered an economically significant regulatory action. It will cost the NRC approximately $65,000 to implement this rule.

The benefits of this final rule are associated with reducing unnecessary radiation exposure to patients, removing the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, and affording greater flexibility to licensees. This final rule also updates, clarifies, and strengthens the existing regulatory requirements, and, thereby, promotes public health and safety.

A regulatory analysis has been developed for this rulemaking and is discussed in Section VIII., Regulatory Analysis, of this document.

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## I. Background

The NRC published a final rule in the **Federal Register** on April 24, 2002 (67 FR 20250), that revised the medical use regulations in 10 CFR part 35 in their entirety. The T&E requirements in 10 CFR part 35 were further revised through an additional rulemaking, ''Medical Use of Byproduct Material—Recognition of Specialty Boards,'' published in the **Federal Register** on March 30, 2005 (70 FR 16336).

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process. As a result, the NRC is amending its regulations in 10 CFR part 35 to address these issues. This final rule modifies the written directive (WD) requirements in § 35.40 and the ME reporting requirements in § 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy. This final rule also modifies the requirements for procedures for administrations requiring a WD in § 35.41 to require licensees to develop written procedures for determining if an ME has occurred as a result of any administrations requiring a WD, including permanent implant brachytherapy. The NRC's purpose for requiring licensees to report MEs is to allow the NRC to follow up on incidents and determine if other licensees might be making the same or similar mistakes, or experiencing the same or similar challenges. When the NRC identifies similarities in the problems reported from multiple facilities, it can provide information that may help prevent additional incidents. The information collected is also valuable in assessing trends or patterns, identifying generic issues, and recognizing any inadequacies or unreliability of specific equipment or procedures.

Currently, the ME criteria for brachytherapy implants in § 35.3045, ''Report and notification of a medical event,'' are based on the dose administered to the patient. The ME criteria amendments establish separate ME criteria for permanent implant brachytherapy in terms of the total source strength administered (activity-based) rather than the dose delivered (dose-based). The ME criteria amendments in this final rule are based on the NRC staff recommendations contained in SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,'' and the comments received on the proposed rule ''Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments,'' published in the **Federal Register** on July 21, 2014 (79 FR 42410). The staff has concluded that dose-based criteria are problematic for permanent implant brachytherapy because absorbed dose can be challenging to calculate resulting in clinically acceptable therapies being reported as medical events. In addition, moving to activity-based criteria should allow for recognition of medical events earlier than dose-based criteria, thus allowing timelier corrective actions.

On August 6, 2008, the NRC published a proposed rule, ''Medical Use of Byproduct Material—Amendments/Medical Event Definitions,'' in the **Federal Register** (73 FR 45635), for public comment. This proposed rule included revised ME criteria for permanent implant brachytherapy. The majority of commenters were in agreement on converting the permanent implant brachytherapy ME criteria from dose-based to activity-based. However, during late summer and early fall of 2008, a substantial number of MEs involving permanent implant brachytherapy were reported to the NRC. Based on the circumstances involving the MEs reported in 2008, the NRC staff re-evaluated the proposed rule that was published in 2008 and developed a draft re-proposed rule.

In SECY–10–0062, ''Re-proposed Rule: Medical Use of Byproduct Material—Amendments/Medical Event Definitions,'' dated May 18, 2010, the NRC staff requested that the Commission approve for publication the draft re-proposed rule for public comment. Prior to a Commission decision on the re-proposed rule, on July 8, 2010, a Commission briefing was held on the draft re-proposed rule. The

presenters included a member of the ACMUI, a representative from the Organization of Agreement States (OAS), a physician from the American Brachytherapy Society, the National Director of the Radiation Oncology Program of the Department of Veterans Affairs, a representative from the American Association of Physicists in Medicine (AAPM), and a representative from Us-TOO (a support group for prostate cancer patients). The presenters urged the Commission not to publish the draft re-proposed rule as developed. They believed that MEs should be based on events of potential clinical significance and recommended that the NRC seek stakeholder input in revising this proposed rule.

In the Staff Requirements Memorandum (SRM) for SECY–10–0062, dated August 10, 2010, the Commission disapproved the NRC staff's recommendation to publish the draft re-proposed rule. The Commission directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions that would protect the interests of patients and allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users (AUs). The SRM also directed the NRC staff to hold a series of stakeholder workshops to discuss issues associated with the ME definition. For more information, including public comments submitted on the proposed rule published on August 6, 2008, (see Docket ID NRC–2008–0071 on *www.regulations.gov*).

Following Commission direction, the NRC conducted two workshops in the summer of 2011. These facilitated workshops were held in New York, New York, in June 2011, and in Houston, Texas, in August 2011. The NRC staff also requested the ACMUI to prepare a report on ME definitions for permanent implant brachytherapy. In February 2012, the ACMUI submitted its final revised report to the NRC. The NRC staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders, to develop the recommendations in SECY–12–0053. The recommendations in SECY–12–0053, along with public comments received on the proposed rule published on July 21, 2014 (79 FR 42410), provided the regulatory basis for the ME reporting criteria in this final rule.

In addition to revising the ME definitions for permanent implant brachytherapy, the NRC is amending its regulations in 10 CFR part 35 to: Revise the preceptor attestation requirements; require increased frequency of testing for measuring Mo-99 concentration in a Mo-99/Tc-99m generator; require reporting and notification when a generator eluate exceeds permissible Mo-99, Sr-82, or Sr-85 concentrations; allow ARSOs to be named on a medical use license; extend the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years; and make several clarifying amendments.

Finally, this final rule addresses issues that were raised in PRM–35–20 filed by E. Russell Ritenour, Ph.D., on behalf of the AAPM on September 13, 2006. The petition requested that the training requirements for experienced RSOs and medical physicists in § 35.57 be amended to recognize board-certified physicists and RSOs as ''grandfathered'' for the modalities that they practiced as of October 24, 2005. The petition is discussed in detail in Section II., Petition for Rulemaking, PRM–35–20, of this document. This final rule completes action on PRM–35–20.

## II. Petition for Rulemaking, PRM–35–20

The NRC has incorporated into this rulemaking the resolution of PRM–35–20 filed by E. Russell Ritenour, Ph.D. (the petitioner), dated September 10, 2006, on behalf of the AAPM (Ritenour Petition). A notice of receipt and request for public comments on this petition was published in the **Federal Register** on November 1, 2006 (71 FR 64168).

The petitioner requested that § 35.57, ''Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist,'' be revised to: (1) Recognize medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics on or before October 24, 2005, as ''grandfathered'' for the modalities that they practiced as of October 24, 2005, regardless of whether a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005; and (2) recognize all individuals certified by the named boards in former subpart J of 10 CFR part 35, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), as RSOs who have relevant timely work experience (even if they have not been formally named as an RSO). The petitioner requested that experienced board-certified RSOs and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempted from the specific T&E requirements in §§ 35.50 and 35.51, respectively. In effect, they would be ''grandfathered'' for these training requirements for the modalities that they practiced on or before October 24, 2005. The petitioner was concerned that as a result of the amendments to the T&E regulations in 2005, an individual could become authorized on a license only if he or she had been certified by a specialty board whose certification process was recognized under this regulation by the NRC or an Agreement State or was already identified on an existing NRC or Agreement State license. If the individual had been certified prior to the effective date for recognition of the certifying board but had not been listed on a license, he or she would not be ''grandfathered,'' and would have to obtain training through the so-called ''alternate pathway,'' which establishes specific training requirements for non-certified individuals. The petitioner did not believe that it was the intent of the Commission to deny recognition to individuals currently practicing or to minimize the importance of certification by a certifying board. The NRC received 168 comments from professional organizations and individuals on the petition. The majority of the commenters supported the petition.

The NRC reviewed the petitioner's request and comments received on the petition and concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board-certified individuals. This group of board-certified individuals may now have to use the alternate pathway option to demonstrate that they meet the T&E requirements in 10 CFR part 35 rather than the certification pathway for recognition on an NRC license as an RSO or an authorized medical physicist (AMP). Therefore, the NRC concluded that the issues raised in the petition would be considered in the rulemaking process if a regulatory basis could be developed to support a rulemaking (73 FR 27773; May 14, 2008).

In October 2008, the NRC staff sent letters to all of the certifying boards whose certification processes are currently recognized by the NRC and to certifying boards previously named in the former 10 CFR part 35, subpart J, whose certification processes currently are not recognized by the NRC. To determine the scope of the medical community that might be negatively impacted by the amendments to the T&E regulations in 2005, the NRC asked each organization to provide the number and percentage of its currently active diplomates who are not grandfathered

under § 35.57 by virtue of not being named on a license or permit. The organizations were asked to include individuals who are now or may seek to be named as an RSO, AMP, AU, or authorized nuclear pharmacist (ANP) on an NRC or an Agreement State medical use license. Based on the responses, the NRC estimates that as many as 10,000 board-certified individuals may have been affected by the 2005 T&E rulemaking.

The NRC believes that these individuals should be eligible for grandfathering for the modalities that they practiced on or before October 24, 2005, because their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint and thus they should be allowed to continue to practice using the same modalities. This final rule, in response to the petition, amends § 35.57 to recognize all individuals who were previously certified by boards recognized under the previous 10 CFR part 35, subpart J, as RSOs, teletherapy or medical physicists, AMPs, AUs, nuclear pharmacists, and ANPs for the modalities that they practiced on or before October 24, 2005.

In his support for grandfathering the RSOs who have relevant work experience and were not formally named on an NRC or an Agreement State license or permit as an RSO, the petitioner stated that these individuals will be required to provide preceptor attestations. In this rulemaking, the NRC has eliminated the requirement for preceptor attestations for individuals certified by NRC- or Agreement State-recognized boards. The NRC believes that attestations are not necessary in this particular situation because the provisions of § 35.59, ''Recentness of training,'' require that the T&E must have been obtained within the 7 years preceding the date of application, or the individual must have had related continuing education and experience since the required T&E was completed. The ''grandfathered'' individuals will fall under the provisions of § 35.59 and will need to provide evidence of continued education and experience. Therefore, the NRC believes that preceptor attestations are not necessary for these ''grandfathered'' individuals as long as the provisions of § 35.59 are met, and the individual only requests authorizations for the modalities the individual practiced on or before October 24, 2005.

## III. Discussion

### *A. What action is the NRC taking?*

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the ACMUI identified numerous issues that need to be addressed through the rulemaking process. The NRC published a proposed rule on July 21, 2014 (79 FR 42410), for a 120-day public comment period to address these issues. The NRC developed this final rule based on the comments received on the proposed rule. The comments are discussed in Section V., Public Comment Analysis, of this document.

The final rule clarifies the current regulations and provides greater flexibility to licensees without compromising patient, worker, or public health and safety. The amendments in this final rule include:

1. Adding separate ME definitions for permanent implant brachytherapy;
2. amending preceptor attestation requirements;
3. grandfathering certain board-certified individuals, as discussed in Section II., Petition for Rulemaking, PRM–35–20, of this document;
4. requiring increased frequency of testing to measure Mo-99 breakthrough;
5. requiring reporting and notification when a generator eluate exceeds permissible concentrations of Mo-99, Sr-82, Sr-85;
6. allowing ARSOs to be named on a medical use license; and
7. additional issues and clarifications.

The major revisions are:

#### a. Adding Separate ME Definitions for Permanent Implant Brachytherapy

This final rule establishes separate ME definitions and reporting requirements for permanent implant brachytherapy. The staff has concluded that dose-based criteria are problematic for permanent implant brachytherapy because absorbed dose can be challenging to calculate resulting in clinically acceptable therapies being reported as medical events. In addition, moving to activity-based criteria should allow for recognition of medical events earlier than dose-based criteria, thus allowing timelier corrective actions. As explained in Section I, Background, of this document, these amendments are based on the recommendations developed in close cooperation with the ACMUI, with substantial input from various stakeholders, and from public comments received on the proposed rule. During its meeting in March 2004, the ACMUI discussed the inadequacy of the definition of MEs as applied to permanent implant brachytherapy. The ACMUI explained that for these implants, the plus or minus 20 percent variance from the WD criteria in the existing rule was only appropriate if both the WD and the variance could be expressed in units of activity, rather than in units of dose. The ACMUI explained that there is no suitable clinically used dose metric available for judging the occurrence of MEs for permanent implant brachytherapy. In June 2005, the ACMUI recommended that new language be developed to define MEs for permanent implant brachytherapy.

Based on the recommendations from the ACMUI, the NRC staff submitted a paper to the Commission, SECY–05–0234, ''Adequacy of Medical Event Definitions in § 35.3045, and Communicating Associated Risks to the Public,'' dated December 27, 2005. In this paper, the NRC staff recommended that the Commission approve, for permanent implant brachytherapy, the NRC staff's plan to revise the ME definitions in § 35.3045 and the associated requirements for WDs in § 35.40 to be activity-based, instead of dose-based. In the SRM for SECY–05–0234, dated February 15, 2006, the Commission directed the NRC staff to proceed directly with the development of a proposed rule to modify both the WD requirements in § 35.40(b)(6) and the ME reporting requirements in § 35.3045 for permanent implant brachytherapy medical use, to convert from dose-based to activity-based ME criteria.

As discussed in Section I., Background, of this document, a proposed rule was published in the **Federal Register** on August 6, 2008 (73 FR 45635). A substantial number of MEs were reported in 2008 that would not have met the criteria for reporting under the activity-based ME reporting criteria as noticed in the proposed rule. Therefore, the NRC staff drafted a different rule that contained absorbed dose-based ME reporting criteria for the treatment site. The NRC staff submitted recommendations for ME reporting criteria to the Commission in SECY–10–0062, ''Reproposed Rule: Medical Use of Byproduct Material—Amendments/Medical Event Definitions,'' dated May 18, 2010. In the SRM for SECY–10–0062, dated August 10, 2010, the Commission disapproved the NRC staff's recommendations and directed the NRC staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions and to hold a series of stakeholder workshops to discuss issues associated with the MEs.

Subsequently, during the ACMUI meeting held on October 20, 2010, the ACMUI unanimously approved its interim report, ''Advisory Committee on Medical Uses of Isotopes Permanent Implant Brachytherapy Interim Report,'' dated October 20, 2010. The ACMUI meeting held in April 2011 was devoted to issues associated with the ME definition. The meeting was webcast, providing an opportunity for further public involvement on this issue.

The ACMUI submitted its final report on permanent implant brachytherapy, dated October 18, 2011, to the NRC following the ACMUI October 18, 2011, public teleconference meeting. The final report reflected the principal positions and recommendations provided by participants during the NRC public workshops. In particular, the report included the recommendation to change from dose-based ME criteria for the treatment site to source-strength based criteria. The final report included a quantitative metric, the ''octant approach,'' for determining that a distribution of implanted sources was irregular enough (*i.e.,* demonstrating ''bunching'') to consider the procedure as an ME. The final report also included a dose-related ME criterion for the treatment site.

However, in a letter to the Chairman of the ACMUI dated November 30, 2011, the American Society for Radiation Oncology (ASTRO) expressed criticism of the ACMUI final report. The ASTRO considered the ME definition recommended by the ACMUI to be complex, difficult to regulate, and likely to cause confusion in practice. Subsequently, the ACMUI issued a revised final report, ''Advisory Committee on Medical Use of Isotopes (ACMUI) Permanent Implant Brachytherapy Revised Final Report,'' dated February 7, 2012. The ACMUI simplified the ME criteria for the treatment site, removing the ''octant approach'' and direct reference to absorbed dose to the treatment site. The revised final report was, with minor modifications, approved by the ACMUI during its public teleconference meeting held on February 7, 2012. The ASTRO, in a letter to the Chairman of the ACMUI, characterized this report as an improvement on the earlier report.

The NRC staff used the recommendations in the ACMUI revised final report dated February 7, 2012, along with the substantial input from stakeholders gathered in the two facilitated public workshops and the three ACMUI public meetings in 2011 and early 2012 (discussed earlier in this section), to develop the recommendations submitted to the Commission on April 6, 2012, in SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs.'' In a Commission meeting held April 24, 2012, participating representatives from ACMUI, ASTRO, and the American Brachytherapy Society (ABS) endorsed the recommendations in SECY–12–0053 for modification of the requirements in §§ 35.40 and 35.3045. The NRC notes that ASTRO and ABS representatives suggested eliminating the recommended criterion for ME reporting that would have required reporting of excessive dose to normal tissue structures within the treatment site. However, this ACMUI-recommended ME reporting criterion for normal tissue structures located within the treatment site was retained in SECY–12–0053 because the ACMUI and the NRC staff determined that there should be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site. In the SRM for SECY–12–0053, dated August 13, 2012, the Commission approved the NRC staff recommendations. The recommendations are applicable to all permanent implant brachytherapy procedures using radioactive sources for all treatment sites.

The proposed rule published on July 21, 2014 (79 FR 42410) also included ME criteria in § 35.3045(a)(2)(iii) and (iv) as follows: For normal-tissue structures, an ME has occurred if: (a) For structures located outside of the treatment site (for example, the bladder or rectum for prostate implant treatments), the dose to the maximally exposed 5 contiguous cubic centimeters of tissue exceeds 150 percent of the absorbed dose prescribed to the treatment site in the pre-implantation portion of the WD; or (b) for intra-target normal structures, the maximum absorbed dose to any 5 contiguous cubic centimeters of tissue exceeds 150 percent of the dose the tissue would have received based on the approved pre-implantation dose distribution. The size of the normal tissue, 5 cubic centimeters, was based on an ACMUI recommendation in its October 20, 2010, report. In its recommendation, the ACMUI stated that the 5 contiguous cubic centimeters dose-volume specification avoids the high variation in dose sometimes seen in point doses and the ACMUI cited literature to support 5 cubic centimeters as being a relevant quantity for toxicity. In the proposed rule, the NRC specifically invited comments on the selection of the specified volume of the normal tissues located both outside and within the treatment site in defining MEs.

The NRC received numerous comments expressing concern about the proposed ME criteria related to the absorbed dose to normal tissues located outside and within the treatment site. The commenters expressed concerns that they would have technical difficulties assessing dose to normal tissues located outside and within the treatment site. They stated that their treatment planning systems are not equipped to make such assessments. They believed the regulators may not be able to inspect such requirements. They stated that these requirements may cause confusion and result in licensees not performing permanent implant brachytherapy treatments. The comments are discussed in Section V., Public Comment Analysis, of this document.

Based on public comments and recommendations from the ACMUI, the ME criteria in this final rule for permanent implant brachytherapy in § 35.3045(a)(2) do not include absorbed doses to normal tissues located outside of or within the treatment site. Instead, the ME criteria in the final rule for permanent implant brachytherapy are:

(1) An ME has occurred if the total source strength administered differs by 20 percent or more from the total source strength documented in the post-implantation portion of the WD;

(2) An ME has occurred if the total source strength administered outside of the treatment site exceeds 20 percent of the total source strength documented in the post-implantation portion of the WD; or

(3) An ME has occurred if an administration involves: (a) Using the wrong radionuclide, (b) delivery to the wrong individual or human research subject, (c) sealed source(s) implanted directly into a location discontiguous from the treatment site as documented in the post-implantation portion of the WD (as discussed in this document, discontiguous means a location that is not physically adjacent to the treatment site), or (d) a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

In supporting these recommendations, the NRC believes that source strength is the appropriate measurable metric for defining MEs involving permanent implant brachytherapy. The 20 percent variance threshold is consistent with the recommendation of the ACMUI for all medical uses of byproduct material as described in SECY–05–0234, discussed earlier in this section.

Another ME criterion included in the proposed rule published on July 21,

2014 (79 FR 42410), was related to source(s) implanted directly into the wrong site or body part (*i.e.,* not in the treatment site identified in the WD). This criterion stated that ''even a single sealed source directly delivered to the wrong treatment site would constitute an ME that must be reported.'' The NRC received several comments on this issue. The commenters believed a single source delivered outside the treatment site was an inappropriate criterion for ME reporting. They proposed that in order to capture instances where a source is implanted in a distinctly wrong location (for example, left breast versus the right breast), the criterion should say, ''Even a single sealed source directly delivered to a noncontiguous wrong treatment site would constitute an ME that must be reported.''

In response to these comments and a recommendation from the ACMUI in its final report on the draft final rule (''Advisory Committee on the Medical Uses of Isotopes Comments on the Draft Final Rule, 10 CFR parts 30, 32, and 35, Final Report,'' dated January 6, 2016), the NRC has changed § 35.3045(a)(2)(v)(C) [redesignated as § 35.3045(a)(2)(iii)(C)] to read ''Sealed source(s) implanted directly into a location discontiguous from the treatment site as documented in the post-implantation portion of the written directive.''

This ''wrong treatment site'' ME criterion will capture cases in which total source strength administered outside of the treatment site did not exceed 20 percent of the total source strength documented in the post-implantation portion of the WD, but one or more sources were directly implanted into a location far from the treatment site. For example, in a case in which 100 sources were implanted, 81 were within the treatment site, 18 sources were outside and contiguous to the treatment site, and one source was erroneously implanted directly into a site discontiguous from the treatment site. This would not be an ME under the ''exceeds 20 percent of the total source strength'' criterion; but would be an ME because one source met the ''wrong treatment site'' criterion.

The proposed criterion specified in § 35.3045(a)(2)(v)(E), ''a 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive,'' in the proposed rule published on July 21, 2014, was not included in the final rule. The decision not to include this criterion is based on the comments received on the proposed rule and is discussed in Section V., Public Comment Analysis, of this document.

The new ME criteria for permanent implant brachytherapy in § 35.3045 require amendments to §§ 35.40 and 35.41. The previous WD requirements were primarily associated with temporary implant brachytherapy medical use. This final rule establishes separate WD requirements in § 35.40, ''Written directives,'' that are appropriate for permanent implant brachytherapy. This rule requires that the WD for permanent implant brachytherapy consist of two portions. The first portion of the WD must be prepared before the implantation, and the second portion of the WD must be completed after the procedure but before the patient leaves the post-treatment recovery area. For permanent implant brachytherapy, this rule requires that the WD portion prepared before the implantation include documentation of the treatment site, the radionuclide, and the total source strength. This final rule requires that the post-implantation portion of the WD contain documentation of the treatment site, the number of sources implanted, the total source strength implanted, and the date.

Based on ACMUI input discussed earlier in this section and information gained at public workshops, the NRC understands that the final WD for these permanent implants must allow for unanticipated medical situations encountered during the procedure. For instance, an AU might need to adjust the number of sources implanted because the volume of the treatment site may have decreased since the treatment plan was developed. Therefore, in defining an ME involving the treatment site for permanent implants, the NRC based the criterion for an ME on the percentage of implanted sources that are outside the treatment site as documented in the post-implantation portion of the WD rather than by defining an ME based on a comparison of the implanted total source strength to the total source strength documented in the pre-implantation portion of the WD. This definition differs from the ME definition for all other brachytherapy procedures where dose comparisons are made with reference to what was prescribed in the WD that was prepared before the procedure.

This final rule also makes changes to § 35.41, ''Procedures for administrations requiring a written directive,'' to include permanent implant brachytherapy. Although § 35.41(a)(2) requires licensees to determine if the administration is in accordance with the WD, there is no specific requirement that a licensee determine that an administered dose or dosage met an ME criterion as defined in § 35.3045. Section 35.41 is amended to require that a licensee develop procedures for determining if an ME has occurred. For all permanent implant brachytherapy, § 35.41 is also amended to require that a licensee develop additional procedures to include an evaluation of the placement of sources as documented in the post-implantation portion of the WD. The procedures must include a provision that these assessments must be made within 60 days from the date the treatment was performed. Although there is no requirement in § 35.41 to use imaging to determine the occurrence of an ME, imaging is the best (and in some circumstances may be the only) method to determine source strength outside of the treatment site and is routinely practiced in most clinical facilities.

b. Amending Preceptor Attestation Requirements

The current regulations in 10 CFR part 35 provide three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: (1) Approval of an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State (certification pathway); (2) approval based on an evaluation of an individual's T&E (alternate pathway); or (3) identification of an individual's approval on an existing NRC or Agreement State license.

Under the certification and the alternate pathway, an individual seeking authorization for medical byproduct material must obtain a written attestation signed by a preceptor with the same authorization. The attestation must state that the individual has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought.

During a Commission briefing held on April 29, 2008, the ACMUI recommended that the attestation requirements be revised. The ACMUI expressed concern that the existing requirements have had unintended consequences that, if not corrected, would impact the availability of authorized individuals. In other words, there would likely be a shortage of authorized individuals to provide medical care as a result of the reluctance of preceptors to sign attestations. The ACMUI recommended that attestations be eliminated for the board certification

pathway. In the ACMUI's view, by meeting the board requirements, a curriculum and a body of knowledge can be defined, and progress toward meeting defined requirements can be measured. Further, the ACMUI asserted that a board certification indicates that the T&E requirements have been met, and the Maintenance of Certification provides ongoing evidence of current knowledge. Therefore, the ACMUI asserted that an additional attestation for the board-certified individuals was not needed.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be amended to delete the requirement to attest to an individual's radiation safety-related competency. The reason for the recommendation was that the ACMUI believed that signing an attestation of competence results in a perceived risk of personal liability on the part of the individual signing the attestation and that preceptors are reluctant to accept this risk.

In addition, the ACMUI recommended that the attestation submitted under the alternate pathway be considered acceptable if it is provided by a residency program director representing a consensus of an authoritative group, irrespective of whether the program director personally met the requirements for AU status. The ACMUI advised that training of residents is a collective process and entails the collective judgment of an entire residency program faculty, whereas preceptor attestation is an individual process, and an individual preceptor typically would provide only a small portion of the T&E.

Following the April 29, 2008, Commission briefing, in an SRM dated May 15, 2008, the Commission directed the NRC staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board-certified individuals and for individuals seeking authorization via the alternate pathway. The Commission also directed the NRC staff to consider additional methods, such as having the attestation provided by consensus of an authoritative group.

Following both consideration of the ACMUI's position, which was consistent with its long-held position on this issue, and interactions with the Agreement States, the NRC staff provided its recommendations on this issue to the Commission on November 20, 2008, in SECY–08–0179, ''Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material.'' The NRC staff recommended that the Commission approve development of the following amendments to the 10 CFR part 35 attestation requirements: (1) Eliminate the attestation requirement for individuals seeking authorized status via the board certification pathway; (2) retain the attestation requirement for individuals seeking authorized status via the alternate pathways; however, replace the text stating that the attestation demonstrates that the individual ''has achieved a level of competency to function independently'' with alternative text such as ''has demonstrated the ability to function independently'' to fulfill the radiation safety-related duties required by the license; and (3) accept attestations from residency program directors, representing consensus of residency program faculties as long as at least one member of the residency program faculty is an authorized individual in the same category as that requested by the applicant seeking authorized status.

In an SRM dated January 16, 2009, to SECY–08–0179, the Commission approved these recommendations and directed the NRC staff to develop the proposed rule language for the attestation requirements for the alternate pathway in concert with the ACMUI and the Agreement States.

Participants at public workshops held in the summer of 2011 broadly supported the proposed changes to remove the attestation requirement for board-certified individuals. The workshop panelists (which included members of the ACMUI and the Agreement States) recommended that the NRC remove the requirement for attestation for board-certified individuals. They believed that board certification coupled with the recentness of training requirements should be sufficient for the regulator's needs. With regard to the language of attestation (for the alternate pathway), they believed that the preceptors should not attest to someone's competency; rather, they should attest that the individuals received the T&E that is necessary to carry out one's responsibility independently. At the April 2011 ACMUI meeting, the ACMUI advised that the attestation language should be revised to say that the individual has received the requisite T&E to fulfill the radiation safety-related duties required by the license. In the final rule, the attestation language is revised accordingly.

The final rule amends T&E requirements in multiple sections of 10 CFR part 35 with regard to the attestation requirements in accordance with the NRC staff's recommendations in SECY–08–0179.

c. Extending Grandfathering to Certain Certified Individuals (PRM–35–20)

The petition and its resolution are discussed in Section II., Petition for Rulemaking, PRM–35–20, of this document.

d. Requiring Increased Frequency of Testing To Measure Mo-99 Breakthrough

When Tc-99m is eluted from a Mo-99 generator, Mo-99 could be co-eluted along with technetium. This is termed ''molybdenum breakthrough.'' Current regulations in § 35.204(a) prohibit a licensee from administering a radiopharmaceutical to humans that exceeds 0.15 microcuries of Mo-99 per millicurie of Tc-99m. Section 35.204(b) requires that a licensee that uses Mo-99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical measure the Mo-99 concentration of the first eluate to demonstrate compliance with the specified concentrations. However, a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for patient use.

If Mo-99 breakthrough exceeds the permissible concentration listed in § 35.204(a), it may cause unnecessary radiation exposures to patients. The administration of higher levels of Mo-99 could potentially affect health and safety and have an adverse effect on nuclear medicine image quality and medical diagnosis.

Generator manufacturers have always recommended testing each elution prior to use in humans. Before 2002, § 35.204 required a licensee to measure the Mo-99 concentration of each eluate. However, the NRC revised § 35.204 in April 2002 because the medical and pharmaceutical community considered frequency of Mo-99 breakthrough to be a rare event. Therefore, the Commission decided that measuring only the first elution from a generator was necessary to detect manufacturing issues or generators that may have been damaged in transport.

From October 2006 to February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. Some licensees reported the failed tests in the first elution, while some reported an acceptable first elution but failed subsequent elutions. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. Based upon the numerous reports of failed Mo-99 breakthrough measurements noted in

the subsequent elutions, the NRC is amending § 35.204 to return to the pre-2002 performance standard, which required licensees to measure the Mo-99 concentration for each elution of the Mo-99/Tc-99m generator at the time of generator elution.

e. Requiring Reporting and Notification of Generator Eluates Exceeding Permissible Concentrations of Molybdenum-99, Strontium-82, or Strontium-85

The regulations do not currently require reporting to the NRC when an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator exceeds the regulatory limit in § 35.204(a). As discussed in this section, eluates from Mo-99/Tc-99m generators exceeded the permissible concentration listed in § 35.204(a) on numerous occasions in 2006, 2007, and 2008. Additionally, in 2011, issues with Sr-82/Rb-82 generators were discovered when several individuals were identified with unexpectedly high levels of Sr-82 and Sr-85. These individuals had undergone Rb-82 chloride cardiac scanning procedures several months prior and had received these radionuclides in levels greatly in excess of the administration levels permitted in § 35.204 for Sr-82/Rb-82 generators. Further investigations showed that at least 90 individuals at one facility and 25 at another facility received levels of Sr-82 or Sr-85 that exceeded the levels permitted in § 35.204. Of these patients, at least three had levels of Sr-82 and Sr-85 high enough to result in reportable MEs as defined in § 35.3045.

Because the reporting of a generator when the eluate exceeded permissible concentrations was voluntary, the NRC had difficulty determining the extent of potential problems. Reporting of results in excess of the levels in § 35.204 for the Sr-82/Rb-82 generators could have alerted users and regulators to issues associated with these generators and possibly reduced the number of patients exposed to excess levels of Sr-82 and Sr-85. Breakthrough of Mo-99, or Sr-82 and Sr-85 contaminants can lead to unnecessary radiation exposure to patients.

This final rule also adds a new reporting requirement for a generator eluate exceeding permissible concentrations of Mo-99 or Sr-82 and Sr-85. This new reporting requirement in § 35.3204(a) requires a licensee to report to the NRC and the manufacturer or distributor of medical generators within 7 calendar days any measurement that exceeds the limits in § 35.204(a), at the time of generator elution.

f. Allowing ARSOs To Be Named on a Medical Use License

Currently, § 35.24(b) requires a licensee's management to appoint an RSO who, in writing, agrees to be responsible for implementing the radiation protection program. Further, the regulations in 10 CFR part 35 do not allow the naming of more than one permanent RSO on a license.

During an ACMUI meeting in June 2007, ACMUI members expressed a concern that this restriction has contributed to a shortage of available RSOs to serve as preceptors. The ACMUI stated that the restriction has created a situation in which an individual who is qualified and performing the same duties as an RSO cannot be recognized or listed as an RSO, and that this restriction has created a situation in which an individual working as a contractor RSO at several hospitals or other licensed locations is unable to have actual day-to-day oversight at the various facilities.

The final rule amends the regulations in 10 CFR part 35 to allow a licensee to appoint a qualified individual with expertise in certain uses of byproduct material to serve as an ARSO. This individual will be required to complete the same T&E requirements as the named RSO for the individual's assigned sections of the radiation safety program. The ARSOs will have oversight duties for the radiation safety operations of their assigned sections, while reporting to the named RSO. The regulation will continue to allow a licensee to name only one RSO on a license. The RSO will continue to be responsible for the day-to-day oversight of the entire radiation safety program. Similarly, a licensee with multiple operating locations could appoint a qualified ARSO at each location where byproduct material is used; however, the named RSO will remain responsible for the overall licensed program. Under the final rule, the ARSO will be named on the license for the types of use of byproduct material for which this individual is qualified and has been assigned duties and tasks by the RSO.

The NRC believes that allowing an ARSO to be named on a license will increase the number of individuals who will be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, an ARSO named on a license could more easily become an RSO on other licenses for the types of uses for which the ARSO is qualified.

In addition, the current regulations allow AUs, AMPs, and ANPs to serve as the RSO only on the license for which they are listed. Because AUs, AMPs, and ANPs must meet the same requirements to serve as the RSO regardless of which medical use license they are identified on, the NRC believes that it is overly restrictive not to allow them to serve as an RSO on any medical use license. Therefore, a modification is made that will allow an AU, AMP, or ANP listed on any medical use license or permit to serve as an RSO or ARSO. This change will increase the number of individuals available to serve as RSOs and ARSOs on NRC medical licenses. Additionally, these ARSOs and RSOs could serve as preceptors for an individual seeking to be named as the RSO.

Participants at the public workshops held in the summer of 2011 broadly supported the proposed change to allow an ARSO to be named on a license. The T&E requirements for an ARSO were discussed, and stakeholders strongly supported the NRC's position that the ARSOs must meet the same qualifications as the RSO for their assigned sections of the radiation safety program.

The final rule amends multiple sections of 10 CFR part 35 to accommodate the new ARSO position.

g. Additional Issues and Clarifications

Additional amendments are discussed in Section VI, Section-by-Section Analysis, of this document.

*B. When will these actions become effective?*

The final rule will become effective 180 days from its publication in the **Federal Register**. In the proposed rule published on July 21, 2014, the NRC requested comments on whether a 180-day effective date for the final rule is sufficient to communicate the changes to all practitioners, and for practitioners to revise procedures, train on them, and implement the changes. The NRC received three comments on this question. These comments are discussed in Section V., Public Comment Analysis, of this document. Based on the comments received, the NRC has determined that a 180-day effective date is sufficient to implement the final rule.

## IV. Opportunities for Public Participation

The NRC staff submitted a proposed rule to the Commission for approval on August 8, 2013, SECY–13–0084, ''Proposed Rule: Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments.'' The Commission approved the NRC staff's recommendation to publish the proposed rule, with certain changes

directed by the Commission, in the SRM to SECY–13–0084, dated, January 6, 2014. The proposed rule (79 FR 42410) was published on July 21, 2014, for a 120-day comment period that ended on November 18, 2014. However, the proposed rule inadvertently omitted the one-time implementation costs from the information collection burden estimate. Therefore, a correction to the proposed rule (79 FR 56524) was published in the **Federal Register** on September 22, 2014, correcting the information collection burden estimate and allowing the public 30 days to comment on the information collection burden.

During the comment period, the NRC staff held a public meeting on October 8, 2014, to better inform stakeholders of the proposed amendments and the various methods by which to provide comments on the proposed rule. Also, a public meeting was held on February 10, 2015, to better understand the comments made by Spectrum Pharmaceuticals. Spectrum Pharmaceuticals expressed concern about the proposed additional case work requirements in § 35.396 for the radionuclides used primarily for their alpha emissions and requested the NRC require 80 hours rather than the required 700 hours of specialized training for any physician so that an oncologist or a hematologist may administer parenteral radioactive drugs.

Early public input on the proposed rule was solicited through various mechanisms. The proposed amendments and preliminary draft rule text were discussed at the two transcribed facilitated public workshops that were conducted in New York City, New York, on June 20–21, 2011; and in Houston, Texas, on August 11–12, 2011. The purpose of the workshops was to solicit key stakeholder input on topics associated with the definition of an ME, including the requirements for reporting and notifications of MEs for permanent implant brachytherapy, and on other medical issues that were being considered in the proposed rulemaking. These workshops were initiated as a result of the Commission's direction to the NRC staff in the SRM to SECY–10–0062, which specified that the staff should work closely with the ACMUI and the medical community to develop ME definitions that would protect the interests of patients. The Commission also directed that these definitions should allow physicians the flexibility to take actions that they deem medically necessary, while preserving the NRC's ability to detect misapplications of radioactive material and failures in processes, procedures, and training. The panelists for the workshops included representatives from the ACMUI, Agreement States, and professional societies, and a patients' rights advocate.

For certain amendments, the NRC posted preliminary draft rule text (ADAMS Accession No. ML111390420) for a 75-day comment period on *www.regulations.gov.* The availability of the draft rule language was noticed in the **Federal Register** on May 20, 2011 (76 FR 29171). The NRC received 11 comment letters on this preliminary draft rule text. These comment letters are also posted on *www.regulations.gov* under Docket ID NRC–2008–0175. The NRC staff reviewed the comments and considered them in developing the proposed rule text.

## V. Public Comment Analysis

### *A. Overview of Public Comments*

The NRC received 69 comment letters that contained over 100 individual comments. The comment letters are posted on *www.regulations.gov* under Docket ID NRC–2008–0175. The commenters included several professional societies including the American Brachytherapy Society, American College of Radiology, Health Physics Society, American Academy of Health Physics, American Society for Radiation Oncology, American Association of Physicists in Medicine, Council on Radionuclides and Radiopharmaceuticals, the Organization of the Agreement States, and the Conference of Radiation Control Program Directors. Other commenters included individual States, practicing physicians, medical physicists, RSOs, nuclear pharmacists, individual members of the public, and a member of Congress. The NRC also received several comment letters after the public comment period closed. The NRC was able to consider and respond to several of these comments. However, two comment letters on the T&E requirements for alpha and beta emitters were submitted so late in the rulemaking process that it was not practical for the NRC to consider these comments in this rulemaking.

For the ME criteria for permanent implant brachytherapy, the commenters generally supported the activity-based criteria instead of the current dose-based criteria for the treatment site. The commenters did not support the criteria related to the dose to normal tissues located outside the treatment site, and normal tissues located within the treatment site. The commenters also expressed concern with the proposed 5 cubic centimeter volume of the normal tissue specification for the absorbed dose criteria for normal tissues. The commenters stated numerous practical difficulties in making these dose assessments. They stated that the volume of a maximally exposed 5 contiguous cubic centimeters of normal tissue appears reasonable in theory. However, it will be difficult to determine in practice with current technology. They expressed concern that the treatment planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes. Based on these concerns, this final rule ME criteria in § 35.3045 does not include dose to normal tissues located outside, or within the treatment site.

There were numerous comments on the compatibility category for the Agreement States for § 35.3045, Report and notification of a medical event. Members of the medical community submitted ten comments in support of Compatibility Category B. The OAS, the Conference of Radiation Control Program Directors (CRCPD), and all 7 of the Agreement States that submitted comments supported Compatibility Category C. This issue is fully discussed in Part I, Public Comments on the Specific Issues on Which the NRC Requested Comments.

The commenters expressed concern about confusion among AUs surrounding the definition of ME and WDs related to Yttrium-90 (Y-90) microspheres. The NRC staff has determined that the use of Y-90 would continue to be licensed under § 35.1000, ''Other medical uses of byproduct material or radiation from byproduct material.''

The commenters were generally supportive of the proposed regulation that allows for the naming of an ARSO on the license.

The commenters were supportive of the proposed removal of attestation requirements for the board-certified individuals, and other changes to the attestation requirements that are retained for individuals applying through the alternate pathway.

The commenters were not supportive of the proposed additional case work requirements for the radionuclides used primarily for their alpha emissions. They were concerned that the proposed regulation has the unintended consequence of increasing the burden of the work experience requirement for those seeking to administer therapeutic radiopharmaceuticals such as alpha and beta emitters. They indicated that it may prove too burdensome for certain practitioners, particularly those in areas far removed from teaching hospitals and urban centers, to participate in three

proctored cases in each of these specific categories. They stated that the result will be to limit patient access to these safe and effective pharmaceuticals among what is already a disadvantaged population.

With regard to the proposed reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators in § 35.3204, the commenters stated that the 30-day deadline to report should be shortened to more effectively address patient safety concerns. In response to this comment, the final rule has been changed to require a 7-calendar-day reporting and notification time for a failed generator.

*B. Public Comments and NRC Responses*

The NRC carefully considered the public comments in developing the final rule. This section summarizes the comments that the NRC received on the proposed rule and provides responses to these comments. Part I discusses the specific comments received on the issues on which the NRC specifically requested comments and discusses the NRC's responses to these comments. Part II discusses comments received on the specific sections of the 10 CFR part 35 amendments in the proposed rule and the NRC's responses to these comments.

Part I Public Comments on the Specific Issues on Which the NRC Requested Comments

In the proposed rule, the NRC requested comments on the following specific issues:

i. Dose-Volume Specification for Determining Absorbed Dose to Normal Tissue for MEs Under § 35.3045, Report and Notification of an ME

The NRC asked whether, in defining MEs, the proposed volume of 5 contiguous cubic centimeters dose-volume specification for an absorbed dose to normal tissue located both outside and within the treatment site is appropriate. The NRC also asked whether the application of the proposed ME definition for normal tissue based on the absorbed dose to the maximally exposed 5 contiguous cubic centimeters during permanent implant brachytherapy is appropriate for all potential treatment modalities, or whether it may result in unintended consequences for tissues or organs adjacent to the treatment site.

The NRC received numerous comments on this issue. The comment summaries and NRC responses to comments on this issue are discussed in Part II, Comments on Specific Sections in the Proposed Rule, under §§ 35.41 and 35.3045.

ii. Implementation Period

The NRC asked whether a 180-day effective date for the final rule is sufficient to communicate the changes to all practitioners and for practitioners to revise procedures, train on them, and implement the changes. Three commenters responded to this question. One commenter stated that 180 days is sufficient to implement the rule. However, two commenters stated that 365 days or more is needed to implement significant changes related to the dose evaluation requirements proposed for the ME criteria portion of the rule. Two commenters also recommended that the amendments related to PRM–35–20 should be implemented immediately, or in no more than 30 days. Because the ME criteria related to the dose evaluations to normal tissues are removed in the final rule, the NRC determined that 180 days is sufficient to implement the final rule.

iii. Impact on Clinical Practice

The NRC asked if any of the changes in the proposed rule are likely to discourage licensees from using certain therapy options or otherwise adversely impact clinical practice, and if so, how.

The NRC received several comments on this issue. The comment summaries and NRC responses to comments on this issue are discussed in Part II, Comments on Specific Sections in the Proposed Rule, under §§ 35.390 and 35.396.

iv. Compatibility Category for the Agreement States for § 35.3045, Report and Notification of a Medical Event

Currently § 35.3045, Report and notification of a medical event, is designated as Compatibility Category C for the Agreement States. This designation means that the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirements need not be the same as NRC requirements, provided the essential objectives are met. Under Compatibility Category C, Agreement States may require the reporting of MEs with more restrictive criteria than those required by the NRC if they do not create a conflict, duplication or gap with the essential objectives of the regulation.

Some medical licensees have multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. Many of these licensees would prefer a Compatibility Category B designation for uniformity of practice and procedures among their different locations. A Compatibility Category B designation is for those program elements that apply to activities that have direct and significant effects in multiple jurisdictions.

During the development of the proposed rule, the OAS expressed a strong desire to retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include only activity-based criteria for determining MEs for permanent implant brachytherapy. The OAS had no objection to the introduction of the activity-based criteria, as long as the dose-based criteria could be retained by the Agreement States. With a Compatibility Category C designation, some Agreement States indicated they could require both the dose-based criterion and source-strength based criterion, as long as the Agreement State reports to the NRC using the reporting criteria that meets the essential objectives of the NRC regulatory requirements. As discussed in the proposed rule published on July 21, 2014, for some Agreement States, Compatibility Category B is difficult to achieve because their regulations must also meet specific state requirements based on the state agencies in which the radiation control regulators reside. Also, Agreement States may have existing laws requiring the collection of additional information on medical diagnostic and therapy procedures.

If the level of compatibility for § 35.3045 were to be raised to Compatibility Category B, Agreement State requirements would need to be essentially identical to those of the NRC. Compatibility Category B is applied to requirements that have significant direct transboundary health and safety implications.

The ACMUI in its report to the NRC (Enclosure 4 to SECY–13–0084) recommended that MEs related to permanent implant brachytherapy be designated as Compatibility Category B. The ACMUI was concerned with the proposed designation as Compatibility Category C, which would allow the Agreement States to retain the dose-based criteria for an ME for permanent implant brachytherapy. The ACMUI asserted that a Compatibility Category C would continue to result in clinically insignificant occurrences being identified as MEs by Agreement States and thereby perpetuate the confusion associated with the current dose-based criteria. The ACMUI stated that the most important component of the rationale for conversion from dose-based to

activity-based criteria is the failure of dose-based criteria to sensitively and only specifically capture clinically significant MEs in permanent implant brachytherapy.

The Commission, in the SRM to SECY–13–0084, directed the NRC staff to designate § 35.3045 as Compatibility Category B in the proposed rule, which was subsequently published on July 21, 2014 (79 FR 42410). The NRC specifically invited comments on the appropriate compatibility category for ME reporting under § 35.3045.

The NRC received 19 comments on this issue. The medical community submitted ten comments in support of Compatibility Category B. The Organization of the Agreement States (OAS), the Conference of Radiation Control Program Directors (CRCPD), and 7 Agreement States submitted comments in support of Compatibility Category C. The medical community commenters stated that some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. These commenters stated that a Compatibility Category B designation would allow for uniformity of practice and procedures across the country. They stated that moving § 35.3045 from Compatibility Category C to B is appropriate and necessary. The commenters from the medical community also stated that they recognize that the Agreement States oppose a change in Compatibility Category, citing state legislative requirements, the difficulty in changing state regulations, and the fact that States do not perceive a problem with the current dose-based definition. While the commenters from the medical community appreciate these concerns, they believed these concerns are outweighed by the importance of having a consistent definition throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable events. They expressed concern that a Compatibility C designation would allow Agreement States to implement unnecessarily more expansive criteria that may classify medically acceptable procedures as an ME.

The Agreement States, OAS, and CRCPD recommended that the compatibility designation for ME reporting under § 35.3045 be designated as Compatibility C. They argued that under Compatibility Category C the Agreement States would continue to have the flexibility to add additional reporting terms (for example, shorter timelines for reporting, or a requirement to report diagnostic MEs). Several Agreement States questioned how a single medical incident at a single facility can have ''direct and significant effects in multiple jurisdictions.'' They further added that the Compatibility Category C designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who routinely work in multiple jurisdictions. One Agreement State stated that the proposed activity-based ME reporting criteria should be added to the existing dose-based criteria, rather than replace it. The Agreement State stated that it would require licensees to apply both criteria, and only those MEs that meet the NRC's proposed activity-based criteria would be reported to the NRC.

Based on these comments, and review of the NRC's Management Directive 5.9 ''Adequacy and Compatibility of Agreement State Programs,'' NRC staff determined that ME reporting under § 35.3045 should be designated as Compatibility Category C. Under Compatibility Category C, the Agreement States must adopt the essential objective of the requirement to avoid conflicts, duplications, or gaps. The essential objective of § 35.3045 is to maintain a consistent national program for reporting MEs. A consistent national program for reporting MEs allows the NRC to identify trends or patterns, identify generic issues or concerns, recognize inadequacies or unreliability of specific equipment or procedures, and determine why an event occurred and whether any actions are necessary to improve the effectiveness of NRC and Agreement State regulatory programs.

The NRC has determined that allowing Agreement States to use the dose-based criteria in addition to the activity-based criteria for permanent implant brachytherapy MEs in § 35.3045(a)(2) would create inconsistencies in the national reporting program and disrupt the NRC and Agreement States' ability to use the national program for reporting MEs for the purposes described above. As a result, the use of dose-base criteria instead of activity-based criteria would create a conflict with the NRC's essential objective of this regulatory provision, which could impair the effective and orderly regulation of agreement material on a nationwide basis.

The NRC staff concluded that the continued use of a dose-based criteria could: (1) Preclude a practice in the national interest to have consistent reporting and notification standard; (2) impair effective communication; and (3) preclude an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. Under Compatibility Category C for reporting permanent implant brachytherapy ME's, the regulatory provision uses activity-based criteria to ensure the consistent reporting of significant events as MEs across the country. Agreement States' use of dose-based criteria for these reporting requirements would not be compatible with this provision because it conflicts with the essential objective of this provision to maintain a consistent national program for reporting MEs.

The NRC staff considered Compatibility Category B for the ME criteria for permanent implant brachytherapy in § 35.3045(a)(2), but concluded that this designation is not justified, because ME reporting, while important to the effective and orderly regulation of agreement material on a nationwide basis, does not have significant direct transboundary implications. As a Compatibility Category C regulatory provision, the Agreement States have the flexibility to include, for example, a shorter reporting time, but the use of dose-based ME reporting criteria for permanent implant brachytherapy would create conflicts and inconsistencies with respect to the national reporting program. Therefore, the NRC will not accept, under Compatibility Category C, Agreement State use of dose-based criteria for permanent implant brachytherapy ME reporting.

The comment summaries and NRC responses on this issue are discussed in Part II of this section, under § 35.3045.

## Part II Comments Received on the Specific Sections in the Proposed Rule

### Section 30.34(g) Terms and Conditions of Licenses

*Comment:* One commenter noted that Tc-99m decays much faster than Mo-99, therefore, every Tc-99m generator eluate will eventually exceed the regulatory limit. Because of this, the commenter stated that the language in the proposed rule text would require every eluate to be reported. The commenter proposed revising the rule text in § 30.34(g) to clarify that the licensee would only report measurements of a Tc-99m generator elution that exceeded the regulatory limits at the time of generator elution.

*Response:* The rule text was modified in response to this comment. The NRC agrees with the commenter that the proposed rule text was not clear in § 35.204(e) and has amended it to clarify

that the reporting requirements only apply at the time of generator elution.

Section 35.2 Definitions

Issue 1: Definition of an Associate Radiation Safety Officer

*Comment:* One commenter agreed with and supported the new definition of an Associate Radiation Safety Officer.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter stated that some Agreement States are already using the term Assistant Radiation Safety Officer and suggested the NRC allow the use of a term other than ''Associate,'' such as ''Assistant.'' The commenter stated that this change would alleviate the workload required to modify certain Agreement States' medical licenses. Another commenter requested that the terms Assistant and Associate be used interchangeably.

*Response:* No change was made to the rule text based on this comment. To establish a clear regulatory requirement, the term Associate Radiation Safety Officer (ARSO) is retained. Although the term Assistant RSO is used in some Agreement States, each Agreement State may require individuals to meet different T&E standards to be named as an Assistant RSO on a license. Therefore, any individual whom an Agreement State has designated as an Assistant RSO is not recognized by the NRC and may not be recognized by other Agreement States. The new definition will establish clear and concise requirements that an individual would need to meet in order to be recognized as an Associate RSO by the NRC and Agreement States.

Issue 2: Definition of an Ophthalmic Physicist

*Comment:* One commenter asserted that there was not a sufficient need to create an ophthalmic physicist designation and that by doing so the NRC will set a precedent for other source-specific designations, rendering the AMP obsolete.

*Response:* No change was made to the rule text based on this comment. The designation of an *ophthalmic physicist* is retained. Authorized Users who work in remote areas may not have ready access to an AMP to perform the necessary calculations and other activities outlined in the new § 35.433 to support the ophthalmic treatments. This rule change will make the procedure involving the use of Sr-90 sources for ophthalmic treatments available to more patients located in remote areas. The NRC does not believe the addition of the ophthalmic physicist will render the AMP obsolete because the primary role of the AMP is to support the medical uses under § 35.600 and certain uses under § 35.1000. The proposed revision would not prohibit an AMP from assisting the ophthalmic AU.

Issue 3: Definition of a Preceptor

*Comment:* One commenter agreed with and supported the new definition of a *Preceptor*.

*Response:* The comment supports language in the rule; therefore, no response is required.

Section 35.24 Authority and Responsibilities for the Radiation Protection Program

*Comment:* One commenter asserted that ARSOs should not be named on a medical license but licensees should be allowed to name ARSOs in their radiation programs. The commenter disagreed with the NRC's argument that licensees are having a difficult time in naming an RSO due to an RSO not being able to sign a preceptor form. Further, the commenter stated that ''[t]he NRC and Agreement States are authorized to approve a proposed licensee's RSO based upon their T&E without the preceptor attestation.''

*Response:* No change was made to the rule text based on this comment. The NRC maintained the provision to name ARSOs on medical licenses to avoid confusion between individuals named on a license as opposed to individuals working in a radiation program and to establish regulatory requirements for training and experience. This will allow the individual who is named as an ARSO to be recognized by Agreement States and the NRC as an RSO or ARSO for the same medical uses on another license without resubmitting his or her T&E documents.

The ACMUI identified two issues with respect to securing an RSO's signature on a preceptor statement: There were not enough preceptors and some preceptors were not willing to sign preceptor statements. Naming the ARSOs on a license and permitting them to sign preceptor forms will increase the number of individuals who may sign the preceptor forms. Changes to the attestation language will remove impediments for individuals who were not willing to sign the previous preceptor statements. These changes will enhance opportunities for RSO candidates.

The NRC disagrees with the comment that RSOs are approved based upon their T&E without a preceptor statement. Under current regulations, an individual seeking to be named as an RSO on a medical license must submit a preceptor statement. The new provision in this rulemaking will only remove the preceptor attestation requirements for individuals who are certified by a board recognized by the NRC or Agreement States. Individuals seeking to be named as an RSO or ARSO under the alternate pathway will need to submit a preceptor statement.

*Comment:* One commenter recommended revising the rule text in § 35.24(b) to read, ''These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on the license as an AU, AMP or ANP, or has training in the radiation safety, regulatory issues and emergency procedures.'' The commenter believed that this revision ''would align it with 30.50(d).''

*Response:* The NRC assumes the commenter intended to reference proposed § 35.50(d) not § 30.50(d). The ARSO must be listed on a license before being assigned duties and tasks as an ARSO. The individual may be assigned tasks outside of the agreed upon list of ARSO duties and tasks in order to obtain additional T&E.

The commenter's proposed text would imply that the ARSO is listed on a license as an AU, AMP, or ANP. This is not always the case. Further, as written in the proposed rule and in the rule text suggested by the commenter, the regulations could have permitted the RSO to assign duties and tasks to the individual as the ARSO for which he or she was not fully qualified (*i.e.,* assigned duties and tasks for a type of use for which he or she was not listed on the license). Therefore, for clarification, the NRC has revised the rule text in § 35.24(b) to read, ''These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on the license.''

*Comment:* Two commenters expressed concern that there is no clear guidance or a policy on the number of licenses on which an individual could be named as an RSO or an ARSO. One commenter requested that the NRC develop this policy or guidance. The other commenter recommended that the NRC, Agreement States, ACMUI, and the medical community work together to develop guidance or a policy that can be consistently applied across all regulatory jurisdictions to establish the minimum amount of time an RSO or an ARSO listed on multiple licenses would be required to spend at each licensed facility.

*Response:* No change was made to the rule text based on these comments. Current NRC regulations do not limit the number of licenses on which an

RSO can be listed concurrently. Some Agreement States limit the number of licenses on which an individual may be named as the RSO. The NRC regulations do not impose any such limit. Rather, the NRC evaluates, on a case-by-case basis, whether the proposed RSO would have sufficient involvement in the program and if necessary, limits the number of licenses on which that RSO is named.

Section 35.40 Written Directives

*Comment:* One commenter questioned the phrase in § 35.40 (b)(6)(i): ''. . . if appropriate, the expected absorbed doses to normal tissues located within the treatment site,'' and stated that the term ''appropriate'' is very subjective. The commenter also asked who decides if normal tissues are located within the treatment site and if this is a clinical decision. The commenter was concerned that an inspector might determine appropriateness differently than the licensee's AU or AMP, resulting in a potential violation based on a difference in interpretation. The commenter believes that the WD should not include expected doses to normal tissues located within the treatment site because there may be clinical reasons for an AU to accept a higher dose to a normal structure in close proximity to involved tissues.

*Response:* The rule text was modified based on this and other comments. The NRC agrees that, for permanent implant brachytherapy, the determination of the appropriate dose to normal tissue (if any) located within the treatment site is a matter of medical judgment. The NRC has removed the reference to dose to normal tissue located within the treatment site. The rule text in § 35.40(b)(6)(i) was modified to remove the requirement to include in the pre-implantation WD the language ''if appropriate, the expected doses to normal tissues located within the treatment site.''

*Comment:* One commenter stated that the wording of § 35.40(b)(6) refers to ''permanent implant brachytherapy,'' but the remainder of the rule reads as if it was written for brachytherapy seeds. The commenter noted that Y-90 microspheres are sealed brachytherapy sources that are permanently implanted. The commenter asked if the new rule may be used in place of the existing guidance for Y-90 microsphere use under § 35.1000.

*Response:* No change was made to the rule text based on this comment. The term ''permanent implant brachytherapy'' is used to refer to manual brachytherapy procedures performed in accordance with § 35.400. The NRC considers Y-90 microspheres to be manual brachytherapy sources; however, they have unique properties that prevent them from being regulated under all the provisions of § 35.400. Therefore, they are regulated under § 35.1000. Consequently, the new rule does not apply to the use of Y-90 microspheres.

*Comment:* One commenter supported specification of a ''before implantation'' and an ''after implantation'' assessment as an excellent improvement from the current regulations. However, the commenter stated that defining the ''treatment site'' is a concern for prostate procedures. The commenter noted that an AU may need to change the definition of the treatment site and intended doses to critical structures based on intraoperative imaging results. This could result in the evaluation for an ME for absorbed dose to normal tissue to be based on a condition that changed during the implant procedure.

*Response:* The rule text was modified in response to this comment. The rule text in § 35.40(b)(6)(ii) was changed to allow the AU to change the description of the treatment site in the post-implantation WD. The NRC agrees that an AU needs flexibility to change the definition of the treatment site based on the condition of the patient and imaging results obtained during the implant procedure. Further, based on other comments, the NRC removed the requirements to include, in the WD, the absorbed dose to normal tissue in § 35.40(b)(6)(i).

*Comment:* One commenter stated that the after implantation WD requirement in § 35.40(b)(6)(ii) is consistent with clinically relevant circumstances. However, the commenter believes that it would be appropriate to list the number of seeds purposely implanted outside ''the prostate plus margin specified in the prescription,'' because this information will be needed when determining an ME.

*Response:* No change was made to the rule text based on this comment. The AU defines the treatment site in the WD in the way he or she believes to be medically appropriate, including any margin. The AU may define the treatment site to include all tissues into which sources have been purposely implanted.

*Comment:* Two commenters supported the requirement in § 35.40(b)(6) for a two-part WD for permanent implant brachytherapy, with one part before implantation and a second part after implantation. One commenter stated that ''documentation of the number of sources and total source strength is easily determined within 24 hours after implant completion.''

*Response:* The comment supports language in the rule; therefore, no response is required. However, the NRC notes that the post-treatment WD has to be completed before the patient leaves the post-treatment recovery area.

*Comment:* Two commenters supported the proposal to allow modification of the WD based on the medical situation encountered by the physician during the permanent implant brachytherapy procedure. One of the commenters noted that when modifications to the WD are medically necessary, these modifications should not constitute an ME.

*Response:* The comment supports language in the rule; therefore, no response is required.

Section 35.41 Procedures for Administrations Requiring a Written Directive

*Comment:* One commenter stated that the method and timing of the comparison in § 35.41(b)(6)(i) is unclear. The commenter noted that there is no requirement to include in the post-implantation WD the number of sources implanted outside the treatment site. The commenter believes that comparing the total source strength implanted outside of the treatment site with the total source strength implanted inside the treatment site is unreasonable because some sources may intentionally be implanted outside the treatment site as defined in the pre-implantation WD. The commenter suggested rewriting this section to clearly specify that the concern is errors in source placement, not sources outside the treatment site.

*Response:* No change was made to the rule text based on this comment. Section 35.41(b)(6)(i) requires a licensee to determine, within 60 days from the date the permanent brachytherapy implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the WD. The AU defines the treatment site (as defined in § 35.2) in the WD in any way he or she believes to be medically appropriate. The AU may define the treatment site to include all tissues into which sources will be purposely implanted. Therefore, the total source strength implanted in unintended locations would be compared with the total source strength documented in the post-implantation portion of the WD.

*Comment:* One commenter stated that it appears reasonable in theory to determine absorbed dose to the maximally exposed 5 contiguous cubic

centimeters of normal tissue. However, the commenter believes that it will be difficult to make this determination using current technology. The commenter stated that ''planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes.''

*Response:* The rule text was modified based on this comment. The rule text in § 35.41(b)(6) was modified to remove § 35.41(b)(6)(ii) and (iii). The NRC acknowledges that while some treatment planning systems can identify contiguous volumes, others cannot. In response to this concern and concerns raised by other commenters, the NRC removed subparagraphs (ii) and (iii), which would have required the licensee to determine the absorbed dose to normal tissues located both outside and within the treatment site.

*Comment:* One commenter recommended modifying § 35.41(a) by adding: ''(3) After administration, an ME as defined in § 35.3045 has not occurred . . .''

*Response:* No change was made to the rule text based on this comment. The NRC determined that the recommended rule change is not necessary because § 35.41(b)(5) requires that at a minimum, the procedures required by § 35.41(a) include ''[d]etermining if a medical event, as defined in § 35.3045, has occurred.''

*Comment:* Several commenters noted that the proposed regulation would apply to all permanent brachytherapy implants, including lung mesh procedures. They stated that licensees do not routinely perform dose assessments because the mesh is visually sewn to the lung in the prescribed location and the sources are not vulnerable to migration. The commenters recommended excluding lung mesh treatments from the requirements of § 35.41(b)(6).

*Response:* The rule text was modified based on this and other comments. The NRC recognizes the difficulty in determining the absorbed dose to normal tissues for treatments that use mesh material with permanent brachytherapy sources incorporated into the mesh. In response to this concern and those raised by other commenters, the NRC removed subparagraphs (ii) and (iii) in § 35.41(b)(6), which would have required the licensee to determine the absorbed dose to normal tissues located both outside and within the treatment site. The NRC retained § 35.41(b)(6)(i) to determine the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation WD for all permanent brachytherapy, including mesh procedures. The NRC retained this requirement because it is important to ensure that the use of the radionuclide is in accordance with the WD.

*Comment:* Several commenters stated that they support the requirement for performing a post-implant dosimetric evaluation of each permanent brachytherapy implant within 60 days. However, there may be other obstacles to meeting this 60-day requirement, beyond patient unavailability, that should be added to the rule text. For example, one commenter noted that a machine may be broken and the facility may not have a backup, or the facility may have lost electricity because of a storm. The commenters suggested modifying the language in § 35.41(b)(6) to also allow written justification related to other factors ''outside the control'' of the licensee.

*Response:* No change was made to the rule text based on these comments. A 60-calendar-day time frame ensures that the licensee has ample time to make arrangements for the required determination in § 35.41(b)(6). If the licensee's imaging device malfunctioned or the facility lost electricity, it should be possible to refer the patient to another facility for the imaging study within the 60-day time frame. Further, in response to other comments, NRC re-evaluated the requirements for post-implant dosimetric evaluation to the normal tissue and has removed this requirement.

*Comment:* One commenter believes that the assessment of permanent brachytherapy implants described in § 35.41(b)(6) should be part of the medical evaluation of the treatment and not part of the procedures to provide high confidence that the administration is in accordance with the WD. The commenter also noted the difficulty in meeting this requirement, if it is retained, for permanent implants of certain large tumors. In these cases, a surgical procedure to remove part of the tumor may be performed shortly after the implant and this may result in intentional removal of many of the seeds. Post-implant removal of sources will change the dose to normal tissues. The commenter stated that the proposed regulation appears to require re-imaging to localize the remaining sources to perform the required assessment; however, it is unlikely that this additional assessment was intended.

*Response:* The rule text was modified in response to other comments. The NRC modified the rule text in § 35.41(b)(6) to remove the requirement to determine the absorbed dose to normal tissues located outside the treatment site and within the treatment site. The NRC retained the requirement to determine the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation WD. It is likely that most licensees will perform the determination of total source strength administered outside of the treatment site by performing an imaging study such as a computed tomography scan. If it is necessary to remove part of the tumor shortly after the implant, this imaging study may be performed before the tumor removal.

Section 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer

*Comment:* One commenter agreed with the changes in the T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists. The commenter also supported the establishment of the ARSO because they believe it provides a pathway for more individuals to be RSOs and increases the number of preceptors available for future RSOs and ARSOs.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter supported the inclusion of an ANP in the pathway to be identified as an ARSO on a medical license.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* Several commenters supported the removal of the preceptor statement requirement for individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and are applying to be named as an RSO, ARSO, ANP, AMP, or AU.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter supported ARSOs being named on licenses and being able to serve as preceptors.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter stated that the ARSO position created in the proposed rule does not create a new pathway for an individual to become an RSO. The commenter proposed that the NRC create a new pathway for an individual to qualify as an RSO by relaxing the T&E requirements for an ARSO. This new pathway would require an individual to meet only the education requirements in § 35.50 to be

named as an ARSO and then participate in a year-long training program. The commenter's expectation was that, at the end of the year-long training program, the ARSO would have gained proficiency in each of the areas listed in the regulations and could work independently and be qualified to be an RSO. The commenter also proposed that management would have the ARSO agree in writing to be responsible for implementing the radiation protection program.

*Response:* No change was made to the rule text based on this comment. The ARSO position created in the proposed rule does create a new pathway for an individual to become an RSO. An ARSO can become an RSO for the same types of use of byproduct material for which he or she was assigned duties and tasks as an ARSO on a medical license. This new pathway requires the same T&E for ARSOs as the current regulations for individuals seeking to be an RSO.

The commenter proposed adding a pathway for an individual to qualify as an RSO via the ARSO position. This proposed pathway is problematic because it would create a training program for an individual to become an ARSO without the individual meeting all the required T&E for an ARSO or an RSO. The NRC does not intend for this rule to create a training program for an individual to become an ARSO who is not fully qualified to be an RSO. The NRC did not include a provision to require management to have the ARSO agree in writing to be responsible for implementing the radiation safety program because the RSO is responsible for the radiation safety program. The RSO may delegate tasks and duties to the ARSO but the final rule at § 35.24(b) states that the RSO ''*shall not delegate the authority or responsibilities for implementing the radiation protection program.*''

*Comment:* Two commenters recommended relaxing the qualifications for the ARSO to allow on-the-job training while serving in an assistant or associate position.

*Response:* No change was made to the rule text based on these comments. The commenters' proposal would have resulted in recognition of an individual as an ARSO when the individual had not satisfactorily completed all the training and experience qualifications to perform his or her duties and tasks and could be recognized as an RSO at a later date. An ARSO may receive additional on-the-job training to expand his or her training and skills to apply for ARSO status for additional types of use.

*Comment:* One commenter asserted that the changes to the regulations would permit AUs to be RSOs. Doing so, according to the commenter, would weaken the position held by the RSO because a physician AU acting as the RSO is doing so as an additional duty. The commenter asserted that these RSOs were neither familiar with the regulations nor the recordkeeping requirements of a radiation safety program. The commenter further stated that if they made a mistake as an AU, it was often overlooked or corrected by simply re-writing a prescription for a particular treatment.

*Response:* No change was made to the rule text based on this comment. Current regulations recognize an AU as being qualified to be an RSO consistent with the AU's authorization and required radiation safety experience. This provision was unchanged in this rulemaking. The NRC expects that all AUs/RSOs take their responsibilities and obligations seriously and notes that AUs/RSOs should not overlook or ''correct'' errors by ''simply re-writing a prescription for a particular treatment.''

*Comment:* Several commenters opposed having an ARSO provide a preceptor attestation for an individual seeking to be named as an RSO. The commenters stated that an ARSO is only responsible for certain duties or limited sections of the program while the RSO is responsible for the entire radiation safety program. One commenter further recommended that an ARSO should only be permitted to provide a preceptor statement for an individual seeking to be named as an ARSO.

*Response:* No change was made to the rule text based on these comments. For each medical use for which an ARSO is authorized, the T&E requirements are the same as that of an RSO. Further, the requirements for the preceptor are the same, regardless of whether they are an RSO or an ARSO. Therefore, an ARSO can be a preceptor for a potential RSO or a potential ARSO, but only for those uses for which the preceptor ARSO is authorized.

*Comment:* Two commenters recommended that AUs, ANPs, or AMPs be allowed to serve as RSOs on individual licenses for private practices (*i.e.,* non-hospital sites).

*Response:* No change was made to the rule text based on these comments. The current regulations already allow AUs, AMPs, and ANPs to serve as RSOs on private practice licenses and other non-hospital medical facilities.

*Comment:* One commenter requested that the rule text in § 35.50(c)(1), (2), and (3) be consistent with respect to the description of the radiation safety experience and types of use to avoid confusion. The commenter pointed out that the text in paragraphs (c)(1) and (2) included ''similar types of use'' whereas paragraph (c)(3) implies the exact same types of use.

*Response:* The rule text was modified based on this comment. The NRC agrees with the commenter that there should be consistency between the rule text in § 35.50 (c)(1) and (2). The rule text in paragraphs (c)(1) and (2) was changed to read ''has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer.'' However, a similar change was not made to the rule text in § 35.50(c)(3). The provisions in § 35.50(c)(3) only address a new license application where the applicant is requesting that a qualified individual, who has not previously been named on a license, be named as both an AU and the RSO on the new license. The new license will authorize only those types of uses for which the proposed AU/RSO has T&E.

*Comment:* One commenter sought clarification on whether § 35.50(c)(3) applied to a new license with just one potential AU. The commenter believes that license reviewers would use paragraph (c)(3), as written in the proposed rule, to add the first AU/RSO and then process a separate licensing action to add other AUs.

*Response:* The rule text was modified based on this comment. The NRC's intent in the proposed rule was for the provision in § 35.50(c)(3) to apply to a single physician applicant who was not yet authorized to be an AU and has requested to be both the AU and RSO. Based on the comment, the NRC has broadened the provision in § 35.50(c)(3) to include an applicant for a new medical use license with multiple AUs who requests an individual, qualified but not yet recognized to be an AU, to be both an AU and the RSO on the new license.

*Comment:* One commenter asserted that the provisions in § 35.50(c)(2) were all that were needed in a rural setting to appoint an individual as both an AU and an RSO simultaneously, and § 35.50(c)(3) was not needed, unless § 35.50(c)(3) individuals are not subject to the requirements in § 35.50(d).

*Response:* The rule text was modified based on this comment. For clarity, the rule text was revised to add a reference to § 35.50(d) in § 35.50(c)(3) based on both this and another comment. The provisions in § 35.50(c)(3) are distinctly different from the provisions of § 35.50(c)(2) and both can be used in rural areas. Section 35.50(c)(3) addresses only a new license where the

physician whom the applicant is requesting to be named as an RSO has not yet been listed on a license as an AU. Section 35.50(c)(2) applies to a new application or amendment to an existing license where the applicant or licensee is requesting to identify an individual already identified as an AU, AMP, or ANP on a license or permit as the RSO. The individuals who meet the requirements in § 35.50(c)(2) or (c)(3) must also meet the requirements in paragraph (d) of this section.

*Comment:* One commenter stated that the provisions in § 35.50 in the proposed rule could be interpreted two ways. Due to the word ''and'' between § 35.50(c)(3) and § 35.50(d), the provision in § 35.50(d) could be interpreted to apply to § 35.50(c)(3). Alternatively, the provision in § 35.50(d) could be interpreted not to apply to § 35.50(c)(3). The commenter stated that a revision is necessary to clarify whether or not paragraph (d) applies to (c)(3). The commenter also stated that if paragraph (d) does not apply to § 35.50(c)(3), this pathway would permit a large institution applying for a new license to have an RSO that did not demonstrate compliance with § 35.50(d).

*Response:* The rule text was revised based on this comment. The rule text was revised to add a reference to § 35.50(d) in § 35.50(c)(3). The NRC agrees that § 35.50(d) applies to § 35.50(c)(3). Although the NRC intended to provide a pathway for a single practice physician, if a medical institution wants to apply for a Part 35 medical use license by adding a physician (who is qualified but not yet authorized as an AU) to be both an AU and the RSO, then the institution could also use the provisions of § 35.50(c)(3) to obtain a medical use license. Note that once a hospital has obtained a medical use license, the provisions of § 35.50(c)(3) no longer apply because they only apply to new licenses.

*Comment:* One commenter stated that the rule text in § 35.50(c)(3) appeared to be ''backward'' and suggested that the paragraph should read ''Is an individual who is seeking simultaneous approval both as the Radiation Safety Officer and the AU on the same new Commission or Agreement State license and who has experience with the radiation safety aspects of the types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.''

*Response:* No change was made to the rule text based on this comment. Starting the paragraph with ''Is an individual who . . .'' would result in redundant language because § 35.50 reads ''Except as provided in 35.57, the licensee shall require an individual . . . to be an individual who—. . . (c)(3).'' Additionally, because the individual has not yet been identified as an AU or RSO, the individual does not yet have the responsibilities of an RSO.

*Comment:* One commenter stated that the ARSOs should be fully trained to manage the radiation safety program issues for all modalities authorized on the license. This would simplify the license in that specialty areas of use would not have to be listed and amendments would not be needed for changes to ARSO specialty areas. The ARSO would be ready to replace the RSO with only the delegation of authority letter from management needed to qualify the ARSO as RSO.

*Response:* No change was made to the rule text based on this comment. Limiting the ARSO designation to only those individuals that have T&E in all the medical types and uses on the license would not permit individuals with T&E for some of the medical types of use on the license to be recognized as ARSOs. The NRC disagrees with the commenter's assertion that the individuals should be trained for all modalities so that they could be ready to replace the RSO. A trained individual is not necessarily qualified to be the RSO; the individual would also need to meet the experience requirements. Additionally, the NRC disagrees with the commenter's assertion that only a delegation of authority letter is needed for the ARSO to become an RSO. Only a regulator can name an individual as the RSO on a license.

*Comment:* One commenter agreed with the proposed addition of ARSOs but requested a requirement that the ARSO's performance and level of activity be reviewed on an annual basis by the licensee's RSO or Radiation Safety Committee. The commenter believed this would ensure that only the active ARSOs with recent experience are listed on the license.

*Response:* No change was made to the rule text based on this comment. The requirement in § 35.14(b) for a licensee to notify NRC no later than 30 days after an ARSO permanently discontinues performance of duties as an ARSO is adequate without adding a prescriptive requirement to annually review the performance of the ARSO.

*Comment:* One commenter believed the T&E of the ARSO should be designated as Compatibility Category ''C.'' This would give the state program the flexibility to more effectively monitor the roll out of this new provision without adversely affecting either the individuals seeking ARSO listing/approval or the licensees.

*Response:* No change was made to the Compatibility Category for the ARSO training and experience requirements. The NRC has determined that § 35.50 is a Compatibility Category B because T&E requirements have ''significant direct transboundary implications.'' Assistant RSOs might not meet the requirements to be an ARSO. Therefore, they may not be automatically listed as an ARSO on a license. Individuals named as assistant RSOs on a state license may continue to work as an assistant RSO on that license, but will be required to meet the requirements in §§ 35.50 and 35.51 if they would like to be named as an ARSO.

*Comment:* Two commenters supported the establishment of an ARSO, but the commenters believed the NRC overemphasized the need to provide more preceptors. The commenters stated that the more important reason for establishing an ARSO is to recognize more qualified individuals and increase the pool of RSOs. One of the commenters further stated that many states have had ARSOs or similar individuals or multiple RSOs on a license for many years and this has not caused problems.

*Response:* No change was made to the rule text based on these comments. The NRC recognizes that the increase in the number of individuals meeting the qualifications in § 35.50 and being recognized as ARSOs both increases the number of individuals recognized as meeting the qualifications for being RSOs and the number of available preceptors. The NRC continues to require under § 35.24(b) that only one RSO be listed on each medical use license because that is the individual responsible for the day-to-day oversight of the entire radiation safety program.

Section 35.55 Training for an Authorized Nuclear Pharmacist

*Comment:* One commenter asserted that specialized residencies in pharmacy practice are available and more are emerging, including nuclear pharmacy practice residency programs. The commenter provided a website for the American Society of Health-System Pharmacists residency directory, which contains an online directory of pharmacy residency programs, in support of this assertion. The commenter recommended amending § 35.55(b)(2) to read:

> Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an

authorized nuclear pharmacist. The attestation must be obtained from either: (i) A preceptor authorized nuclear pharmacist who meets the requirements in §§ 35.57 or 35.55, or equivalent Agreement State requirements; or (ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized nuclear pharmacist who meets the requirements in §§ 35.57 or 35.55 or equivalent Agreement State requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Commission on Credentialing of the American Society of Health-System Pharmacists and must include training and experience specified in § 35.55(b)(1).

The recommended amendment would add provisions that would allow the residency program director to provide an attestation to the T&E requirements for an ANP similar to those provisions added for an AU, AMP, and RSO.

*Response:* No change was made to the rule text based on this comment. The NRC reviewed the American Society of Health-System Pharmacists residency directory at the provided website. The residency directory included residency programs in the United States and two foreign countries. The website lists only one nuclear pharmacy residency program in the United States. Other residency programs included in Part 35 have been accredited by either the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association. The Commission on Credentialing of the American Society of Health-System Pharmacists has not been evaluated by the NRC to determine if this accreditation group is equivalent to the accreditation groups listed above, and to do so would be beyond the scope of this rulemaking. Therefore, the nuclear pharmacy residency program has not been included in this rulemaking. The commenter may submit its recommendation to the NRC as a petition for rulemaking under § 2.802.

*Comment:* One commenter recommended that the NRC recognize structured nuclear pharmacy training programs, sometimes referred to as certificate programs, by amending § 35.55(b)(2) to provide:

(iii) A program director of a structured nuclear pharmacy training program who affirms in in [sic] writing that the attestation represents the consensus of the training program faculty where at least one faculty member is an authorized nuclear pharmacist who meets the requirements in §§ 35.57 or 35.55, or equivalent Agreement State requirements and concurs with the attestation provided by the program director. The nuclear pharmacy training program must be part of a College or School of Pharmacy that is accredited by the Accreditation Council for Pharmacy Education.

This recommended amendment would permit program directors of these programs to sign the preceptor statement when certain conditions, similar to the medical residency criteria, are met. The commenter also stated that the nuclear pharmacy training program must be part of a College or School of Pharmacy and accredited by the Accreditation Council of Pharmacy Education.

*Response:* No change was made to the rule text based on this comment. The regulations permit a pharmacist to be recognized as an ANP as long as the § 35.55 T&E requirements are met. Therefore, if the pharmacist receives his or her training from a nuclear pharmacy training program in a college or school of pharmacy that meets this criterion, the pharmacist can be recognized as an ANP. The NRC has not had an opportunity to evaluate the Accreditation Council of Pharmacy Education's nuclear pharmacy educational programs, and to do so would be beyond the scope of this rulemaking. The commenter may submit its recommendation to the NRC as a petition for rulemaking under § 2.802.

Section 35.57 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist

*Comment:* Several commenters supported the revision of § 35.57 to recognize individuals certified by the boards named in the previous Subpart J of 10 CFR part 35 for the modalities that they practiced on or before October 24, 2005.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter requested clarification on the type and extent of documentation an individual will need to produce to demonstrate that he or she was practicing certain modalities prior to 2005 in order to meet the requirements in § 35.57.

*Response:* No change was made to the rule text based on this comment. The NRC provides T&E guidance in NUREG–1556, Vol. 9 ''Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licensees.'' This NUREG provides information for meeting the requirements in § 35.57. Because each situation is unique, the applicant's submitted documentation will need to be evaluated on a case-by-case basis.

*Comment:* One commenter stated that the proposed additional dosage category at § 35.390(b)(1)(ii)(G)(*4*) for the medical use of alpha-emitting radionuclides such as Radium-223 dichloride would result in an unintended consequence. Specifically, an AU currently authorized to use Radium-223 dichloride would be required to have additional work experience to be authorized for parenteral use of radiopharmaceuticals used primarily for their alpha-emitting characteristics under § 35.390(b)(1)(ii)(G)(*4*). The commenter requested that, if the NRC retained the additional proposed dosage category, that the NRC amend the date in § 35.57(b)(1) and (2) from October 24, 2005, to December 31, 2014, or a later date, to grandfather such individuals.

*Response:* The rule text was modified based on a recommendation from the ACMUI. The effective date of the grandfathering provisions in the rule text in § 35.57(b)(1) is changed from October 24, 2005, to the effective date of the rule. The commenter is correct that, as proposed, the rule text would not permit an AU currently administering Radium-223 dichloride to be authorized to use it after the effective date of the rule, and that was not the intent of the NRC. The final rule grandfathers all AUs authorized for medical uses, including Radium-223 dichloride, on the effective date of the rule to continue to be able to administer it after the rule becomes effective without needing to reapply for authorization under the new requirements in §§ 35.390 or 35.396. However, no change was made to the rule text in § 35.57(b)(2) because this section pertains only to those individuals certified by boards recognized in Subpart J.

Note that § 35.390(b)(1)(ii)(G)(*4*) was deleted and provisions within that section have been incorporated within § 35.390(b)(1)(ii)(G)(*3*) based on other comments. Therefore, the category ''parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required'' is now included in § 35.390(b)(1)(ii)(G)(*3*). After reviewing the ACMUI final recommendations on the revised part 35 rule, the NRC has determined that an additional three cases of administering dosages of radioactive drugs for alpha-emitting radiopharmaceuticals for parenteral administration is not necessary.

*Comment:* Two commenters support the concept of grandfathering the RSO,

medical physicist, teletherapy physicist, AMP, AU, nuclear pharmacist, and ANP. However, the commenters stated that the date of certification does not have an impact on an individual's qualifications to perform the duties of an RSO and they do not agree with limiting the grandfathering provisions to ''those materials and uses that these individuals performed on or before October 24, 2005.'' The commenters believe the continuing education requirements for periodic certification renewal assures that the individual remains qualified. Thus, all board certified individuals, regardless of the date of their initial certification, are equally qualified to be named as an RSO or ARSO and that the initial certification date is immaterial to one's present technical expertise.

*Response:* No change was made to the rule text based on these comments. The board certification pathway includes not only the requirement to be certified but also that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. That is why the grandfathering provisions for the RSO include the phrase ''those materials and uses that these individuals performed on or before October 24, 2005.'' The NRC retained the date of October 24, 2005, because that was the expiration date of the prior T&E requirements (Subpart J).

*Comment:* Several commenters supported the grandfathering of board-certified individuals but requested the rule text be changed from ''for the modalities that they practiced on or before October 24, 2005,'' to the ACMUI-recommended language ''for the uses [or procedures] covered by their board certification on October 24, 2005.'' These commenters stated that the ACMUI language would eliminate any potential uncertainty concerning what the term ''practiced'' means.

*Response:* No change was made to the rule text based on these comments. In the Ritenour Petition, the petitioner requested that the NRC grandfather individuals certified by boards listed in Subpart J for the modalities that they practiced as of October 24, 2005. Further, the board certification pathway includes not only the requirement to be certified but also that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. Therefore, it is necessary to identify the modalities that the individual performed and not ''the uses [or procedures] covered by their board certification.''

*Comment:* Two commenters supported the revisions to § 35.57 with respect to the Ritenour Petition. However, the commenters stated that the preceptor statements should not be required for those individuals requesting to be grandfathered under the provisions of § 35.57.

*Response:* No change was made to the rule text based on these comments. The revised rule text in §§ 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690 also applies to board-certified individuals under § 35.57 and does not require preceptor statements for individuals who are qualified to be authorized under the board certification T&E requirements.

*Comment:* Two commenters requested that individuals meeting the board certification requirements in § 35.57(a)(2), (a)(3), and (b)(2) must be immediately grandfathered because the NRC failed to respond to the Ritenour Petition in a timely manner. Further, the commenters stated that these individuals should not have to fulfill the burdensome ''alternate pathway'' or preceptor attestation if they wish to become authorized on a license, but have not been so named by an NRC or Agreement State license.

*Response:* No change was made to the rule text based on these comments. The NRC recognizes that individuals may not have been listed on a license but were practicing certain modalities on or before October 24, 2005. Individuals meeting the board certification requirements in § 35.57 have to provide evidence that they practiced the modalities for which they are seeking authorized status and may also have to provide evidence of continuing education and experience if it has been more than 7 years since their certification. Individuals being grandfathered under the provisions of § 35.57(a)(2), (a)(3), and (b)(2) do not need preceptor attestations and do not need to meet the training requirements of the alternate pathway.

*Comment:* Two commenters requested that the NRC consider removing dates from the board certification requirements for the currently recognized boards, as well as the boards affected by the Ritenour Petition. They based the request on their assertion that there has not been any evidence of an ME or regulatory violation before 2005 or since that has demonstrated, or even suggested, that the year of board certification has any association with better or worse regulatory compliance or radiation safety.

*Response:* No change was made to the rule text based on these comments. The NRC is retaining the board certification dates for all boards recognized under the requirements in 10 CFR part 35. This is because the boards change their certification processes; no longer certify individuals for life; and, in some cases, only guarantee the certification status for a few years requiring verification of the current certification status of its diplomates. Further, the NRC does not require reporting of the board certification status of an individual associated with an ME or a violation of NRC requirements.

Section 35.65 Authorization for Calibration, Transmission, and Reference Sources

*Comment:* One commenter noted that the explanation for the proposed changes for § 35.65 in the **Federal Register** notice stated that there were two new paragraphs whereas the text contained three new paragraphs.

*Response:* The NRC agrees with the commenter's observation. Section VI, Section-by-Section Analysis, of this document indicates that three new paragraphs were added to § 35.65.

*Comment:* One commenter stated that the transmission sources should be removed entirely from §§ 35.65 and 35.500 and should be placed in § 35.200. Additionally, the commenter stated that the use of spot markers/anatomical markers should be added to § 35.200 because they are used on patients and are not used for instrument calibration purposes. The commenter explained that transmission sources, unlike sources currently in § 35.500, are not used to render a diagnosis and are not consistent with that category of use. The commenter agreed with the NRC that materials authorized by § 35.65 should be prohibited for human use but went further to say that sources authorized by § 35.65 should be limited to only non-human use including calibration and reference sources for instrument/equipment calibration and testing. The commenter further recommended that the text proposed in § 35.500 should be edited and moved to § 35.200.

*Response:* No change was made to the rule text based on this comment. The final rule clarifies that some sealed sources authorized under § 35.65 may be used under both §§ 35.65 and 35.500. Furthermore, sources that meet the § 35.65 criteria are not required to be listed on a license when they are used under the provisions of § 35.500. The NRC considers the use of a transmission source to be diagnostic medical use when a patient is exposed to its

radiation. Additionally, § 35.200, which authorizes the medical use of unsealed byproduct material, is not the appropriate section for sealed sources.

*Comment:* Several commenters stated that referring to § 35.500 in the proposed rule text in § 35.65 was confusing. They recommended that the phrase ''except in accordance with the requirements in § 35.500'' be removed from § 35.65(b)(1). They stated that the sources in § 35.65 do not need to be listed on a license but the current regulation in § 35.500 requires that sources and users be listed on a license. Furthermore, the commenters stated that sources in § 35.65 are to be used for reference, transmission, and calibration, but sources in § 35.500 are to be used for diagnosis.

*Response:* No change was made to the rule text based on these comments. The rule text was not changed because removal of the phrase ''except in accordance with the requirements in § 35.500'' would change paragraph (b)(1) to read that the byproduct material authorized under § 35.65 would not be permitted for medical use. For example, removing this text would prohibit the use of a transmission source when a patient is exposed to its radiation, which is a diagnostic medical use.

*Comment:* One commenter noted that it listed transmission sources and transmission source devices on medical use licenses. It was ''unaware of any circumstances in which a licensee bundled sources currently authorized by 35.65 (individual source activity limit) in aggregation that are not listed or approved in the SS&D registry.'' The commenter stated ''that the proposed rule should be modified to clearly distinguish authorization for medical use and instrument calibration.''

*Response:* No change was made to the rule text based on this comment. The commenter noted correctly that licensees cannot use sealed sources in a manner inconsistent with the sealed source and device registry (SSDR). The SSDR does not prohibit the ''bundling'' of sealed sources to create a greater source activity, but § 35.65 limits the activity of each sealed source authorized under this section. Some licensees have interpreted § 35.65 incorrectly to mean that these sealed sources could be bundled to create an aggregated source with a greater activity than is allowed. The rule change makes it clear that the maximum activity authorized by § 35.65 applies to all sealed sources whether used singularly or in a bundled configuration.

The NRC reviewed the rule language and believes it is clear that when sealed sources are used as part of a diagnostic medical procedure, these uses are authorized under § 35.500. Possession of the sources may be authorized under § 35.65, but medical use of the sources is only authorized under § 35.500. For example, a transmission source may be possessed under § 35.65, but can only be used as part of a medical diagnostic procedure under § 35.500.

The Following Comments Were Common to the Training and Experience Requirements in Sections 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490 and 35.690

*Comment:* Several commenters agreed with the NRC's proposal to remove the preceptor attestation requirements for individuals seeking authorized status via the board certification pathway.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* Several commenters agreed with the proposed change to the attestation language from ''achieved a level of competency to function independently'' to ''verify that the individual can independently fulfill the radiation safety-related duties'' for those individuals applying through the alternate pathway. They further stated that the term ''competency'' has certain implications and liabilities in the medical domain that should not factor into an attestation statement, which is meant to assure regulators that the individual received an adequate amount of radiation safety-specific T&E.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter noted that based on the revision to the T&E requirements, an individual who is board certified will no longer need a preceptor attestation to become an AU or AMP. Further, the commenter noted that the argument for this change is that some preceptors have been reluctant to attest due to concerns related to personal liability based on possible future actions of the proposed AU or AMP. The commenter stated that if someone truly has these reservations, there may be a good reason they are not willing to sign off on the attestation.

*Response:* No change was made to the rule text based on this comment. The NRC believes that certification by a specialty board coupled with the recentness of training requirements in § 35.59 and, as appropriate, the requirements in §§ 35.50(d), 35.51(c), 35.390(b)(1)(ii)(G), or 35.690(c) is sufficient to demonstrate that the individual seeking authorization on a license has met the T&E requirements in the board certification pathway. The NRC concluded that these three elements show the individual has the requisite knowledge and that an additional attestation is not necessary. For the non-board certified applicants, the attestation requirement is retained but the attestation language is revised in response to concerns that preceptors are reluctant to sign preceptor attestations due to personal liability concerns.

*Comment:* Two commenters endorsed retaining the attestation requirement for those individuals pursuing initial board certification (but not yet certified) and alternate pathways. The commenters stated that retaining the preceptor attestation helps ensure accountability and credibility by clearly identifying an AU who can attest that the individual has satisfactorily completed the required NRC training.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter pointed out that the correct terminology for the American Osteopathic Association residency approval organization is the ''Council on Postdoctoral Training.''

*Response:* The rule text was modified based on this comment. The rule text is changed to replace the ''Committee on Post-Graduate Training'' with the phrase ''Council on Postdoctoral Training.''

*Comment:* One commenter supported permitting residency program directors to provide attestations based on the consensus of the residency faculty.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter recommended that the NRC recognize the Nuclear Medicine Advanced Associate (NMAA) position as an AU for § 35.100 and § 35.200 medical uses. The commenter described the NMAA as a physician extender in Nuclear Medicine who has been trained at the master's level, tested, and board certified in advanced nuclear medicine practice. The commenter stated that:

> [t]he nuclear medicine advanced associate prescribes and administers pharmacologic and non-pharmacologic interventions under the direction of the supervising physician and, as indicated by patient profile and diagnostic procedure as allowable by state and federal statutes, which includes, but is not limited to:
>
> 1. Perform pre-procedure requirements and interventions as may be required.
> 2. Perform intra-procedure requirements as may be required.
> 3. Perform post-procedure requirements as may be required.

The commenter clarified that, as with other physician extenders, *i.e.,* physician assistants and nurse

practitioners, NMAAs are allowed to prescribe substances that are allowed under the scope of their practice, such as radiopharmaceuticals. The commenter believes that this opens the pathway for physician extenders in nuclear medicine to become authorized users, just as physician assistants and nurse practitioners are allowed to prescribe medications on behalf of their supervising physicians. The commenter believes that the training and practical experience of NMAAs creates ideal candidates for AUs and that the NMAA has met the qualifications required under § 35.200 to become AUs. The commenter concluded that the NRC should also recognize their board certification (Nuclear Medicine Technology Certification Board (NMTCB)) under §§ 35.190 and 35.290. The commenter recommended that NMAAs be added to the candidates for authorized user for radioactive byproduct materials use for uptake, dilution, excretion, imaging and localization and that their board certification be added to NRC recognized boards. The commenter proposed specific rule text to accomplish this.

*Response:* No change was made to the rule text based on this comment. The comment is outside the scope of this rulemaking. Currently, an AU under § 35.190, ''Training for uptake, dilution, and excretion studies,'' or § 35.290, ''Training for imaging and localization studies,'' must be ''a physician.'' An AU is defined at § 35.2 as ''a physician, dentist, or podiatrist . . .'' and a physician is defined as ''a medical doctor or doctor of osteopathy licensed . . . to prescribe drugs in the practice of medicine.'' AU recognition under §§ 35.190 and 35.290 is currently limited to physicians because these T&E requirements and board recognition criteria are premised on the high level of education and training obtained by medical doctors and doctors of osteopathy who are licensed to practice medicine. These T&E requirements are not premised on the level of education and training obtained by physician extenders or assistants. These T&E requirements ensure that AUs use byproduct material for medical purposes in a way that is radiologically safe for workers, patients, and the public. The change that the commenter requests would require the NRC to consider whether it is acceptable, from a radiological health and safety standpoint, to permit physician extenders or assistants such as NMAAs to be eligible to become AUs. Such a change is outside the scope of this rulemaking. Moreover, before making any such change, the NRC would need to carefully consider the radiological health and safety issues attendant to such a change and consult with the ACMUI. Although the commenter's recommendation is outside the scope of this rulemaking, the commenter may submit a petition for rulemaking on this issue pursuant to § 2.802.

Section 35.204 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

*Comment:* Several commenters agreed with the proposed changes to measure every elution. One commenter noted that the new elution requirements are already included in standards of practice and manufacturer recommendations.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter noted that Tc-99m decays much faster than Mo-99; therefore, every Tc-99m generator eluate will eventually exceed the regulatory limit. Because of this, the commenter stated that the language in the proposed rule text would require every eluate to be reported. The commenter proposed revising the rule text in § 35.204(e) to clarify that the licensee would only report measurements of a Tc-99m generator elution that exceeded the regulatory limits at the time of generator elution.

*Response:* The rule text was modified based on this comment. The NRC agrees with the commenter that the proposed rule text was not clear in § 35.204(e) and has amended it to clarify that the reporting requirements only apply at the time of generator elution.

*Comment:* One commenter stated that on two occasions in the last 10 years its generator elution measurements exceeded the regulatory limit, but on subsequent elutions, the measurements were below the limit. The Tc-99m from these subsequent elutions was used for patients. The commenter recommended that the reporting requirement of § 35.204 be revised to require a licensee to report to the NRC and the manufacturer or the distributor of medical generators within 30 days when ''consecutive measurements on the same generator'' exceed the limits specified in § 35.204(a).

*Response:* No change was made to the rule text based on this comment. The commenter suggested changing the regulation to require consecutive measurements on the same generator to exceed the regulatory limits before reporting the failure. The ratio of Mo-99 to Tc-99m measured in any eluate intended for patient use must never exceed the regulatory limits. Because safety of patients is paramount, reporting any failure to the NRC and the distributor, which may also sometimes be the manufacturer, allows for determinations to be made and actions to be taken to prevent similar occurrences. If any eluate measurement exceeds the regulatory limit, the generator should be removed from service until the cause is determined.

*Comment:* One commenter suggested revising § 35.204(b) to remove the phrase ''after receipt'' in the proposed requirements to measure the eluate from the generator in order to demonstrate compliance with the regulations because measuring the eluate after receipt of the generator is already implied.

*Response:* The rule text was modified based, in part, on this comment. The rule text was changed to delete ''after receipt'' in § 35.204(b). The previously proposed language could be subject to misinterpretation by the regulated community and, as suggested by the commenter, measuring the eluate after receipt of the generator is already implied. Deletion of ''after receipt'' more clearly describes the intent of this change to the regulation that each and every eluate intended for medical use of each generator must be tested for breakthrough.

Section 35.300 Use of Unsealed Byproduct Material for Which a Written Directive Is Required

*Comment:* One commenter questioned the statement about § 35.300 in the ''Discussion of Proposed Amendments by Section'' in the **Federal Register** notice for the proposed rule. The statement was that an AU may be authorized for one or more of the specific categories described in § 35.390(b)(1)(ii)(G), but not for all unsealed byproduct material. The commenter specifically wanted to know what other unsealed therapeutic byproduct material is referenced and why a trained and experienced AU could not be authorized for all unsealed therapeutic byproduct material.

*Response:* No change was made to the rule text based on this comment. Any new unsealed byproduct material requiring a WD that is not specifically addressed in § 35.390(b)(1)(ii)(G) would be regulated under the provisions of § 35.1000. This allows the NRC to evaluate each new radionuclide for possible unsealed byproduct material use and determine whether it falls within the scope of § 35.390(b)(1)(ii)(G) or instead should be regulated under the provisions of § 35.1000.

Section 35.390 Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

*Comment:* One commenter suggested the elimination of the attestation requirement for physicians meeting the ''alternate pathway'' T&E criteria in § 35.390(b) as was done for the ''board certification pathway'' under § 35.390(a).

*Response:* No change was made to the rule text based on this comment. The NRC is retaining the attestation statement requirement for individuals authorized under the ''alternate pathway'' provisions. This is because it is important to know that the individual not only successfully completed the T&E requirements but is also able to independently fulfill the radiation safety-related duties of an AU.

*Comment:* One commenter believed the use of the word ''radiopharmaceutical'' in the introduction section of § 35.390(b)(1)(ii)(G) and the phrase ''any radionuclide'' in the parenteral administration regulations (*i.e.,* § 35.390(b)(1)(ii)(G)(*3*) or (b)(1)(ii)(G)(*4*)) was confusing and would permit the use of a radionuclide that is not a component of a radiopharmaceutical. The commenter used the example of yttrium-90 (Y-90) microspheres containing the radionuclide Y-90. The commenter recommended revising the wording in § 35.390(b)(1)(ii)(G)(*3*) and (b)(1)(ii)(G)(*4*) to say, ''Parenteral administration of any radioactive drug. . . .''

*Response:* The rule text was modified based on this and other comments. The rule text was changed to include the phrase ''radioactive drug that contains a'' in § 35.390(b)(1)(ii)(G)(*3*). The NRC agrees that the proposed language could be clearer. Additionally, based on a recommendation from the ACMUI, the NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*).

*Comment:* One commenter stated that both the current and proposed categories in § 35.390(b)(1)(ii)(G)(*3*) and (*4*) are confusing. The commenter asked what the purpose is for specifying the 150 keV limit in category (*3*). The commenter stated that if there is a new use for a photon emission greater than 150 keV then there is no provision for it under the regulations.

*Response:* No change was made to the rule text based on this comment. The NRC believes it is unlikely that there will be a radioactive drug requiring a WD that will be used *primarily* for its photon energy greater than 150 keV. However, as stated in § 35.390(b)(1)(ii)(G), any radioactive drugs not specifically addressed in paragraph (G) would be regulated under the provisions of § 35.1000.

*Comment:* One commenter stated that § 35.390(b)(1)(ii)(G)(*4*) would require an AU currently authorized under § 35.390(b)(1)(ii)(G)(*3*) to administer radium-223 dichloride to obtain additional work experience, unless revisions are made to § 35.57. The commenter stated that these physicians do not need additional training to use materials for which they are already authorized.

*Response:* The rule text was modified based on a recommendation from the ACMUI. The NRC revised § 35.57(b)(1) to grandfather physicians for those medical uses for which they were authorized prior to the effective date of the rule. Also, the NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*). These changes ensure that physicians already using Ra-223 dichloride at the time the rule becomes effective are permitted to continue use of the radioactive drug.

*Comment:* Several commenters questioned the purpose of the proposed paragraph (c) in § 35.390 that applied only to parenteral administrations. They questioned how a physician could be an AU under the provisions of § 35.390 without completing the I–131 cases listed in § 35.390(b)(1)(ii)(G). The commenters questioned whether paragraph (c) should be moved to § 35.396.

*Response:* The rule text was modified based on these and other comments. Section 35.390(c) was removed in the final rule because § 35.390(b)(1)(ii)(G)(*3)* and (*4)* was merged into one category of parenteral administrations of radioactive drugs in the final rule in response to a recommendation from the ACMUI. Section 35.390(c) was no longer needed with this revision in the final rule. Section 35.390(b)(ii)(G) now has three separate categories of radioactive drugs, and a proposed AU is evaluated and authorized for each category separately. The NRC recognizes that individuals that are board certified or have completed the other T&E criteria under § 35.390 may not have completed their supervised work experience administering all the categories of radioactive drugs in § 35.390(b)(1)(ii)(G). These individuals will be authorized for only those categories for which they have completed their T&E.

*Comment:* Several commenters opposed the proposed new dosage category for alpha emitters under § 35.390(b)(1)(ii)(G)(*4*) because it would require physicians authorized for the parenteral administration of radioactive drugs containing radionuclides used primarily for their electron emitters or for its photon energy of less than 150 keV to have additional work experience involving dosage administrations in a minimum of three cases to attain AU status. The commenter pointed out that under the proposed regulations, those seeking to administer both types would need work experience in a minimum of six cases of administration, three with alpha emitters and three with beta emitters. The commenter referenced the ACMUI recommendation not to separate the parenteral administration of beta and gamma-emitting radiopharmaceuticals from the alpha-emitting radiopharmaceuticals. The commenter also stated that according to the ACMUI, the NRC staff has not provided a compelling radiation safety justification for emission-specific T&E requirements.

*Response:* The rule text was modified based on a recommendation from the ACMUI. Section 35.390(b)(1)(ii)(G)(*4*) was deleted and provisions within that section have been incorporated into § 35.390(b)(1)(ii)(G)(*3*). The category ''parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required'' is now included in § 35.390(b)(1)(ii)(G)(*3*). The NRC has determined that an AU who is authorized under § 35.390(b)(1)(ii)(G)(*3*) would not need three additional cases to administer alpha-emitting radioactive drugs.

*Comment:* One commenter believed NRC's separation of categories in § 35.390(b)(ii)(G)(*3*) and 35.390(b)(ii)(G)(*4*) based on the primary emission used for medical use was not the best approach. The commenter cited Lutetium-177 as an example of a radionuclide with a significant gamma emitting branch with energy exceeding 150 keV. The commenter proposed the distinction be based on the prevalence of gamma emissions greater than 150 keV. The commenter's proposal was to modify § 35.390(b)(ii)(G)(*3*) to read, ''Parenteral administration for which a written directive is required of any radionuclide which emits a photon with energy greater than 150 keV in less than or equal to 10% of all decays, or of any less than 1.0 GBq (27 mCi) of any other radionuclide;'' and modify § 35.390(b)(ii)(G)(*4*) to read, ''Parenteral administration for which a written directive is required of 1.0 GBq (27 mCi) or more of any radionuclide which emits a photon with energy greater than

150 keV in more than 10 percent of all decays.'' The commenter concluded that most, if not all alpha emitters, would be in the newly defined category 3 and be consistent with the placement of radium-223 dichloride.

*Response:* No change was made to the rule text based on this comment. The commenter provided an alternative approach for categorizing various radioactive drugs for parenteral administration, but the NRC believes that the categorization is better delineated based upon the most clinically effective emissions of the radioactive drug requiring a WD. The commenter's proposal would result in implementation difficulties without a commensurate increase in safety. Further, the NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*).

*Comment:* One commenter recommended eliminating the separate dosage category used primarily for alpha emitters. The commenter suggested that if a new radioactive drug became available that was more hazardous than radium-223 dichloride and warranted additional radiation safety regulatory requirements, then NRC could license it under the provisions of § 35.1000.

*Response:* The rule text was modified based on a recommendation from the ACMUI. The NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*). The NRC anticipates that all radioactive drugs that will be used for their alpha-emitting characteristics can be regulated under § 35.390(b)(1)(ii)(G)(*3*). However, the NRC may regulate radionuclides under § 35.1000 as appropriate.

*Comment:* One commenter noted that NRC regulations are designed to provide flexibility for emerging technologies and could be adjusted to recognize that alpha and beta emitters are a new class of therapeutic radiopharmaceutical products. The commenter referenced Radium-223 dichloride and a potential new actinium alpha emitter. The commenter suggested that the NRC should create a new T&E requirement specific to therapeutic radiopharmaceuticals based upon their unique characteristics, typical setting for administration, and safety record (such as was done for sodium iodide I-131 at §§ 35.392 and 35.394). The NRC could give license applicants an option to petition NRC for review under § 35.1000 for a drug that technically fits within the four categories listed in § 35.390(b)(1)(ii)(G), but is deserving of an individualized T&E requirement review, due to its administration profile and safety characteristics.

*Response:* No change was made to the rule text based on this comment. The NRC's regulations under § 35.1000 allow the NRC to determine when a particular medical use of byproduct material or radiation from byproduct material should be regulated under § 35.1000. In accordance with § 35.12(d), the NRC will license a new radionuclide under § 35.1000 if it has unique properties that prohibit it from meeting existing requirements or if additional requirements are needed for safety. When a radionuclide is licensed under § 35.1000, specific T&E requirements are included in the licensing guidance for that particular radioactive drug.

*Comment:* Several commenters stated it would be difficult for AUs to get the additional supervised work experience associated with three cases using radioactive drugs containing radionuclides used primarily for their alpha emissions. One commenter pointed out that there is only one FDA-approved alpha-emitting radioactive drug and that it is used in a limited population. Several other commenters stated that patients who do not live near teaching hospitals and urban centers may have limited access to radioactive drugs in the two parenteral categories. Certain practitioners, particularly those in areas far removed from teaching hospitals and urban centers, may find it too burdensome to participate in three proctored cases in each of these very specific categories.

Several commenters stated that the proposed changes in § 35.390(b)(1)(ii)(G) would discourage clinicians from seeking authorization to administer these radioactive drugs and would make an already burdensome regulatory scheme more onerous. The commenters suggested that the NRC revise the proposed work experience requirement in categories in § 35.390(b)(1)(ii)(G)(*3*) or 35.390(b)(1)(ii)(G)(*4*) to have three proctored cases in either category be satisfactory to meet the requirements for both categories.

Several commenters acknowledged that the clarifications of the categories of parenteral administrations were useful and logical. However, they agreed with another commenter that there was an unintended consequence of increasing the work experience burden for those seeking administration of radiopharmaceuticals with alpha and beta emitters.

*Response:* The rule text was modified based on a recommendation from the ACMUI. The NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*).

Section 35.396 Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

*Comment:* One commenter supported changes in the proposed rulemaking to permit physicians who have completed the 80 hours of classroom and laboratory training specified in § 35.396(d)(1) and who have the relevant work experience described in § 35.396(d)(2) to be eligible for AU status to administer parenteral radioactive drugs. The commenter stated that this is an appropriate level of T&E for administration by hematologists and oncologists of a specific radioactive drug, Zevalin®, used primarily for its beta emissions.

*Response:* No change was made to the rule text based on this comment. The NRC did not intend to propose any change to this T&E requirement in the proposed rule, and, therefore has not developed the regulatory basis to make any change to this requirement in this final rule. During the preparation of the proposed rule, an administrative error resulted in the addition of the word ''or'' between the rule text in § 35.396(c) and (d). The NRC did not intend to put an ''or'' between paragraphs (c) and (d) and is correcting the error by removing the word ''or'' in the final rule text between paragraphs (c) and (d). This administrative error could have been interpreted to require that a physician complete only 80 hours of T&E for parenteral administration of unsealed byproduct material requiring a WD.

The NRC notes that to obtain authorization to use parenteral radioactive drugs requiring a WD, the physician must either (1) meet the T&E requirement or be certified by a medical specialty board recognized under § 35.390 and meet the clinical case work criteria in § 35.390, or (2) meet the T&E requirement or be certified by a medical specialty board recognized under §§ 35.490 or 35.690 and satisfy the additional 80 hours of T&E requirement specified in § 35.396(d).

*Comment:* Two commenters stated that NRC's regulations create a shortage of AUs able to administer certain therapeutic radioactive drugs. Specifically, under current regulations, a radioactive drug requiring a WD that is administered parenterally and used primarily for its beta radiation characteristics can only be administered by an AU who has met the T&E requirement set forth in § 35.396. This requirement involves either board

certification or 700 hours of T&E specifically in radionuclide handling. One of the commenters stated that hematologists and oncologists who typically prescribe therapeutic radiopharmaceuticals outside of the hospital setting often do not have the T&E required to meet the AU requirements and do not work at facilities that have such AUs. They have extensive T&E, and are frequently board certified, but in different specialized fields.

*Response:* No change was made to the rule text based on these comments. The NRC believes that the commenters are referring to the requirement in § 35.390, because the 700 hour criterion is in § 35.390 and not in § 35.396.

Without compromising radiological health and safety, the NRC strives to ensure that its regulations do not restrict patient access to diagnostic and treatment options. The intent of NRC's T&E requirements is to ensure that AUs are adequately trained so that their handling and administration of radioactive drugs is radiologically safe for patients, workers, and the public. The current T&E requirements are protective of radiological health and safety. As explained in greater detail in a response to another comment on parenteral administrations, throughout 2015 and early 2016 the ACMUI assessed the concerns raised in this comment. Additionally, the ACMUI established a standing subcommittee that will periodically assess the T&E requirements across all modalities and make recommendations for changes as warranted. The NRC will also continue to consider whether changes to these T&E requirements are warranted.

With respect to the comment that hematologists and oncologists ''typically prescribe therapeutic radiopharmaceuticals . . . ,'' the NRC regulations require that such radiopharmaceuticals be administered in accordance with a WD. A WD is an AU's—not a hematologist's or oncologist's—written order for the administration of byproduct material or radiation from byproduct material to a specific patient, as specified in § 35.40.

*Comment:* Several commenters provided comments after the public comment period on whether the NRC should amend the T&E requirement for the parenteral administration of radioactive drugs as part of this final rule.

One commenter stated that amending § 35.396 to reduce the T&E requirement to 80 hours in this final rule would be a logical outgrowth of the proposed rule and thus would satisfy the Administrative Procedure Act of 1946 (APA) requirement to provide notice and an opportunity for comment. The commenter stated that the NRC provided adequate notice of an amendment to this T&E requirement and that the NRC received substantial public input on these T&E requirements. Alternatively, according to the commenter, the NRC could invoke the ''good cause'' exemption from the APA notice and comment requirements because the 700 hour T&E requirement for these parenteral radioactive drugs has caused a decrease in the number of AUs for these drugs and a corresponding decrease in patient access to these drugs. The commenter also proposed that the NRC could, instead of amending T&E requirements at § 35.396(d), include in this final rule a new section that would require 80 hours of T&E specifically for the parenteral administration of patient-ready doses of alpha- and beta-emitting radioactive drugs. One other commenter also supported reducing this T&E requirement to 80 hours as part of this final rule and provided a proposed training program.

Several other commenters also expressed support for reducing this T&E requirement in this final rule. The commenters asserted that the 700 hour T&E requirement has caused a lack of AUs available to administer these radioactive drugs; administration of these drugs presents no greater radiation health and safety risk than oral administration of I-131; and 80 hours of T&E is sufficiently protective of radiological health and safety.

Several commenters opposed changing this T&E requirement in the final rule. One commenter stated that the NRC and ACMUI would need to analyze key issues before proposing any changes to this T&E requirement, including whether a reduction in the requirement is advisable from a radiation health and safety perspective. These commenters stated that an AU would need to receive adequate training on a broad array of radiation health and safety topics and that an 80-hour course would not sufficiently cover these topics. These commenters also described the range of activities, considerations, and procedures necessary to ensure the safe handling and administration of these radioactive drugs.

*Response:* No change was made to the rule text based on these comments. As stated in response to another comment on § 35.396, the proposed rule text that could have been interpreted to require only 80 hours of T&E for a physician to obtain AU status to administer parenteral radioactive drugs was the result of an administrative error. The NRC did not mention or discuss any changes to these T&E requirements in any other part of the proposed rule **Federal Register** notice. The NRC did not intend to propose any changes to this T&E requirement, and therefore the NRC has not developed a regulatory basis to make any such change in this final rule. The NRC agrees with the comment that, before proposing any changes to this T&E requirement, the NRC and ACMUI should analyze whether a change in the requirement is warranted and advisable from a radiation health and safety perspective.

In response to commenter's concerns about this T&E requirement, the NRC and ACMUI began considering whether a change in this requirement is warranted. Spectrum Pharmaceuticals, Inc. requested a meeting with NRC staff to explain its comments concerning this T&E requirement. The NRC staff agreed and held a public meeting on February 12, 2015, at which Spectrum Pharmaceuticals, Inc. and Florida Cancer Specialists & Research Institute presented their comments and concerns that this T&E requirement causes a shortage of AUs, and, therefore a barrier to patient access. In response to these comments and concerns, throughout 2015 and early 2016 the ACMUI assessed whether this T&E requirement places a hardship on the patient community. In a public teleconference held on June 16, 2015, the Florida Cancer Specialists & Research Institute presented to the ACMUI its concerns that this T&E requirement caused a lack of AUs and thus a barrier to patient access to these radioactive drugs. After this teleconference, the ACMUI formed a subcommittee to assess whether the 700 hour T&E requirement for parenteral administration of this class of radiopharmaceuticals places a hardship on the patient community by creating a shortage of AUs. In its subcommittee report dated September 21, 2015, which the ACMUI unanimously approved at its Fall 2015 meeting, the ACMUI concluded that it was unable to substantiate this claim. The ACMUI found that the infrequent and steadily decreasing use of specific beta-emitting radioactive drugs—specifically radioactive drugs that are used to treat lymphoma, such as Spectrum Pharmaceuticals, Inc.'s drug Zevalin®—is due to many factors. The ACMUI concluded that it could not determine whether there is a shortage of AUs and, if so, whether the NRC's T&E requirement caused the shortage. The subcommittee was then charged with continuing to assess this issue and

establishing a recommendation for the total number of hours of T&E for AUs of this class of radioactive drugs that appropriately balances safety with reasonable patient access to these radioactive drugs.

In its subcommittee report dated March 10, 2016, which the ACMUI unanimously approved at its meeting on this same date, the ACMUI reiterated its conclusion that it could not substantiate the claim that the T&E requirement caused a shortage of AUs and thus a hardship on the patient community. For this reason, and because the ACMUI identified several issues raised by the reduction in T&E requirements that some commenters recommended, the ACMUI recommended against reducing the T&E. However, the ACMUI recognized the need for a thorough review of T&E requirements across all modalities because of the introduction of new radioactive drugs since the requirements were established 15 years ago and because the educational paradigm has shifted from prescriptive curricula to competency-based education. The ACMUI established a standing subcommittee to assess T&E requirements for all modalities and provide recommendations to the NRC staff. As stated in response to other comments, the NRC will continue to consider concerns regarding T&E requirements to ensure that these requirements are sufficient to ensure radiological health and safety for patients, workers, and the public without unnecessarily creating barriers to patient access to diagnostic and treatment options.

Section 35.400 Use of Sources for Manual Brachytherapy

*Comment:* Several commenters did not agree with the proposal in § 35.400 that manual brachytherapy sources may be used for medical purposes not listed in the SSDR. The commenters believed that this change would permit sources to be used by medical personnel who have not received any radiation safety training. As an example, they cited the case where brachytherapy sources are used in temporary diagnostic localization procedures under the provisions of § 35.1000. In this case, the guidance requires licensees to submit their training program for nonmedical staff that are not covered under their current medical license. The commenters believed that by requiring these uses under the provisions of § 35.1000, the regulatory agencies can ensure that radiation safety for all workers is verified before use.

*Response:* No change was made to the rule text based on these comments. Although the statement of considerations for the proposed rule stated ''manual brachytherapy sources can be used for medical uses not listed in the SSDR'', the rule text is more limiting and states ''. . . manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the SSDR.'' The commenters' example of using a manual brachytherapy source for a temporary diagnostic localization procedure is not permitted under the provisions of § 35.400 because it is a diagnostic use and not a manual brachytherapy use. However, such use may be authorized under the provisions of § 35.1000.

*Comment:* One commenter agreed with the NRC that the limitations and consideration of use listed in the SSDR be followed. The commenter believed that the ''SSDR reviewer should identify and list requirement [sic] and discuss issues on how to license these products for safe use.'' The commenter stated that, by doing this, the SSDR reviewer helps ensure uniformity in the licensing requirements, and saves resources for industry and regulatory agencies in not having to independently obtain this information.

*Response:* No change was made to the rule text based on this comment. The NRC revised § 35.400 because existing SSDR sheets do not, nor are they expected to, describe all manual brachytherapy medical procedures for which the manual brachytherapy seeds can be used. During the evaluation, the reviewer focuses on radiation safety conditions and limitations of use.

Section 35.433 Strontium-90 Sources for Ophthalmic Treatments

*Comment:* One commenter stated that the proposed regulations concerning ophthalmic physicists in § 35.433, which separate physicists who assist in ophthalmic procedures from AMPs who are involved in the uses allowed under §§ 35.600 and 35.1000, were an improvement.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter recommended a revision of § 35.433(a)(2) to specifically include the term ''ophthalmic physicist.'' The commenter pointed out that although the NRC defined the ''ophthalmic physicist'' to be ''an individual who meets the requirements of § 35.433(a)(2) . . . ,'' the NRC did not use the term ''ophthalmic physicist'' in § 35.433. The commenter recommends changing the text in § 35.433(a)(2) to read: An individual named as an ophthalmic physicist who: (i) Holds a masters . . .''

*Response:* The rule text was modified based on this comment. The rule text was changed to include the term ophthalmic physicist in § 35.433(a)(2). The NRC agrees that, for clarity, the term ophthalmic physicist must be included in this section. By including the term ''ophthalmic physicist,'' it is clear that the requirements in § 35.433(a)(2) apply to an individual who is named as an ophthalmic physicist and meets the definition of an ''ophthalmic physicist'' in § 35.2.

*Comment:* Several commenters questioned the need for § 35.433(b)(2) and recommended its removal. They thought that the actions regarding the WD were already required by the licensee in § 35.41 and that no other modality requires a procedure regarding the frequency of involvement by the medical physicist. The commenters also asked why the other individual [identified in § 35.433(b)(2)] could not work under the supervision of the AMP or request an exemption from the requirement.

*Response:* No change was made to the rule text based on these comments. Although the regulations do not prohibit a licensee that has an AMP from also having an ophthalmic physicist, the primary purpose of the ophthalmic physicist is to provide physics support to the ophthalmic AU when the licensee does not have access to an AMP. The ophthalmic physicist is an individual recognized by the NRC, Agreement States, medical licensees of broad scope, master material licensees or master material medical permittees of broad scope by T&E, to perform certain functions listed under § 35.433. This individual is authorized to work independently and is not required to work under the supervision of an AMP.

The purpose of § 35.433(b) is to describe the minimum performance-based tasks expected of either the AMP or the ophthalmic physicist in assisting the licensee and AU with the ophthalmic treatment program. The requirement that only an AMP shall calculate the activity of each Sr-90 source is an existing requirement in the regulations under § 35.433(a) and is not a new requirement. The requirement in § 35.433(b)(2) codifies that the AMP, or ophthalmic physicist, is to assist the licensee and AU in assuring that the requirements in § 35.41 are met. Ophthalmologists using these devices are frequently in small programs with limited access to services of an AMP. The proposed rule change was made in part to ensure that the ophthalmic physicist (or AMP) performs a minimum number of tasks at the ophthalmology office.

The NRC did not specify the frequency of involvement of the AMP or ophthalmic physicist because the licensee should determine the best frequency for its program. The NRC requires AMPs to perform certain tasks at specified frequencies for certain medical use programs. Specifically, AMPs are required to participate initially, and at least annually, in drills of emergency procedures under § 35.610. They also must be physically present during initiation of patient treatment, continuation of the treatment, or the entire treatment, depending on the unit being used under § 35.615. In addition, AMPs must perform the full calibration measurements and decay corrections before first medical use, before medical use under certain conditions, and at intervals not to exceed one year under §§ 35.632, 35.633, and 35.635.

*Comment:* An Agreement State pointed out that in its State statutes, an individual who practices medical physics is required to be licensed by the State. Because § 35.422 is designated as ''Health and Safety'' (H&S), the Agreement State must promulgate its rule to require medical physicists to comply with its statute. The commenter recommended that the rule text be changed to ''allow the individual to work under the supervision of an AMP as authorized by state laws.''

*Response:* No change was made to the rule text based on this comment. The NRC believes that the commenter is referring to § 35.433, not § 35.422 (as there is no § 35.422 in the regulation). The revision of the rule does not prohibit a State from requiring the ''ophthalmic physicist'' to be licensed by the State as long as the licensure requirements include components essentially identical to NRC T&E requirements. The purpose of adding the ophthalmic physicist was to identify an individual who could assist the licensee when the licensee does not have access to an AMP. In this situation, the ophthalmic physicist cannot work under the supervision of an AMP because the licensee does not have an AMP to perform the activities listed in § 35.433(b). Further, the ophthalmic physicist is authorized independently and is not required to work under the supervision of an AMP. The designation ''H&S'' in the summary refers to program elements that are not required for compatibility, but are identified as having a particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

*Comment:* An Agreement State pointed out that its licensure requirements for ''Medical Physicist'' are currently consistent with NRC's requirement for an AMP in 10 CFR part 35. The T&E of the ''ophthalmic physicist'' does not meet its licensure requirements and it is unclear whether the individual would meet the accreditation standards set by the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO) in radiation oncology, which the State requires for manual brachytherapy. All state licensees that are authorized for possession and use of a Sr-90 eye applicator have the services of an AMP for other brachytherapy and external beam therapy uses. The commenter also questioned whether it would relieve a shortage of physicists in rural areas, because the proposed rule does not require an AMP or ophthalmic physicist to be physically present at the licensee's authorized location of use, with the possible exception of the initial source calibration that is performed on site or to be on site to perform the decay correction and treatment times. The commenter concluded that the addition of this proposed category of physicist did not appear to be applicable in its state and therefore should not be required for state adoption. The commenter proposed that the NRC assign Compatibility Category ''B'' to those states that will and category ''D'' to those that will not use the designation of ophthalmic physicist.

*Response:* No change was made to the rule text or to the compatibility category designation for the T&E requirements for an ophthalmic physicist under § 35.433(a) based on this comment. All NRC T&E requirements in 10 CFR part 35 are designated as Compatibility Category B, which means they have direct and significant transboundary effects. The licensee is required to have procedures that specify the frequency at which the AMP or ophthalmic physicist would observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the treatment was in accordance with the WD. The individual must be physically present at the licensee's authorized location of use on a set frequency to complete these tasks. The NRC believes that having an individual who is not an AMP, but is qualified to perform the tasks specified and to perform some of them on site, will benefit rural licensees.

Section 35.490 Training for Use of Manual Brachytherapy Source

*Comment:* One commenter stated that the requirements for supervised work experience under § 35.490(b)(1)(ii) were written vaguely, and that it can and has been interpreted as 500 hours of work related to radiation therapy, not specifically to brachytherapy. The commenter believed that this interpretation is reasonable, but that it would be helpful to have some specific brachytherapy related guidance on, *e.g.,* the number of cases the proposed AU or AMP should observe and/or perform under supervision, or the length of time they should perform these procedures under supervision.

*Response:* No change was made to the rule text based on this comment. It appears that the commenter's statement is limited to the rule text in § 35.490(b)(1)(ii). However, § 35.490(b)(1)(ii) should be taken in the context of all of the training requirements in § 35.490(b)(1), which states, ''Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes [(i) and (ii)].'' Further, the tasks that are to be performed under § 35.490(b)(1)(ii) include § 35.490(b)(1)(ii)(C): Preparing, implanting, and removing brachytherapy sources. The NRC does not require a minimum number of cases because the requirement for a total of 500 hours of supervised work experience, including the tasks required under § 35.490(b)(1)(ii)(C), is sufficient to ensure the safe use of manual brachytherapy sources.

Section 35.500 Use of Sealed Sources and Medical Devices for Diagnosis

*Comment:* Several commenters noted that NRC's revision to § 35.500(a) and (b) states that ''[a] licensee must only use sealed sources or diagnostic devices that are approved in the Sealed Source and Device Registry . . .'' and also states ''may be used for . . . .'' One commenter stated that these revisions contradicted each other, because the revision states that the licensee ''must'' for some uses but then uses ''may'' for other uses. Several commenters thought this provision put a burden on the SSD reviewing agency to ensure that proper conditions are included in the SSD allowing for other uses. They disagreed with the revision and recommended that any other uses of these sealed sources should be approved by the licensing regulatory agency.

*Response:* The rule text was modified based on these comments. The rule text

in § 35.500(a) was changed in order to make it clear that it is the sealed sources, as opposed to the diagnostic medical uses, that must be approved in the Sealed Source and Device Registry (SSDR). The rule text in § 35.500(b) was not changed because the NRC believes the language in this section is clear. The revision in § 35.500(a) now states, ''A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.'' The revision in § 35.500(b) continues to state: ''A licensee must only use diagnostic devices containing sealed sources for diagnostic medical uses if both the sealed sources and diagnostic devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.'' To clarify, the first part of the requirement in each paragraph is to restrict the licensee to only use sealed sources and devices for diagnostic purposes if they are approved for diagnostic purposes in the SSDR. The purpose of the second part of the requirement in each paragraph is to allow the licensee the flexibility to use diagnostic sealed sources and devices for medical uses other than those that are explicitly included in the SSDR. As long as the limitations and conditions included in the SSDR address those generally needed for diagnostic uses, there is no additional burden on the SSD reviewer to revise the SSD for a new diagnostic use not explicitly stated. If the licensee intends to use a diagnostic sealed source or device for a non-diagnostic use, then the licensing regulatory agency will need to determine how to license such use.

Section 35.600 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

*Comment:* Several commenters stated that the revision splits the section into two paragraphs where (a) is used for sources and (b) is used for units. They recommend either changing the name of the section or adding a new section for the units.

*Response:* No change was made to the rule text based on these comments. The current title of the section already includes the sealed sources and the devices in which the sources are used. The requirements in paragraphs (a) and (b) parallel this structure.

*Comment:* Several commenters recommended that § 35.600(b) be revised to read: ''A licensee must use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units:

i. That are approved in the Sealed Source and Device Registry; or

ii. In research . . . .''

*Response:* No change was made to the rule text based on these comments. The purpose of the revisions to § 35.600(b) is to clarify that the photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic units must be used in accordance with the limitations and considerations of use listed in the SSDR and to allow the licensee to use the units for medical uses not explicitly listed in the SSDR. The commenters' proposed change would not address these issues.

Section 35.610 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

*Comment:* One commenter questioned why the revisions to § 35.610(d)(1) require training on a new unit to be provided only by the vendor or individuals certified by the vendor. The commenter does not believe there is clear evidence that vendor training is superior to a course the licensee might develop and that the quality of vendor training is quite variable. The commenter was also concerned that if a staff member missed the vendor's training, the licensee would be required to make special arrangements, probably at considerable cost, to have that person trained as required. The commenter stated that in most cases the licensee will choose to have all staff trained by the vendor when a new device is installed. The commenter believed that licensees should be allowed to provide training to their personnel in the manner they deem the best as is the case today and would be the case at existing installations under the proposed rule.

*Response:* The rule text was modified based on this comment. The rule text was changed to clarify that the individuals certified by the device manufacturer to provide vendor training must be specifically certified to provide this training. The medical device manufacturer is the most knowledgeable entity when it comes to its new devices or upgrades to devices that affect their safety and operation. The NRC's intent is that before the device can be used on the first patient, each staff member involved in the operation of the device for that first patient's treatment must receive training on the operational and safety features and procedures from the vendor or individuals certified by the vendor to provide the training. For subsequent patient treatments, the requirements in § 35.610(d)(2) apply.

*Comment:* One commenter agreed that, with respect to the revisions to § 35.610(d)(1), after modifications to the unit, staff authorized to use the unit needs to be trained on the upgrade and how the upgrade affects the operation of the unit. The commenter wanted clarification on whether ''. . . upgrade that affects the operation and safety of the unit'' is meant to cover changes to the actual device itself or changes to the device and any changes to the treatment planning system (software/hardware).

*Response:* No change was made to the rule text based on this comment. The rule covers both software and hardware changes that affect the operation and safety of the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

*Comment:* One commenter wanted clarification on whether the requirement ''or by an individual certified by the device manufacturer . . .'' included a person at the organization (one of the authorized operators) who received the device upgrade training from the manufacturer and would then be able to train all other authorized operators at the organization.

*Response:* The rule text was modified based on this comment. The rule text in § 35.610(d)(1) was revised to clarify that the vendor training can only be provided by either the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. Therefore, an authorized operator at the licensee's facility that is certified by the device manufacturer to provide the operational and safety training may provide initial instruction to other authorized operators at the facility.

Section 35.655 Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units

*Comment:* One commenter stated that a full inspection is only possible when the sources in a gamma stereotactic radiosurgery unit are replaced. The commenter recommended that the full

inspection frequency be revised to occur upon source exchange.

*Response:* No change was made to the rule text based on this comment. The NRC agrees that the full inspection is only possible when the sources in a gamma stereotactic radiosurgery unit are replaced. Further, the NRC believes that the source replacement interval for a gamma stereotactic radiosurgery unit can be extended to 7 years because of the 6-month routine preventive maintenance performed on these units.

Section 35.690 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

*Comment:* One commenter stated that it was unclear how an individual who is board certified but beyond 7 years of the required training may seek AU or AMP status. The commenter believed that, for safety, there should be some minimum number of cases the individual must observe prior to obtaining AU or AMP status especially in light of the complexity of interstitial procedures such as LDR or HDR prostate.

*Response:* No change was made to the rule text based on this comment. The NRC reviews, on a case by-case basis, each applicant who received board certification more than 7 years ago and requests to be authorized as an AU or AMP. The licensee must demonstrate that the individual has had related continuing education and experience since the required training was completed. Because of the rigorous T&E requirements already in place, the NRC has not set a minimum number of cases a physician or a medical physicist must observe prior to obtaining AU or AMP status.

*Comment:* One commenter stated that replacing ''institution'' in § 35.690(b)(1)(ii) with ''facility that is authorized to use byproduct material in 35.600'' may cause difficulties without any apparent benefit. Under current regulations, a residency program at an institution that has only linear accelerators can provide some of the work experience pertinent to the requirements at its institution so long as it has the appropriate AUs on staff (which is common with physician faculty practicing at affiliated outpatient facilities). While residents need some direct work experience with, for example, treatment planning for HDR after loaders, there are concepts learned in a linear accelerator treatment planning that apply. This is especially true of external beam therapy from radioactive sources. Therefore, if a preceptor judges it to be appropriate, an individual should be allowed to acquire a portion of the required 500 hours of work experience at a facility that does not use byproduct material in § 35.600.

*Response:* No change was made to the rule text based on this comment. The amendment the commenter described was made to ensure that the supervised work experience was obtained at a medical facility (including a stand-alone single discipline clinic) where the facility is authorized for uses under § 35.600. Section 35.690 also includes a requirement that the individual complete a 3-year accredited residency program in radiation therapy. This residency program is not restricted to a facility that is authorized for § 35.600 uses. The NRC recognizes that the ''concepts learned'' that the commenter referred to may be obtained from such a facility but that the individual still needs 500 hours of supervised work experience with the § 35.600 devices.

*Comment:* One commenter expressed concern regarding whether a residency program approved by the Royal College of Physicians and Surgeons of Canada can be used to meet the requirements in § 35.690(b)(2) because of the specific mention of a medical facility authorized to use byproduct material in § 35.600. Currently, the NRC's, ''Procedures for Recognition of Foreign Trained Physicians and Physicists Applying for Authorized User (AU) and Authorized Medical Physicist (AMP) Status,'' states that a physician coming out of a residency approved by the Royal College of Physicians and Surgeons of Canada would need to work under a physician who also practices in the United States. While such physicians likely exist, adding the additional requirement that the facility is authorized to use byproduct material in § 35.600 appears to add an additional hurdle to allowing hours from these residencies.

*Response:* No change was made to the rule text based on this comment. The commenter is correct that a physician completing a residency program approved by the Royal College of Physicians and Surgeons of Canada may have to complete his or her 500 hours of supervised work experience at another facility that is authorized for uses under § 35.600.

Section 35.3045 Report and Notification of a Medical Event

The NRC received many comments on various issues related to the permanent brachytherapy event reporting criteria under this section. For better understanding of the concerned raised, the comments are grouped according to the distinct issues commenters raised.

Issue: The Medical Event Reporting Criterion Are Based on the Term ''Potential Harm''

*Comment:* Several commenters stated that they do not agree with the use of the term ''potential harm'' in the discussion of MEs in the **Federal Register** notice for the proposed rule. The commenters believe that ''potential harm'' is a medical decision and that this approach is a significant departure from the current definition of an ME. The commenters believe that this approach will eliminate the opportunity for licensees to identify precursor events and make process improvements, and that it could have the unintended consequence of providing additional support for malpractice suits. In articulating their objection to NRC's position, some commenters stated that ''[a]s regulators, we are not tasked for determining what the 'potential harm' is, our mission is to ensure licensees abide by the required regulations.''

*Response:* The NRC believes that the rule will not discourage licensees from identifying precursor events or making process improvements. The rule continues to reflect the NRC's position that an ME may be indicative of potential problems in a medical facility's use of radioactive materials and does not necessarily result in harm to the patient. This position is based on the NRC staff recommendations submitted to the Commission in SECY–05–0234, ''Adequacy of Medical Event Definitions in § 35.3045, and Communicating Associated Risks to the Public,'' dated December 27, 2005. The NRC staff recommendations were approved by the Commission in SRM to SECY–05–0234, dated February 15, 2006. The ME criteria for permanent implant brachytherapy are now consistent with the criteria for other therapeutic modalities by reflecting circumstances in which there may be harm or potential harm to the patient.

Issue: The Medical Event Reporting Criterion Related to the Absorbed Dose to Normal Tissues Located Within the Treatment Site

*Comment:* One commenter had questions and expressed concerns about the ME reporting criterion in § 35.3045 related to ''intra-target'' normal tissue. The commenter stated that for prostate implants the urethra is the only such structure to consider, and the volume is much less than 5 cubic centimeters. The commenter wanted to know whether, if the dose threshold for reporting an ME was exceeded for the urethra, given that the volume is less than 5 cubic centimeters, if that instance would

require reporting. The commenter also expressed concern that treatment planning systems could not distinguish between a 5 cubic centimeters volume and a summation of five 1 cubic centimeters volumes receiving 150 percent of the prescribed dose.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC understands that the volume of the urethra within the treatment site is typically less than 5 cubic centimeters. In addition, the NRC acknowledges the commenter's concern that treatment planning systems may not distinguish contiguous volumes from non-contiguous, summated volumes. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

*Comment:* One commenter expressed concerns about the absorbed dose-based criterion for normal tissue within the treatment site and stated that it is common for 50 percent or more of the treatment site to receive a dose that exceeds the prescribed dose by greater than 50 percent. The commenter was concerned that quality implants may be categorized as MEs using this criterion. The commenter also stated that its vendor's software does not provide a method to evaluate dose to contiguous volumes of tissue within the treatment site.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC agrees that quality implants may be categorized as MEs if 50 percent or more of the treatment site intentionally receives a dose that exceeds the prescribed dose by greater than 50 percent. The NRC understands that some treatment planning software may be unable to distinguish contiguous volumes of tissue. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

*Comment:* One commenter expressed concerns about the ME reporting criterion in § 35.3045(a)(2)(iv). The commenter stated that, using this criterion, it would be difficult for licensees to determine if an ME had occurred and nearly impossible for regulators to independently determine if a licensee is appropriately classifying and reporting MEs.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC understands that it may be difficult for licensees and regulators to determine if an ME occurred under this criterion. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

*Comment:* One commenter expressed concerns about the ME reporting criterion in § 35.3045 related to the normal tissue located within the treatment site. The commenter stated that the normal tissue within the treatment site for prostate implants is the urethra and it is necessary to place a catheter in the urethra to assess dose to this tissue. The commenter noted that licensees may not routinely catheterize the patient during post-implantation imaging; therefore, they do not have the imaging information necessary to assess urethral dose. The commenter further stated that pre-implantation images performed on catheterized patients show that the urethral volume is typically 1 cubic centimeter or less. The commenter concluded that an ME would never be found for normal urethral tissue for a prostate implant because there is not 5 cubic centimeters of contiguous urethral tissue within the treatment site.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue within the treatment site. The NRC understands that licensees may not routinely acquire the imaging information necessary to assess post-implantation urethral dose. The NRC also understands that the urethral volume within the treatment site is typically considerably less than 5 cubic centimeters, and as a result it is unlikely that an ME would occur using the proposed criterion.

*Comment:* One commenter stated that using absorbed dose-based criteria may limit the licensee's ability to determine if an ME has occurred when evaluating dose to normal structures located within the treatment site that are even more difficult to contour than the prostate. The commenter suggested removing the use of absorbed dose-based criterion for normal tissue within the treatment site.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC agrees with the commenter's suggestion and in response to this concern and those raised by other commenters, the NRC removed the use of absorbed dose-based criteria for reporting MEs in § 35.3045(a)(2)(iv).

*Comment:* One commenter expressed concern about the ME reporting criterion in § 35.3045(a)(2)(iv) related to the absorbed dose to normal tissue located within the treatment site. The commenter stated that ''precise control of source location inside the treatment site over several half-lives is impossible (and not necessary), so absorbed dose to intra-target structures is impossible to control.'' The commenter believes this is a medical decision, not a suitable ME criterion. The commenter stated ''[m]edicine has to operate in a risk-benefit balance when it comes to normal tissues, so the NRC has no role here.''

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC acknowledges the commenter's concern that absorbed dose to intra-target structures is impossible to control and is a medical decision. In response to this concern and those raised by other commenters, the NRC removed the dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

*Comment:* One commenter stated that ''[i]dentification of normal tissue in the treatment volume (urethra) [during a prostate implant procedure] is difficult if not impossible with a CT scan.'' The commenter also stated that the radiation dose is variable across the treatment site and therefore the ''determination'' of the dose to the normal tissue within the treatment site is ''ambiguous.'' The commenter further stated that ''[t]he only way to clearly define the urethra during the post Dosimetry CT scan would be to catheterize the patient, which would cause significant pain to the patient, and therefore is not performed.''

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC acknowledges the commenter's concerns related to difficulties associated with imaging the urethra and estimating the dose to it. In

response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

*Comment:* One commenter expressed difficulty in understanding how clinics that use a nomogram-based approach to ''pre-planning,'' where there is no pre-implant dose distribution, would evaluate the ME definition for ''intra-target normal structures'' in § 35.3045(a)(2)(iv).

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC understands the commenter's concern that clinics that use a nomogram-based approach to ''pre-planning,'' where there is no pre-implant dose distribution, may have difficulty in evaluating the dose to normal tissue within the treatment site under the proposed ME definition. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Issue: The Medical Event Reporting Criterion in § 35.3045 Related to the Absorbed Dose to Normal Tissues Located Outside the Treatment Site

*Comment:* One commenter expressed concerns about the ME reporting criterion in § 35.3045(a)(2)(iii) related to the absorbed dose to normal tissue located outside the treatment site. The commenter stated that their treatment planning software does not have an automated method for determining the volume of normal tissue that exceeds the prescribed dose by 50 percent. They stated that a manual method for making such a determination would lead to different results depending on who contours the normal tissue volume being assessed. The commenter also noted that the definition of ''contiguous normal tissue'' is not clear.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii), which would have required the assessment of the absorbed dose to normal tissue outside the treatment site. The NRC acknowledges the commenter's concern that some treatment planning software may is not capable of automatically determining the volume of normal tissue that exceeds the prescribed dose by 50 percent. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii).

*Comment:* Two commenters expressed concerns about the requirement to evaluate and determine the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue ''around'' the treatment site. The commenters further stated that these proposed ME reporting criteria are not consistent with current medical practice and may discourage licensees from performing permanent brachytherapy, which would deny patients access to this technology.

*Response:* The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue outside and within the treatment site. The NRC acknowledges the commenters' concern that the proposed rule text is not consistent with current medical practice and may discourage some licensees from performing permanent brachytherapy. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

*Comment:* Two commenters expressed concerns about the use of absorbed dose to 5 contiguous cubic centimeters as a criterion for reporting MEs. The commenters noted that the absorbed dose to 5 contiguous cubic centimeters was proposed as a guideline for treating cancer of the cervix in a single journal article published 10 years ago. The commenters also pointed out that these guidelines were proposed ''for research purposes,'' reflected the personal opinions of the authors, and were not endorsed or adopted by any of the radiation oncology professional organizations. The commenters requested that the NRC provide further justification for establishing a 5 contiguous cubic centimeters regulatory standard.

*Response:* The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue outside and within the treatment site. The NRC included these requirements in the proposed rule based on a recommendation from the ACMUI. However, based on these and other comments, the NRC concluded that absorbed dose to 5 contiguous cubic centimeters is not a suitable criterion for reporting MEs. Therefore, the NRC removed subparagraphs (iii) and (iv), which would have required licensees to use absorbed dose criteria to report MEs for permanent brachytherapy.

*Comment:* One commenter stated that the volume for determining an absorbed dose to normal tissue for compliance with the reporting requirements in § 35.3045 is not clearly defined. The commenter noted that it appears reasonable in theory to determine absorbed dose to the maximally exposed 5 contiguous centimeters of normal tissue. However, the commenter believes that it will be difficult to make this determination using current technology. The commenter stated that ''planning systems typically report dose volume histograms to structures, but they do not identify contiguous volumes.''

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissue outside and within the treatment site. The NRC acknowledges that while some treatment planning systems can identify contiguous volumes, others cannot. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

*Comment:* One commenter stated that the requirement in § 35.3045(a)(2)(iii) (absorbed dose to the maximally exposed 5 contiguous centimeters of normal tissue located outside of the treatment site) will be difficult to implement. The commenter stated that treatment planning systems report dose-volume histograms to structures but do not identify contiguous volumes. The commenter also stated that the term ''treatment site'' is not well defined. The commenter used the prostate as an example and pointed out that some licensees identify the prostate as the treatment site and develop the treatment plan with a particular margin of normal tissue around it, while others include a PTV (planning treatment volume) around the prostate and plan for that volume. The commenter explained that seeds may be placed in interstitial tissue outside the prostate to ensure adequate dose is delivered to the prostate. The commenter expressed concern that ''[i]f the normal tissue involved interstitial tissue, it would not cause a medically significant event to the patient.''

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii), which would have required the assessment of the absorbed

dose to normal tissue outside the treatment site. The NRC acknowledges the commenter's concern that some treatment planning software may be unable to automatically determine the volume of normal tissue that exceeds the prescribed dose by 50 percent. The NRC also acknowledges that AUs describe ''treatment site'' in different ways. The NRC expects the AU to describe the treatment site (as defined in § 35.2) in the WD in any way he or she believes to be medically appropriate. In response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii).

Issue: Source-Strength-Based Criteria as the Metric for Permanent Brachytherapy Versus Absorbed Dose-Based Criteria

*Comment:* Two commenters stated that the use of source-strength based criteria as the metric for permanent brachytherapy is directly proportional to the absorbed dose, and consistent with nuclear medicine administrations of radiopharmaceutical therapy whose purpose is to achieve a prescribed tumor dose. The commenters also pointed out that dose is not factored into the ME definition for radiopharmaceuticals, and has been an auditable measure by inspectors since the definition of ''misadministration'' that was created decades ago.

*Response:* The rule text was modified based on this and other comments. While the NRC agrees that source strength is a major factor impacting absorbed dose for permanent brachytherapy, the absorbed dose is determined by a combination of source strength and spatial positioning. Despite this fact, in response to this comment and different concerns raised by other commenters, the NRC determined that a source-strength based criterion is appropriate to define MEs for permanent implant brachytherapy and removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Issue: Require Licensees To Establish Certain Documented Criteria for a Medically Acceptable Implant Instead of the Absorbed Dose to Normal Tissues

*Comment:* Two commenters suggested the modification of § 35.3045(a)(2) to remove both criteria for absorbed dose to 5 contiguous centimeters of tissue and require instead that licensees establish documented criteria such as D90 or V100 that provide for a medically acceptable permanent implant.

*Response:* The rule text was modified based on other comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue outside and within the treatment site. The NRC agrees with removing the proposed absorbed dose-based criteria for reporting MEs for normal tissue. However, the NRC is not changing the rule text to require licensees to establish documented dose-based criteria such as D90 or V100 that would provide for a medically acceptable implant, as suggested by the commenter. The term ''D90'' is the dose reported in Gray or as a percentage of the prescribed dose that covers 90 percent of the target volume. The term ''V100'' is the fractional volume of the target usually reported as a percentage that receives 100 percent of the prescribed dose. The effect of making the commenter's proposed change would be a requirement to report as an ME under § 35.3045(a)(2) any permanent implant that is not deemed medically acceptable. The NRC believes that such a requirement could risk interfering with the practice of medicine. The NRC determined, for reasons explained in response to other comments, that the dose-based criteria should be removed and not replaced.

Issue: Sealed Source(s) Directly Delivered to the Wrong Treatment Site

*Comment:* Several commenters expressed concern with the proposed rule text in § 35.3045(a)(2)(v)(C), which requires reporting sealed source(s) directly delivered to the wrong treatment site as an ME. Two commenters specifically pointed out that § 35.3045(a)(2)(v)(*C*) is in direct conflict with § 35.3045(a)(2)(ii), which allows for 20 percent of the implanted source activity to be outside of the intended treatment site. Further, the commenters pointed out that, as proposed, this section would require that even a single sealed source directly delivered to the wrong treatment site be reported as an ME. Several commenters pointed out that when performing a normal implant procedure, sources can occasionally be deposited outside the treatment site due to various factors such as uncertainties in intraoperative imaging, patient motion, suction of seeds due to needle withdrawal, or seed migration. For example, one commenter stated that because in a prostate implant 90 to 100 seeds are routinely implanted, ''[a] seed could end up in tissue surrounding the prostate, in the bladder, or in the rectum. The overall impact would be numerous MEs of no clinical significance reported.'' Other commenters stated that source(s) implanted directly into the wrong site or body part, *e.g.,* if the right breast was implanted when the left breast was intended to be implanted, should constitute a reportable ME. One commenter suggested that the NRC establish a reasonable de minimis threshold. Several commenters suggested revising § 35.3045(a)(2)(v)(C) to require that ''sealed source(s) directly delivered to a ''non-contiguous'' wrong treatment site'' be reported as MEs.

*Response:* The rule text was modified based on these comments and a recommendation from the ACMUI. The NRC agrees that typical permanent implant procedures result in some sources being implanted outside the treatment site as described in the WD. In accordance with § 35.3045(a)(2)(ii), an ME has not occurred when less than 20 percent of the sources are implanted outside the treatment site. The NRC also agrees that § 35.3045(a)(2)(v)(*C*), as proposed [now § 35.3045(a)(2)(iii)(*C*)], appears to be in conflict with the provisions of § 35.3045(a)(2)(ii). To ensure that the provisions of § 35.3045(a)(2)(iii)(*C*) can be distinguished from those in § 35.3045(a)(2)(ii), the NRC has changed § 35.3045(a)(2)(iii)(*C)* to read: ''Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the WD.''

Issue: Sources That Were Implanted in the Correct Site but Migrated Outside the Treatment Site

*Comment:* Several commenters noted that § 35.3045(a)(3) currently includes the phrase, ''excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site'' but that this provision was not included in the proposed rule. They said that removal of this provision ''will cause numerous spurious reported MEs which will be unnecessarily burdensome and time consuming to the NRC and the licensee without increasing patient safety.'' One commenter stated that migration of seeds from a prostate treatment site is a potential clinical occurrence. The commenters asked the NRC to restore the provision for migrated seeds.

One commenter expressed concern that failure to include an exclusion for migrated sources would require reporting as ME permanent implant brachytherapy procedures in which the sources were placed correctly then migrated. The commenter suggested that ''. . . images taken 15, or 30, or 60 days after an implant cannot unambiguously

determine the placement of sources at the time of implant. Only placement meeting Medical Event criteria in § 35.3045(a)(2) at time of implant should constitute a Medical Event.'' The commenter also stated that some licensees do not offer permanent brachytherapy because of a concern that MEs could occur due to circumstances beyond their control, and the damage that can result from the publicity surrounding an ME.

One commenter noted that in the 2002 revisions to 10 CFR part 35, the term ''recordable event'' was eliminated and the term ''misadministration'' was changed to ''medical event.'' The commenter stated that the definition (of an ME) did not change. The definition compares the treatment administered to what the AU intended to administer. The commenter expressed concern that, as proposed, a treatment could be identified as an ME if the seeds moved after they were implanted correctly. The commenter stated that the proposed rule as written may inhibit a physician from helping a patient if migration of seeds is not taken into account in defining an ME for permanent implant brachytherapy implants.

*Response:* The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to restore the provision for sources that were implanted in the correct site but migrated outside the treatment site. The NRC agrees that migration of sources that were implanted in the correct site should not be considered an ME.

*Comment:* One commenter expressed concern about the phrase ''outside of the treatment site'' at § 35.3045(a)(2)(ii). This is the proposed criterion to define as an ME a permanent implant brachytherapy administration that results in the total source strength administered outside of the treatment site exceeding 20 percent of the source strength documented in the post-administration WD. The commenter noted that, for permanent prostate implants, most of the seeds are purposely implanted in and around the periphery of the gland and many can drift. The commenter stated that 20 percent of the sources may drift, even when linked together, and asked if the NRC has established a cutoff distance for drift. The commenter also expressed concern about the statement that if even one source is apparently ''directly implanted . . . into another (distant from the treatment site) location,'' it is an ME, and noted that it may be difficult to distinguish a seed that drifted a long distance from one that was directly implanted into a location distant from the treatment site. The commenter believes that these questions will force AUs to define a treatment site ''with huge margins for seed drift.''

The commenter also asked what rule would apply if all seeds are in the treatment site, but ''badly distributed around the periphery.'' The commenter stated that this could result in a ''bad cold spot'' in the treatment site dose distribution and noted that many permanent prostate implants ''show this tendency naturally 30 days after implant.''

The commenter stated that these issues pertain to the practice of medicine and should not be regulated by the NRC.

*Response:* No change was made to the rule text based on this comment. The NRC has not established a cutoff distance for ''drift'' or source migration. The AU defines the treatment site in the WD in any way he or she believes to be medically appropriate, including any margins. The NRC agrees that migration of sources that were implanted into the correct site should not be considered an ME. In response to other comments, the rule text at § 35.3045(a)(2) was changed to restore the exclusion to ME reporting requirements for sources that were implanted in the correct site but migrated outside the treatment site. In response to other comments, the rule text at § 35.3045(a)(2)(v)(C) [now § 35.3045(a)(2)(iii)(C)] was also changed to replace the phrase ''[s]ealed source(s) directly delivered into the wrong treatment site'' with ''[s]ealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive.''

The NRC agrees that the dose distribution within the treatment site is not a suitable ME criterion because it can vary over time and is not fully under the control of the AU. In response to other comments, the NRC revised the permanent implant brachytherapy ME criteria at § 35.3045(a)(2) to be based only on total source strength, not dose. As a result, no ME has occurred if at least 80 percent of the sources are in the treatment site, regardless of the distribution of the sources or the existence of a ''cold spot'' in the dose distribution. The NRC agrees, and it is the NRC policy, that the NRC should not (and does not) regulate the practice of medicine.

Issue: Medical Event Definition Should Allow an Exception for Causes Outside of the Physician's Control

*Comment:* One commenter suggested that the ME definition should allow exceptions for patient-related and procedure-related causes (other than seed migration) that are outside of the physician's control. The commenter noted that the exception for MEs resulting from patient intervention does not address procedure-related causes that are outside of the physician's control. The commenter recommended that § 35.3045(a)(2) be revised to read: ''For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (not resulting from patient-related or procedure-related causes—such as edema, source migration after placement or imaging uncertainties) that results in . . .'' The commenter expressed concern that, without an exception for patient-related and procedure-related causes, ''many medically acceptable procedures will be labeled as MEs, contrary to our understanding of the NRC's intent.''

*Response:* No change was made to the rule text based on this comment. The NRC did not modify the rule to include exceptions for patient-related and procedure-related causes (other than seed migration) that are outside of the physician's control. Factors outside of the physician's control, such as edema and imaging uncertainties, should have limited impact under the source-strength based ME reporting criteria in § 35.3045(a)(2)(ii).

Issue: Error in Calculating the Total Source Strength

*Comment:* One commenter stated that it is not clear why the ME criterion in § 35.3045(a)(2)(v)(E), *i.e.,* ''[a] 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive,'' was proposed. The commenter believes that this criterion was based on an ''ACMUI proposal of using the wrong activity or source strength (+ / − 20 percent) as specified in the written directive,'' and noted that the ACMUI did not specify whether this is ''wrong'' as compared to the pre-implantation or post-implantation portion of the WD. The commenter stated that the requirement in § 35.3045(a)(2)(v)(E) appears to be a duplication of the intent of § 35.3045(a)(2)(i) and recommended deleting § 35.3045(a)(2)(v)(E).

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2)(v) was revised to delete the ME criterion described in § 35.3045(a)(2)(v)(E), ''[a] 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive.'' However, the NRC determined that § 35.3045(a)(2)(v)(E) was not a duplication of

§ 35.3045(a)(2)(i), but agrees that the provision is not needed. As stated by the commenter, this criterion was originally recommended by the ACMUI. In July 2005, the ACMUI submitted to the NRC a set of guiding principles to assist the NRC staff in defining a rule to capture MEs from permanent implant brachytherapy procedures. One of the principles recommended a limited dose-based ME criterion: ''[a]n implant is a medical event if the dose calculations used to determine the total source strength documented in the written directive are in error by more than 20 percent in either direction.'' The ACMUI explained that this ''limited'' ME dose pathway would ''focus only on preplanning or intraoperative planning, not post-implant evaluation.'' Because the revised ME criteria are based on post-implant evaluations, the NRC agrees that the criterion at § 35.3045(a)(2)(v)(E) is not needed.

*Comment:* One commenter stated that the criterion in § 35.3045(a)(2)(i) is consistent with clinically relevant circumstances. The commenter expressed concern that this is exactly the same as the requirement in § 35.3045(a)(2)(v)(E). The commenter noted that the rationale is unclear for comparing against the post-implantation source strength in § 35.3045(a)(2)(i) and comparing against the pre-implantation source strength in § 35.3045(a)(2)(v)(E). The commenter also stated that current practice is ''to assay a portion of the seeds to ensure the total source strength is as ordered, which would prevent both of these medical events from occurring.''

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2)(v) was revised to delete the ME criterion in § 35.3045(a)(2)(v)(E) of the proposed rule: ''[a] 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive.'' Although these criteria are not exactly the same, the NRC agrees with the commenter that the criterion at § 35.3045(a)(2)(v)(E) is not needed because such situations will almost always be captured by the criteria at § 35.3045(a)(2)(i) and (a)(2)(ii). In the rare situation where a calculation error would not be captured by the criteria at (a)(2)(i) or (a)(2)(ii)—for example, because the calculation error was later corrected—then the NRC would not deem it appropriate to report the calculation error itself as an ME.

The NRC considered the commenter's statement that these types of MEs would be prevented by assaying a portion of the seeds to ensure the total source strength is as ordered and concluded that this may not be fully correct. For example, it is possible for an ME to occur if there was an error of 20 percent or more in the total source strength ordered and administered.

Issue: Comparison of Source Strength Specified in the Pre-Implantation Written Directive

*Comment:* Several commenters stated that ME reporting for permanent implant brachytherapy must be based on the source strength in the post-administration WD as described in § 35.40(b)(6)(ii). Some of the commenters stated that the proposed changes to § 35.3045 wrongly specified the pre-implantation WD.

*Response:* No changes were made in response to these comments. The source strength comparisons for the ME reporting criteria in § 35.3045(a)(2)(i) and (ii) are with the source strength specified in the post-implantation WD. Although § 35.3045(a)(2)(iii) of the proposed rule included an absorbed dose comparison with information in the pre-implantation WD, the NRC removed this criterion in response to other comments. Also, § 35.3045(a)(2)(v)(E) of the proposed rule included a calculated total source strength with the pre-implantation WD, but NRC removed this criterion in response to different comments. As a result, § 35.3045(a)(2) no longer requires any comparisons with the pre-implantation WD.

Issue: Support Source Strength-Only Approach for Medical Event Criteria for Permanent Implants

*Comment:* One commenter supported the shift to use total source strength administered (activity-based) ME criteria for permanent implants rather than dose delivered (dose-based) criteria for permanent brachytherapy implants.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter expressed several concerns related to the proposed dose-based portion of the criteria for permanent implant brachytherapy ME reporting. The commenter recommended that any ME reporting for permanent implant brachytherapy be based solely on a source-strength based definition for the WD as recommended originally by the ACMUI and the radiological societies rather than the proposed hybrid definition based on source strength and absorbed dose. The commenter's concerns included: (1) That the WD has no absorbed dose specification; (2) that regulatory inspectors do not possess the expertise to assess permanent seed implants and determine if any 5 contiguous cubic centimeters have exceeded an expected absorbed dose by 50 percent; (3) that different licensees use different absorbed dose metrics to determine a successful implant; (4) that the dose to 5 contiguous cubic centimeters introduced by the NRC is arbitrary and not based on any clinical data; and (5) that the ACMUI in 2008 recommended a source strength ME definition for permanent implants and explicitly stated it should not include absorbed dose criteria.

*Response:* The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissue outside and within the treatment site. The rule text, as proposed in § 35.40(b)(6)(i), contains a requirement to include the intended absorbed dose to the treatment site. However, in response to other comments, the NRC has decided to remove this requirement from the final rule. The commenter is correct that in 2008 the ACMUI recommended source-strength based criteria. However, in 2012, the ACMUI recommended the proposed ''hybrid'' criteria for reporting MEs for permanent implants, and that recommendation was endorsed by the American Association for Radiation Oncology. The NRC understands the commenter's concerns that regulatory personnel may have difficulty assessing permanent implants under the proposed rule, and that different licensees may use different criteria for determining a successful implant. The NRC agrees that the proposed absorbed dose-based criteria are not based upon clinical data. In response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

*Comment:* Two commenters stated that in 2008, the ACMUI recommended source strength ME definition for permanent implants. The commenters stated that nevertheless, the NRC staff added an absorbed dose-based criterion to the definition, and the Commission rejected it. The NRC held national stakeholder workshops in 2011 on this issue and the overwhelming consensus at each workshop attended by professional organizations and radiological professionals was to have source-strength ME reporting criteria rather than absorbed dose-based criteria. The commenters also pointed out that the ACMUI presentations at these workshops stated that source strength criteria were preferable. The commenters recommended that the NRC

provide a more comprehensive regulatory basis for deviating from these recommendations. One of the commenters stated that the NRC needs to base the ME definition on source strength rather than the proposed hybrid definition based on source strength and absorbed dose, by removing § 35.41(b)(6)(iii) and (iv) and amending § 35.3045(a)(2).

*Response:* The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissue outside and within the treatment site. A corresponding change was made to the rule text in § 35.41(b)(6) to remove § 35.41(b)(6)(iii) and (iv). The NRC agrees with the commenters' stated timeline of events regarding ME reporting criteria recommendations. However, in 2012, the ACMUI recommended the proposed ''hybrid'' criteria for reporting MEs for permanent implants, and that recommendation was endorsed by the American Association for Radiation Oncology. This recommendation was one of the key components of the NRC's regulatory basis for the proposed rule. In response to other comments, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv) and the requirements in § 35.41(b)(6)(iii) and (iv) for determination of absorbed dose to normal tissue outside and within the treatment site.

Issue: Alternate Recommendations for ME Definitions for Permanent Implants

*Comment:* One commenter suggested that the NRC require licensees to establish a ''peer review'' process in conjunction with the requirements that licensees establish procedures that provide ''high confidence'' that the WD is fulfilled. The commenter stated that MEs should be rare mistakes because the procedures are required to be performed by physicians that have the required T&E. The commenter also stated that the NRC should not try to regulate the ''medicine side'' and that the NRC's determination of '' 'actual or potential harm to a patient' and review of normal tissue doses are not needed.''

*Response:* No change was made to the rule text based on this comment. The NRC agrees that the NRC should not regulate the practice of medicine. In accordance with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654), the NRC does not intrude into medical decisionmaking except as necessary to provide for the safety of workers and the general public and to ensure that radionuclides are used in accordance with the physician's directions. The NRC disagrees that it should require licensees to establish a peer review process for assessing MEs. The licensee makes the determination of the actual or potential harm to patients that might result from an ME. However, the NRC's position is that an ME may be indicative of a potential problem in a medical facility's use of radioactive materials even if it does not actually result in harm to the patient.

In response to the portion of this comment concerning dose to normal tissue and other comments, the NRC removed the absorbed dose-based ME reporting criteria for normal tissue in § 35.3045(a)(2)(iii) and (iv).

*Comment:* One commenter suggested that the reporting criteria for permanent implants should be the ''dose coverage to the intended target,'' which is a much more meaningful indicator of the quality of an implant. The commenter suggested the use of ''D90'' and provided the D90 definition from the AAPM Task Group 137: ''the minimum dose to the hottest 90 percent of the target volume.''

*Response:* No change was made to the rule text based on this comment. This is one of the few comments NRC received that supported dose-based ME reporting criteria for the treatment site. The NRC understands that ''D90'' is one of the absorbed dose-based parameters that is an accepted professional practice for assessing the clinical quality of an implant. However, the NRC also understands that ''D90'' is not the only dose-based parameter that is accepted and used. The NRC also received numerous other comments that identified technical limitations associated with the use of dose-based ME reporting criteria for permanent implant brachytherapy. Therefore, the NRC revised the permanent implant brachytherapy ME reporting criteria in § 35.3045(a)(2) to be based only on total source strength, not dose.

*Comment:* One commenter suggested that the reporting criteria for permanent implants should be based upon the dose to the organs at risk. The commenter provided the examples of the bladder and the rectum as organs at risk when treating the prostate with permanent implants. The commenter stated that this approach would hold the brachytherapist (AU) accountable for protecting the organs at risk but not penalize the AU for intentionally implanting sources in normal tissue for treatment purposes. The commenter also stated that ''[a]nother benefit of both of these suggestions is that current brachytherapy software offers a method of evaluating the dose coverage to the target and organs at risk.''

*Response:* No change was made to the rule text based on this comment. This is one of the few comments NRC received that supported the dose-based ME reporting criteria. The NRC received other comments that identified technical limitations associated with the use of a dose-based ME reporting criteria for dose to normal tissue from permanent implant brachytherapy. The NRC eliminated the dose-based criteria in § 35.3045(a)(2)(iii) and (iv) for normal tissue for reporting MEs. Therefore, the dose to the organs at risk does not need to be determined for ME reporting purposes.

Issue: Concerns Regarding Regulators' Training and Ability To Inspect and Assess Permanent Implants Under the Proposed Criteria

*Comment:* Several commenters expressed concerns about the ability of regulators to assess licensees' implementation of the proposed ME reporting criteria in § 35.3045(a)(2)(iii) and (iv). One commenter asked if inspectors are capable of evaluating the methods used by the licensee to determine the 5 contiguous cubic centimeter volume of normal tissue and related dosimetry. Another commenter stated that the proposed change will require substantial retraining of regulatory personnel to make determinations based on the new criteria. The commenter stated ''[t]his is unduly burdensome and serves no real value since doses may be clinically off by 200 percent and still be viable for treatment.'' Two other commenters stated that most regulatory personnel do not have the tools or expertise to assess a permanent implant and determine if any 5 contiguous cubic centimeters have exceeded an expected absorbed dose by 50 percent. The commenters also expressed concern that the NRC has proposed a dose metric that is not an established standard of clinical practice and appears to infringe on the practice of medicine.

*Response:* The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissues outside and within the treatment site. The NRC understands the commenters' concerns that regulatory personnel may have difficulty assessing permanent implants under the proposed rule and that the NRC proposed a 5 contiguous cubic centimeter volume dose metric that is not an established standard of clinical practice. In response

to these concerns and different concerns raised by other commenters, the NRC removed the absorbed dose-based ME reporting criteria in § 35.3045(a)(2)(iii) and (iv).

Issue: Applicability of the Proposed Criteria to Y–90 Microspheres

*Comment:* Several commenters questioned whether the new permanent implant brachytherapy requirements at § 35.3045 apply to the use of Y–90 microspheres under § 35.1000. One commenter stated that these new requirements cause confusion when read in conjunction with the NRC licensing guidance for Y–90 microspheres, which describes them as ''manual brachytherapy sources used for permanent implantation therapy.'' The commenters suggested that the rule language be clarified to include a definition of the types of sources to which the permanent implant brachytherapy requirements apply so that it is clear whether they apply to Y–90 microspheres.

*Response:* No change was made to the rule text. The term ''permanent implant brachytherapy'' is used to refer to manual brachytherapy procedures performed in accordance with § 35.400. The NRC considers Y–90 microspheres to be manual brachytherapy sources; however, they have unique properties that prevent them from being regulated under all the provisions of § 35.400 and are regulated under § 35.1000. Consequently, the ME reporting requirements for permanent implant brachytherapy do not apply to the use of Y–90 microspheres.

Issue: Defining the Treatment Site in the Written Directive

*Comment:* The commenter expressed concern that under the proposed rule in § 35.3045(a)(2)(ii), a high quality implant with excellent dose statistics, where many seeds are implanted outside the Planning Target Volume (PTV) to ensure adequate dose coverage, would be viewed as an ME. The commenter stated that its prostate implant program allows for the implantation of I–125 seeds into normal tissues surrounding the prostate so that the prescribed dose covers a treatment margin (PTV) in addition to the prostate, in order to treat extra-capsular extension of prostate cancer. The commenter provided recommendations from the American Association of Physicists in Medicine Task Group Report 137 and the American Brachytherapy Society Prostate Low-Dose Rate Task Group Report on treating a margin of tissue outside of the prostate. The commenter also expressed concern with the criterion in § 35.3045(a)(2)(ii) because its vendor's software does not currently have a satisfactory method of determining whether 20 percent of the source strength is outside of the treatment site.

*Response:* No change was made to the rule text based on this comment. The NRC understands that AUs may intentionally implant sources into surrounding normal tissues. The AU defines the treatment site in the WD in any way he or she believes to be medically appropriate, including any margin or PTV structure. The NRC acknowledges that treatment planning software may not have an automated method to determine whether 20 percent of the source strength is outside of the treatment site. It may be necessary for licensees to perform a manual determination of the number of sources outside the treatment site in comparison with the number of sources within the treatment site.

*Comment:* One commenter stated that the requirement at § 35.3045(a)(2)(ii) would have positive impact if the definition of treatment site is clarified to include implantation of seeds in interstitial tissue, and not critical structures. The commenter believes that this criterion is consistent with clinically relevant circumstances when several seeds are accidentally placed in critical organs to the extent that they could cause a medically significant event to the patient.

*Response:* No change was made to the rule text based on this comment. The NRC determined that revising the definition of the treatment site to include implantation of sources in interstitial tissue, and not critical structures, is not warranted. The AU defines the treatment site in the way he or she believes to be medically appropriate, which in some cases may include intentional implantation of sources in critical structures. The NRC has determined that the criterion in § 35.3045(a)(2)(ii) appropriately captures those instances where medically significant events may occur. The NRC is not aware of cases where medically significant events have occurred while 20 percent or less of the source strength was implanted outside the treatment site.

*Comment:* One commenter stated that compliance with the requirements in § 35.3045 is dependent on how the tumor volume is defined by the physician. The commenter explained that if one AU defines the treatment site with ''tight borders'' the licensee may need to report an ME. However, if another AU defines the treatment site more ''loosely,'' an ME may not have to be reported.

*Response:* No change was made to the rule text based on this comment. The AU defines the treatment site in the WD in the way he or she believes to be medically appropriate, including any margin. The AU may define the treatment site to include all tissues into which sources have been purposely implanted. The NRC has determined that the definition of the treatment site is a matter of medical judgment.

*Comment:* One commenter stated that the identification of the ''treatment site'' is not well defined. The commenter stated that some facilities identify the treatment site as the prostate gland only and plan a dose margin around the prostate, while other facilities include a planning target volume (PTV) structure around the prostate as the treatment site and target coverage to that structure.

*Response:* No change was made to the rule text based on this comment. The AU defines the treatment site in the WD in the way he or she believes to be medically appropriate, including any margin or PTV structure.

Issue: The Complexity of the Medical Event Reporting Requirements as Currently Proposed May Create Confusion

*Comment:* One commenter stated that the proposed ME reporting requirements are complex and may create confusion for regulators and the regulated community when applied to permanent prostate implant procedures.

*Response:* The rule text was modified based on other comments. The NRC acknowledges the commenter's concern regarding the complexity of the ME reporting requirements. The NRC received several comments raising concerns about specific portions of the proposed rule and changes were made in response to these comments. One of the major changes was to remove the requirements in § 35.3045(a)(2) related to absorbed dose to normal tissue. The NRC believes that these changes have reduced the complexity of the ME reporting requirements.

Issue: NRC Should Create a New Section in 10 CFR Part 35 for Permanent Implant Brachytherapy Regulations Only

*Comment:* One commenter recommended that the NRC create a new section in 10 CFR part 35 for permanent brachytherapy implants only. This new section should include the procedural requirements included in § 35.41(b)(6) and ME reporting criteria specific to permanent brachytherapy implants included in § 35.3045 of the

proposed rule. The commenter stated that, if the NRC decides to create this new separate section, then the ME requirements for permanent brachytherapy implants should be separated and handled in a rulemaking separate from the remainder of the proposed amendments, to allow the NRC to finalize all other proposed amendments without delay.

*Response:* No change was made to the placement of regulations related to permanent implant brachytherapy. The requirements for procedures requiring a WD, and the requirements for ME reporting appear in two different subparts of part 35—Subpart B—General Administrative requirements, and Subpart M—Reports. To separate the permanent implant brachytherapy requirements from these subparts and put them in a separate section would disrupt the logical flow of 10 CFR part 35.

Issue: The Compatibility Designation for Medical Event Reporting Under § 35.3045

*Comment:* One commenter stated that the WD requirements under § 35.40(b)(6) and the procedures for permanent implant brachytherapy required under § 35.41(b)(6) should be deemed Compatibility Category B (rather than Compatibility Category C) such that the rules are uniform from one state to another to minimize confusion. The commenter stated that because over 90 percent of medical licensees are under Agreement State authority, anything less than Compatibility Category B makes these changes ''an over-regulation of the minority.''

*Response:* The WD requirements under § 35.40(b)(6) and the procedures for permanent implant brachytherapy required under § 35.41(b)(6) are designated as Compatibility Category Health and Safety (H&S). This designation was not changed in the proposed rule. The H&S category contains program elements that are not required for compatibility, but are identified as having a particular health and safety role (*i.e.,* adequacy) in the regulation of agreement material within the State. The commenter appears to be referring to the compatibility designation of ME reporting under § 35.3045, which is designated as Compatibility Category C and which the final rule continues to designate as Compatibility Category C.

*Comment:* One commenter stated that if the NRC were to revert to a lower-than-proposed compatibility category (*i.e.,* Compatibility Category C instead of B), then they recommend, as a last resort, that the NRC explicitly state in the preamble of the final rule that activity-based ME metrics are an essential program element, and that dose-based metrics are unacceptable for use. The commenter stated that the absorbed dose-based ME metrics are not ''more restrictive'' per se, but are unsuitable and confusing when misapplied to the specific procedures in question.

*Response:* The NRC has discussed the program element contained in § 35.3045 and the essential objective of this program element in Part I, item 4 of this section based on this comment. The program element contained in § 35.3045 is ME reporting, not activity-based ME metrics. The essential objective of this program element is to maintain a consistent national ME reporting program. In the final rule, the ME criteria for permanent brachytherapy is activity-based and not dose-based. Dose-based ME reporting criteria for permanent implant brachytherapy would conflict with the essential objective of maintaining a consistent national reporting program because it would result in insignificant events being reported as MEs. As explained in Part I, item 4 of this section, consistency in the national reporting program allows the NRC to identify trends or patterns, identify generic issues or concerns, recognize inadequacies or unreliability of specific equipment or procedures, and determine why an event occurred and whether any actions are necessary to improve the effectiveness of NRC and Agreement State regulatory programs. Dose-based ME reporting criteria would result in inconsistent reporting of permanent implant brachytherapy MEs, and thus would disrupt these efforts.

*Comment:* One commenter stated that they support the Compatibility Category B designation for ME reporting, in agreement with the opinion of the ACMUI and for the reasons provided in the proposed rule. The commenter stated that, considering the details and clinical implications of the prostate implant procedures, it only makes sense to have activity-based criteria for an ME. The commenter believes that there is merit in consistent rules for subjects that have significant implications, such as the criteria for an ME, and standardization should remove uncertainty and confusion.

*Response:* The NRC agrees with the commenter that activity-based criteria are appropriate for MEs for permanent implant brachytherapy procedures, including the prostate implant procedures. As discussed earlier in this section, the NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045. The NRC determined that Compatibility Category B is not the appropriate designation because the ME reporting criteria, while important to the effective and orderly regulation of agreement material on a nationwide basis, do not have significant direct transboundary implications. The essential objective of § 35.3045 is to maintain a consistent national program for reporting MEs. Agreement State use of dose-based criteria for permanent implant brachytherapy ME reporting would be inconsistent with this essential objective because the NRC has determined that dose-based criteria would result in the reporting of insignificant events. Therefore, for national reporting, Agreement States' use of dose-based reporting criteria either instead of or in addition to activity-based reporting criteria for permanent implant brachytherapy would not be compatible with § 35.3045.

*Comment:* One commenter expressed support of the Compatibility Category B designation for § 35.3045 and noted that, as discussed by the NRC in the proposed rule, some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. The commenter stated that a Compatibility Category B designation would allow for uniformity of practice and procedures across the country. The commenter further suggested that to make the move from Compatibility Category C to B smooth, the NRC should define the ''essential objectives'' of § 35.3045 such that the Agreement States' adoption of the new definition is not met with unnecessary delays.

*Response:* The NRC has determined that Compatibility Category C is the appropriate category for § 35.3045, for the reasons explained in response to another comment and in Part I, item 4 of this section. The essential objective of § 35.3045 is to maintain a consistent national reporting program, as further explained in Part I, item 4 of this section.

*Comment:* One commenter, in support of the Compatibility Category B, stated that they recognize that the Agreement States oppose a change in Compatibility Category, citing state legislative requirements, the difficulty in changing state regulations, and the fact that Agreement States do not perceive a problem with the current dose-based definition. The commenter believes that these concerns are outweighed by the importance of having a consistent definition throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable procedures as MEs. The

commenter expressed concern that a Compatibility Category C designation would allow Agreement States to implement unnecessarily more restrictive definitions that classify medically acceptable procedures as MEs.

*Response:* The NRC understands the importance of having consistent ME reporting criteria throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable procedures as ME. This consistency is necessary to meet the essential objective of § 35.3045, which is to maintain a consistent national reporting program. The NRC disagrees that Compatibility Category B is the appropriate category for § 35.3045 and instead has determined that Compatibility Category C is the appropriate category. Therefore, Agreement States are required to adopt the essential objectives of this provision, but are not required to adopt essentially identical ME reporting criteria. The Agreement States have the flexibility to include, for example, a shorter reporting time in their ME reporting criteria, but the use of dose-based ME reporting criteria for permanent implant brachytherapy would create conflicts and inconsistencies with respect to the national reporting program, because it would capture insignificant events as MEs.

*Comment:* Two commenters in support of Compatibility Category B stated that because over 90 percent of medical licensees are under Agreement State authority, anything less than Compatibility Category B makes the proposed changes an ''over-regulation of the minority.'' The commenters stated that it would be counterproductive for Agreement States to maintain alternative ME criteria not listed in the revised § 35.3045. The commenters further stated that because certain healthcare systems may be providing services in both NRC and Agreement State jurisdictions, § 35.3045 should be designated as Compatibility Category B. One commenter said that they strongly support the proposed designation of Compatibility Category B for § 35.3045, thereby requiring Agreement States to adopt ME reporting and notification program elements essentially identical to NRC's. The commenter also stated that it would be counterproductive for Agreement States to maintain alternative ME criteria not listed in the revised § 35.3045. The commenter stated that if the dose-based ME reporting criteria were interpreted by the States as more ''restrictive,'' and States were to continue to have some manner of ill-fitting ME methodology, this would confuse the regulated community and continue to weaken confidence in the significance of reported permanent brachytherapy MEs.

*Response:* As explained in response to other comments, the NRC has determined that Compatibility Category C is the appropriate category for § 35.3045. Under Compatibility Category C, Agreement States will not be able to maintain alternative ME criteria not listed in the revised § 35.3045, if those criteria would create conflicts or inconsistencies in the national reporting program. The NRC understands the commenter's concern that alternative ME criteria could weaken the public's confidence in the significance of permanent implant brachytherapy MEs. Therefore, the NRC has identified dose-based criteria as an example of alternative ME reporting criteria that would capture insignificant events as MEs and create a conflict and inconsistency in the national reporting program.

*Comment:* Several commenters stated that their medical practices are affected by the compatibility category assigned to § 35.3045. They said that they are pleased with the Commission's decision to move § 35.3045 from Compatibility Category C to Compatibility Category B. The commenters stated that it is essential that § 35.3045 be defined and implemented in a consistent manner across the country. The commenters stated that, as the NRC noted in the proposed rule, some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. The commenters stated that there are many practices that extend beyond one particular jurisdiction, usually when the main center is near a state border. The commenters further stated that they expect this situation to increase significantly in the coming few years as the consolidation of healthcare institutions into larger entities continues to accelerate. Therefore, a Compatibility Category B designation would allow for uniformity of practice and procedures across the country.

*Response:* The NRC understands the commenters' concern that § 35.3045 be defined and implemented in a consistent manner across the country. As noted by the commenter, and as the NRC noted in the proposed rule, some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated.

The NRC disagrees that § 35.3045 should be designated as Compatibility Category B to ensure uniformity of practice and procedures across the country. The NRC designates regulatory program elements as Compatibility Category B if they have significant direct transboundary implications, not simply for the purpose of ensuring uniformity across the country with respect to a program element. The effect of a Compatibility Category B designation is essentially uniformity across the country with respect to a program element, because this designation requires Agreement States to adopt program elements that are ''essentially identical'' to that of the NRC. This uniformity is necessary because a program element has significant direct transboundary implications. As discussed in Part I, item 4 of this section, the NRC has determined that ME reporting does not rise to the level of having significant direct transboundary implications. Therefore, Compatibility Category B is inappropriate.

The NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045. Under Compatibility Category C designation, the essential objectives of the regulation should be adopted by the State to avoid conflicts, duplications or gaps. The essential objective of § 35.3045 is to maintain a consistent national ME reporting program. Agreement States should ensure that their ME reporting criteria do not conflict with or create inconsistency within this program.

*Comment:* One of the Agreement States stated that all MEs are local events and are not transboundary events, regardless of their significance. The commenter stated that even multiple events with a common root cause are considered local events and each licensee is required to submit an ME report to its licensing authority. The commenter also stated that all MEs are reported in the Nuclear Materials Event Database, so NRC is notified of all events that meet the NRC's ME criteria.

*Response:* The NRC acknowledges that, from the perspective of a single medical facility, MEs appear to be local events only. The NRC has determined that ME reporting does not rise to the level of having significant direct transboundary implications and; therefore, Compatibility Category B is inappropriate. However, to ensure that an Agreement State program meets the essential objective of § 35.3045 to maintain a consistent national ME reporting program, the Agreement States, for permanent implant brachytherapy treatments, should not use the dose-based criteria. For the reasons explained in response to other comments and in Part I, item 4 of this

section, the use of dose-based criteria would create conflicts and inconsistencies in the national ME reporting program.

*Comment:* Several commenters opposing the proposed category B designation for ME reporting questioned how a single medical incident at a single facility can have ''direct and significant effects in multiple jurisdictions.'' They further added that the Compatibility Category C designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who routinely work in multiple jurisdictions.

*Response:* The NRC agrees that the Compatibility Category C designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who work routinely in multiple jurisdictions. The NRC has determined that Compatibility Category C is also the appropriate designation for § 35.3045.

The NRC acknowledges that, from the perspective of a single medical facility, MEs appear to be local events only. The NRC agrees that ME reporting does not have direct and significant effects in multiple jurisdictions, and therefore agrees that Compatibility Category B is not the appropriate designation for § 35.3045. Therefore, the ME reporting criteria do not have to be essentially identical. However, the essential objective of § 35.3045 is to maintain a consistent national ME reporting program, and to adopt this essential objective Agreement States should adopt ME reporting criteria that do not create conflicts or inconsistencies in ME reporting. The ME reporting program ensures that the NRC and Agreement States are able to identify trends or patterns, identify generic issues or concerns, recognize inadequacies or unreliability of specific equipment or procedures, and determine why an event occurred and whether any actions are necessary to improve the effectiveness of NRC and Agreement State regulatory programs. Inconsistent or conflicting ME reporting criteria would frustrate these purposes.

*Comment:* Several commenters, in support of the Compatibility Category C designation for ME reporting under § 35.3045, stated that currently the only reporting regulations with a Compatibility Category B designation are related to the security requirements and are located in other parts of 10 CFR. The commenter also stated that all the reporting requirements found in 10 CFR part 35 are Compatibility Categories C, H&S, or D. Since § 35.3045 is a reporting requirement and does not relate to the security of Category 1 or Category 2 sources, the commenter recommended that the compatibility category for the reporting requirements in § 35.3045 remain as Compatibility Category C.

*Response:* It is true that currently the only reporting regulations with Compatibility Category B designation are related to the security requirements and are located in other parts of 10 CFR. However, that does not preclude the NRC from categorizing reporting requirements as Compatibility Category B. Compatibility category designations do not hinge on whether a regulatory requirement pertains to security or any other discrete regulatory issue. Rather, the NRC assigns the appropriate category for each regulatory requirement by considering and applying the criteria for Agreement State compatibility to each particular regulatory requirement. For the reasons stated in response to other comments and as discussed in Section V., Public Comment Analysis, the NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045.

*Comment:* One commenter, in support of the Compatibility Category C designation for ME reporting under § 35.3045, stated that throughout § 35.3045, the term ''treatment site'' is used, that it is specifically defined in § 35.2, and that this definition has been designated Compatibility Category C. The commenter stated that since the definition of ''treatment site'' is remaining a Compatibility Category C, it is possible for an Agreement State to adopt the essential objective of the definition but it may be a slightly different definition. If the definition for treatment site is slightly different in each jurisdiction, even if § 35.3045 is changed to a Compatibility Category B, the requirement may not be ''essentially identical'' in each jurisdiction.

*Response:* It is true that the ''treatment site'' is defined in § 35.2 and that this definition has been designated Compatibility Category C. While the NRC may assign a particular compatibility category to certain definitions, the regulations in which these terms are used are not confined to this same category. Instead, the NRC assigns the appropriate category for each regulatory requirement by considering and applying the criteria for Agreement State compatibility to each particular regulatory requirement.

*Comment:* One commenter recommended that, if the NRC insists on changing the Compatibility Category to B, then the rule language should be changed to only require the Compatibility Category B designation for permanent prostate implant procedures and no other permanent brachytherapy procedures. The commenter further stated that the main impetus for changing the compatibility category for ME reporting appears to be the multiple prostate implant MEs that occurred at the Department of Veterans Affairs facilities.

*Response:* When drafting the ME reporting requirements for permanent implant brachytherapy procedures at § 35.3045(a)(2), the NRC developed requirements that would apply to permanent implant procedures for all treatment sites, including prostate implants. Although prostate implants are more common than other implants, the NRC staff in SECY–12–0053 recommended that the revised ME criteria apply to permanent implant procedures for all treatment sites, not only the prostate. The NRC has determined that the prostate implant procedure does not warrant a separate set of regulations and that including them in the ME reporting requirements for permanent implant procedures for all treatment sites is sufficient to ensure that significant events involving prostate implants will be reported as MEs. As explained in response to other comments and in Part I, item 4 of this section, the NRC has determined that Compatibility Category C is appropriate for all of § 35.3045, including permanent implant brachytherapy procedures, such as prostate implants.

*Comment:* One Agreement State stated that the proposed activity-based ME reporting criteria should be added to the existing dose-based criteria, rather than replace it. The Agreement State stated that it would require licensees to apply both criteria, and only those MEs that meet the NRC's proposed activity-based criteria would be reported to the NRC. The commenter explained that this approach would provide the states with the needed flexibility to regulate both radioactive materials and machine-produced sources of radiation in a consistent manner. The commenter also stated that the ME reporting regulations should not be categorized as Compatibility Category B because that would restrict the State's ability to regulate the clinical aspects of the practice of medicine and patient management.

*Response:* The NRC has determined, as recommended by the medical community, that the activity-based criteria are more appropriate for permanent implant brachytherapy procedures than the dose-based criteria, because activity-based criteria specifically captures significant events for reporting as MEs whereas dose-based criteria would capture insignificant

events as well. The NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045. However, as explained in response to other comments and in Part I, item 4 of this section, the NRC has determined that Agreement State use of dose-based criteria for permanent implant brachytherapy ME reporting would result in inconsistencies and conflicts with the essential objective of § 35.3045, which is to maintain a consistent national ME reporting program.

Section 35.3204 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

*Comment:* Two commenters supported the proposed generator elution breakthrough reporting requirements.

*Response:* The comment supports language in the rule; therefore, no response is required.

*Comment:* One commenter noted that Tc-99m decays much faster than Mo-99; therefore, every Tc-99m generator eluate will eventually exceed the regulatory limit. Because of this, the commenter stated that the language in the proposed rule text would require every eluate to be reported. The commenter proposed revising the rule text in § 35.3204(a) to clarify that the licensee would only report measurements of a Tc-99m generator elution that exceeded the regulatory limits at the time of generator elution.

*Response:* The rule text was modified based on this comment. The NRC agrees with the commenter that the proposed rule text in § 35.3204(a) and (b) was not clear and has amended it to clarify that the reporting requirements only apply at the time of generator elution.

*Comment:* One commenter stated that the reporting and notification requirement for failed Mo-99/Tc-99m and Sr-82/Rb-82 generators was increased from Compatibility Category C to Compatibility Category B. The commenter supports adding specific reporting criteria for failed generators, but wanted to retain the Compatibility Category as C.

*Response:* No change was made to the compatibility category for reporting and notification requirement for failed Mo-99/Tc-99m and Sr-82/Rb-82 generators based on this comment. In the proposed rule, the NRC designated the reporting requirements in § 35.3204(a) and (b) as Compatibility Category C. The final rule retains the same compatibility category for reporting requirements in § 35.3204(a) and (b).

*Comment:* Two commenters agreed with the proposed revision but asserted that the proposed § 35.3204(a) initial requirement to report to the NRC Operations Center within 30 days should be shortened. One commenter stated that a shorter reporting requirement was needed to more effectively address patient safety concerns. The other commenter stated that in order to respond in a timely manner to potential issues regarding the manufacturing and/or use of generators, the reporting period should be less than 30 days.

*Response:* The rule text was modified based on these comments. The rule text in § 35.3204(a) was revised to require notification within 7 calendar days. The NRC agrees that the time period for notification should be shorter than the proposed 30 calendar days. With the short half-lives of the parent radionuclides, the NRC determined that a 7 calendar-day notification requirement is more appropriate. Seven calendar days gives the licensee an opportunity to evaluate its procedures, measurements, and calculations to determine if the generator actually failed, *i.e.,* the eluate actually exceeded the permissible concentration, or if the licensee made an error. The shorter reporting requirement would also permit the NRC to determine the extent of generator failures and take quicker action to protect patient safety.

*Comment:* Several Agreement States disagree that the notification of the discovery of an eluate exceeding the limits should be made to the NRC Operations Center. They recommended that a report be submitted to the NRC regional offices instead. The commenters stated that any 30-day notification to the Agreement States must only be submitted to the NRC using the National Materials Events Database (NMED), not the Operations Center. One commenter stated that the doses received from most generators that exceed the eluate breakthrough limits would not meet the reporting requirement for a diagnostic ME and therefore does not meet the urgency for reporting to the Operation Center. The commenter used the CardioGen® Sr/Rb generator recall as an example. Further, the commenter stated that the current Integrated Materials Performance Evaluation Program requirement to report such events to the NMED is more than sufficient. One commenter stated that ''[s]hould a trend of these events be found, the Agreement States currently report these events to the Regional Agreement State Officer.''

*Response:* No change was made to the rule text based on these comments. The NRC determined that it is appropriate to report generator failures (*i.e.,* when the eluate exceeds the permissible concentration listed in § 35.204(a)) to the NRC Operations Center. Reporting to the NRC Operations Center will permit the NRC to identify whether this is a limited or more widespread failure of generators and share that information in a timely manner.

*Comment:* Several commenters recommended that the NRC implement the ACMUI recommendation to only require licensees to report generator elution results with parent breakthrough beyond the § 35.204(a) limits to the manufacturer/distributor, and not to both the manufacturer/distributor and the NRC. The commenters stated that only the manufacturer/distributor should be responsible for reporting ''the out-of-tolerance parent breakthroughs to the NRC.'' The commenters also stated that requiring the licensee to report to both the company and the NRC, while the company also reports to NRC, is unnecessarily duplicative.

*Response:* A clarifying revision was made to the rule text. The NRC requires that a licensee report to the NRC and the generator distributor, which also may sometimes be the manufacturer, when it identifies a generator with an eluate exceeding the permissible concentration limits in § 35.204(a). The NRC requires this reporting because it is important that the NRC and the distributors be aware of such events in a timely manner. The reporting requirement is not duplicative because the NRC does not require the distributor to report generator failures to the NRC.

## VI. Section-by-Section Analysis

This section describes the specific amendments by section for this final rule.

*Section 30.34 Terms and Conditions of Licenses*

*Paragraph (g).* This paragraph adds a new requirement for licensees to report to the NRC when generator eluates exceed the permissible Mo-99 or Sr-82 and Sr-85 concentration limits listed in § 35.204(a). Reporting must be in accordance with the reporting and notification requirements in § 35.3204. While the reporting requirement as well as the requirement to test every Mo-99 elution is new, the testing by licensees of the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a) and recording the results of these tests is already required by this paragraph.

This change provides the information to allow the NRC to assess a potential situation quickly and efficiently when

issues occur with generators that may cause unwarranted radiation exposure to patients. This issue is discussed further in Section III., Discussion, of this document.

*Section 32.72 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under Part 35*

*Paragraph (a)(4).* This paragraph is amended to clarify that the applicant ''commits to'' rather than ''satisfies'' the labeling requirements. Committing to the prescriptive labeling requirements in the regulation in the license application would remove ambiguity related to what must appear on the label.

*Paragraph (b)(5)(i).* This paragraph is amended to remove the requirement to obtain a written attestation for individuals seeking to be named as an ANP and who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State to be an ANP. This is a conforming change in support of the removal of the attestation requirement in § 35.55(a) of this chapter for a board-certified ANP.

*Paragraph (d).* The existing requirements in paragraph (d) are re-designated as (e), and a new paragraph (d) is added to clarify that the labeling requirements that applicants commit to in paragraph (a) of this section are also applicable to current licensees.

*Section 35.2 Definitions*

New definitions for *Associate Radiation Safety Officer* and for *Ophthalmic physicist* are added to this section and the definition for *Preceptor* is amended.

The new definition for *Associate Radiation Safety Officer* identifies the requirements an individual will need to meet to be recognized as an ARSO. These requirements include that the individual must meet the specified T&E criteria and that the individual be currently listed as an ARSO on a medical use license or permit for the types of use of byproduct material for which the individual had been assigned tasks and duties by the RSO. Additional information on ARSOs is located in Section III, Discussion, of this document.

The new definition for *Ophthalmic physicist* identifies the requirements an individual will need to meet to be recognized as an Ophthalmic physicist. These requirements include that the individual must meet the specified T&E criteria in §§ 35.433(a)(2) and 35.59 and that the individual must be currently listed as an Ophthalmic physicist on a (1) specific medical use license issued by the Commission or an Agreement State; (2) permit issued by a Commission or Agreement State broad scope medical use licensee; (3) medical use permit issued by a Commission master material licensee; or (4) permit issued by a Commission master material licensee broad scope medical use permittee. A written attestation will not be required for this individual.

The definition for Preceptor is amended to add ARSO to the list of individuals whose T&E is provided, directed, or verified by a preceptor. This is a conforming change in support of the new definition for *Associate Radiation Safety Officer.*

*Section 35.8 Information Collection Requirements: OMB Approval*

*Paragraph (b).* This paragraph is amended to include § 35.3204 in the list of sections in which the approved information collection requirements are contained.

*Section 35.12 Application for License, Amendment, or Renewal*

This section is amended to require only the submission of the original NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or renewal. This section clarifies what information should be submitted and adds a requirement to submit information on an individual seeking to be identified as an ARSO or as an ophthalmic physicist.

*Paragraph (b)(1).* As part of the application for a medical use license, this paragraph is amended to require the submittal of only the original NRC Form 313. This change will relieve the burden on the applicant by requiring less paperwork to be submitted. It will also require the applicant to submit the T&E qualifications for one or more ARSOs and ophthalmic physicists that are to be identified on the license.

*Paragraph (c).* For license amendments or renewals, this paragraph is amended to require the submittal of only the original NRC Form 313 or a letter containing information required by NRC Form 313. This change will relieve the burden on the licensee by requiring less paperwork to be submitted. Additionally, it clarifies that the letter submitted in lieu of NRC Form 313 must contain all the information required by NRC Form 313.

*Paragraph (d).* This paragraph is amended and restructured to clarify what information must be included in an application for a license or amendment for medical use of byproduct material as described in § 35.1000.

*Section 35.13 License Amendments*

This section is amended by revising paragraph (b), re-designating paragraphs (d) through (g) as paragraphs (e) through (h), revising re-designated paragraphs (g) and (h), and adding new paragraphs (d) and (i).

*Paragraph (b).* This paragraph is amended to allow a licensee to permit an individual to work as an ophthalmic physicist before applying for a license amendment, provided that the individual is already identified on a medical license or permit provided for in § 35.13(b)(4).

*Paragraph (d).* This new paragraph requires a licensee to apply for and receive a license amendment before permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO currently authorized on the license.

*Paragraph (i).* This new paragraph allows a licensee to receive sealed sources from a new manufacturer or a new model number for a sealed source listed in the SSDR used for manual brachytherapy for quantities and isotopes already authorized by its license without first seeking a license amendment. This change provides manual brachytherapy licensees greater flexibility in obtaining the sealed sources necessary for patient treatments in a timely manner.

*Section 35.14 Notifications*

*Paragraph (a).* The paragraph is restructured to separate the notification requirements for an individual who is certified by a board that is recognized by the NRC or an Agreement State from the requirements for an individual who is not certified by a board that is recognized by the NRC or an Agreement State but is listed on a license. Additionally, the requirement to provide a written attestation is removed for an individual who is certified by a board that is recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III, Discussion, of this document. Licensees may not permit an individual who is not certified by a board that is recognized by the NRC or an Agreement State or does not meet the requirements in § 35.13(b) to work under their license without first obtaining an amendment to their license.

*Paragraph (a)(1).* This paragraph is restructured to more clearly identify the verification that a board-certified individual will need to provide along

with a copy of the individual's board certification. This change does not impose any new requirements.

*Paragraph (a)(2).* This paragraph retains the notification requirements for individuals who are authorized to work under § 35.13(b) who are not certified by a board that is recognized by the NRC or an Agreement State but are listed on a license. The sentence in the proposed rule under § 35.14(a)(2), ''The licensee shall only permit the individual to work with materials and uses previously authorized as an authorized user, an authorized medical physicist, ophthalmic physicist, or an authorized nuclear pharmacist under § 35.13(b)'' is deleted in the final rule. The NRC is removing this sentence because it is not necessary and the requirements are already addressed in § 35.13(b).

*Paragraph (b)(1).* This paragraph is amended to require a licensee to notify the Commission within 30 days after an ARSO or ophthalmic physicist has a name change or discontinues performance of his or her duties under the license.

*Paragraph (b)(5).* This paragraph is revised from the proposed rule language. In the proposed rule, the structure of § 35.14(b)(5) was changed and this resulted in substantive changes to the paragraph. The NRC did not intend to change the requirements in this paragraph.

*Paragraph (b)(6).* This new paragraph requires a licensee to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number listed in the SSDR for manual brachytherapy for quantities and isotopes already authorized by the license.

*Section 35.15 Exemptions Regarding Type A Specific Licenses of Broad Scope*

This section is amended to make corresponding changes based on amendments to § 35.13 and to § 35.14(b)(1).

*Paragraph (c).* This paragraph is amended to update the reference from § 35.13(e) to § 35.13(f) as a result of amendments to § 35.13.

*Paragraph (e).* This paragraph is amended to include ophthalmic physicist as a result of amendments to § 35.14(b).

*Section 35.24 Authority and Responsibilities for the Radiation Protection Program*

This section is amended to allow licensees to appoint qualified individuals with expertise in certain uses of byproduct material to be named as ARSOs on a license or permit.

*Paragraph (b).* This paragraph is modified to specify that a licensee's management may appoint one or more ARSOs. These appointed ARSOs must be named on a medical license or permit for the types of use of byproduct material for which the RSO, with the written agreement of the licensee's management, would assign tasks and duties.

The licensee's management is still limited to naming one RSO who will remain responsible for implementing the entire radiation protection program. The RSO is prohibited from delegating authority and responsibilities for implementing the radiation protection program. The proposed rule would have required each ARSO to agree in writing to the tasks and duties assigned by the RSO. The NRC staff determined that this requirement is not necessary because the NRC holds the RSO responsible for implementing the radiation protection program. Therefore, the proposed requirement for each ARSO to agree in writing to the tasks and duties assigned by the RSO is not included in this final rule.

*Paragraph (c).* An administrative change is made to this paragraph to remove the phrase ''an AU or'' because it is redundant with ''an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59'' in the same sentence.

The position of an ARSO is discussed further in Section III, Discussion, of this document.

*Section 35.40 Written Directives*

*Paragraph (b).* This paragraph is restructured and amended to accommodate specific requirements for a WD for permanent implant brachytherapy. Existing paragraph (b)(6) is re-designated as paragraph (b)(7) and a new paragraph (b)(6) is added to specify the information that must be included in the pre-implantation (before implantation) and post-implantation (after implantation) portions of the WD for permanent implant brachytherapy.

*Paragraph (b)(6).* This new paragraph provides details of the specific WD requirements for permanent implant brachytherapy. Specifically, it clarifies that the WD is divided into two portions, *i.e.,* the pre-implantation portion and the post-implantation portion. The pre-implantation portion of the WD requires documentation of the treatment site, the radionuclide, and the total source strength. The information required by the pre-implantation portion of the WD must be documented prior to the start of the implantation.

The post-implantation portion of the WD requires the documentation of the treatment site, number of sources implanted, the total source strength implanted, and the date. The information required by the post-implantation portion of the WD must be documented before the patient leaves the post-treatment recovery area.

*Paragraph (c).* This paragraph is restructured for clarity.

*Section 35.41 Procedures for Administrations Requiring a Written Directive*

This section is amended by adding two new paragraphs with requirements that the licensee must address when developing, implementing, and maintaining written procedures to provide high confidence that each administration requiring a WD is in accordance with the WD.

*Paragraph (b)(5).* This new paragraph requires that the licensee's procedures for any administration requiring a WD include procedures for determining if an ME, as defined in § 35.3045 of this part, has occurred.

*Paragraph (b)(6).* This new paragraph requires the licensee to develop specific procedures for permanent implant brachytherapy programs. At a minimum, the procedures will include determining post-implant source position within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because the patient is not available, then the licensee must provide written justification that this determination could not be made due to patient unavailability.

The determination that is required includes the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the WD.

A 60-calendar-day time frame ensures that the licensee has ample time to make arrangements for the required determinations. These determinations are used to partially assess if an ME, as defined in § 35.3045, has occurred.

*Section 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer*

Multiple changes are made to this section. They include amending the title of this section to add ''and Associate Radiation Safety Officer'' because the T&E requirements for this new position are also applicable to the ARSO. Other changes are: (1) Removing the requirement to obtain a written attestation for individuals qualified under paragraph (a) of this section; (2) adding a provision that will allow

individuals identified as an AU, AMP, or ANP on a medical license to be an RSO or an ARSO not only on that current license but also on a different medical license; (3) adding a provision to allow an individual to be named simultaneously both as the RSO and AU on a new license application; and (4) making certain administrative clarifications.

*Paragraph (a).* The requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Individuals seeking to be named as RSOs or ARSOs via the certification pathway still need to meet the training requirements in the new paragraph (d) of this section. Further discussion on removing the written attestation requirement can be found in Section III, Discussion, of this document.

*Paragraph (b)(1)(ii).* This paragraph is amended to allow an ARSO, in addition to the RSO, to provide supervised work experience for individuals under the alternate pathway. The ARSO is limited to providing supervised work experience in those areas for which the ARSO is authorized on a medical license or permit.

*Paragraph (b)(2).* Reserved paragraph (b)(2) is revised to include the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. The language that is required in the written attestation is amended to state that the individual ''is able to independently fulfill the radiation safety-related duties as an RSO or ARSO,'' rather than that the individual ''has achieved a level of radiation safety knowledge to function independently'' as an RSO or ARSO.

*Paragraph (c)(1).* This paragraph is modified to allow medical physicists who have been certified by a specialty board whose process has been recognized by the Commission or an Agreement State under § 35.51(a) to be named as ARSOs. Additionally, the requirement for a written attestation for these medical physicists is removed. A medical physicist seeking to be named as an RSO or an ARSO still must meet the training requirements in paragraph (d) of this section.

*Paragraph (c)(2).* This paragraph is modified to allow AUs, AMPs, and ANPs identified on a Commission or an Agreement State medical license or permit to be an RSO or ARSO on any Commission or an Agreement State license or Commission master material license permit provided that the AU, AMP, or ANP has experience with the radiation safety aspects of similar types of use of byproduct material. The current regulations limit AUs, AMPs, and ANPs to serve as an RSO only on the license on which they are listed.

The AUs, AMPs, and ANPs must meet the same requirements to serve as the RSO regardless of which Commission medical license they are identified on. Therefore, not allowing them to serve as an RSO on any Commission medical license is unnecessarily restrictive. This change will increase the number of individuals available to serve as RSOs and ARSOs on NRC medical licenses.

*Paragraph (c)(3).* This new paragraph allows an individual who is not named as an AU on a medical use license or permit, but is qualified to be an AU, to be named simultaneously as the RSO and the AU on the same new medical license. Current regulations, under § 35.50(c)(2), do not permit an individual who is not an AU on a license, but qualified to be an AU, to be an RSO. The individual must have the experience with the radiation safety aspects of the byproduct material for which the authorization is sought. An individual may meet the qualifications of an AU via the board certification or alternate pathway. An individual who uses the alternate pathway to be named simultaneously as the RSO and the AU on the same new medical use license must obtain a written attestation.

The provision will provide flexibility for an individual to serve as both an AU and as the RSO on a new medical use license (a clinic or a medical institution) and may help to make medical procedures more widely available, especially in rural areas.

*Paragraph (d).* This paragraph is amended to include ARSOs as individuals who can provide supervised training to an individual seeking recognition as an RSO or ARSO.

*Section 35.51 Training for an Authorized Medical Physicist*

*Paragraph (a).* The requirement for individuals seeking to be named as an AMP to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III, Discussion, of this document.

*Paragraph (a)(2)(i).* This paragraph is amended to clarify that an AMP who provides supervision for meeting the requirements of this section must be certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State.

Current regulations allow a medical physicist with any board certification in diagnostic or therapeutic medical physics to serve as a supervising medical physicist in therapeutic procedures. The NRC believes that the supervision for therapeutic procedures must be provided by a therapy medical physicist who is certified in medical physics by a specialty board recognized under § 35.51 by the Commission or an Agreement State.

*Paragraph (b)(2).* The wording in this paragraph is revised to remove the requirement for a written attestation that is required in § 35.51(a). It is also amended to incorporate the new language that the written attestation must verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AMP.

*Section 35.55 Training for an Authorized Nuclear Pharmacist*

*Paragraph (a).* The requirement for individuals seeking to be named as an ANP to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

*Paragraph (b)(2).* This paragraph is revised to conform to the removal of the attestation requirement in paragraph (a) of this section. It is also amended to incorporate the new language that the written attestation must verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an ANP.

*Section 35.57 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist*

Multiple changes are made to this section. Most of the changes are to the T&E requirements in response to the requested amendments in PRM–35–20. This includes recognizing the board certifications of individuals certified by boards recognized under subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), and making administrative clarifications. Additional information on PRM–35–20, as it relates to this rulemaking, is located in Section

II., Petition for Rulemaking, PRM–35–20, of this document.

*Paragraph (a)(1).* This paragraph is modified to add AMPs and ANPs. This paragraph is also modified to grandfather individuals listed in this paragraph who were identified on a license or permit on or before January 14, 2019. These individuals will not need to comply with the applicable training requirements of §§ 35.50, 35.51, or 35.55.

However, this paragraph is also modified such that RSOs and AMPs identified by this paragraph must meet the training requirements in §§ 35.50(d) or 35.51(c), as appropriate, for any materials or uses for which they were not authorized prior to the effective date of this rule. This is not a new training requirement. Current regulations require individuals qualifying under §§ 35.50 and 35.51 as RSOs and AMPs to meet the training requirements in §§ 35.50(e) and 35.51(c).

*Paragraph (a)(2).* This paragraph is amended to recognize individuals certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005. These individuals do not need to comply with the training requirements of § 35.50 to be identified as an RSO or as an ARSO on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

*Paragraph (a)(3).* This paragraph is amended to recognize individuals certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005. These individuals do not need to comply with the training requirements of § 35.51 to be identified as an AMP on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. These individuals are exempted from these training requirements only for those materials and uses these individuals performed on or before October, 24, 2005.

*Paragraph (a)(4).* This paragraph is renumbered from current paragraph (a)(3) and is not revised.

*Paragraph (b)(1).* This paragraph is amended to change the date before which an individual is named on a license as an AU to be on or before January 14, 2019.

Additionally, this paragraph is amended to clarify that an individual authorized on or before this date will not be required to comply with the T&E requirements in subparts D through H of 10 CFR part 35 for those materials and uses that the individual performed on or before January 14, 2019.

*Paragraph (b)(2).* This paragraph is restructured and expanded to recognize a physician, dentist, or podiatrist who was certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005. These individuals do not need to comply with the training requirements of subparts D through H of 10 CFR part 35 to be identified as an AU on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that the individual performed on or before October 24, 2005.

*Section 35.65 Authorization for Calibration, Transmission, and Reference Sources*

This section is restructured and amended to include three new paragraphs.

*Paragraph (b)(1).* This new paragraph requires that medical use of any byproduct material in sealed sources authorized by this section can only be used in accordance with the requirements in § 35.500. This is a clarification that all of the specified byproduct material for medical use must be under the supervision of an AU.

*Paragraph (b)(2).* This new paragraph prohibits the bundling or aggregating of single-sealed sources to create a sealed source with an activity greater than authorized by § 35.65.

*Paragraph (c).* This new paragraph clarifies that a licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

*Section 35.190 Training for Uptake, Dilution, and Excretion Studies*

*Paragraph (a).* For a physician seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100, the requirement to obtain a written attestation is removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (c)(2).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for a physician seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.190.

The residency program director who provides written attestations does not have to be an AU who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements. However, the director must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.204 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations*

*Paragraph (b).* The current requirement to measure the Mo-99 concentration only after the first eluate is changed to require that the Mo-99 concentration be measured after each elution. A generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use. Current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

*Paragraph (e).* This new paragraph adds a requirement that licensees report any measurement that exceeds the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators at the time of generator elution.

Further discussion on this issue can be found in Section III., Discussion, of this document.

*Section 35.290 Training for Imaging and Localization Studies*

*Paragraph (a).* For physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200, the requirement to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification

process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (c)(1)(ii).* This paragraph is amended to allow an ANP who meets the requirements in §§ 35.55 or 35.57 to provide the supervised work experience specified in paragraph (c)(1)(ii)(G) of this section for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200. Paragraph (c)(1)(ii)(G) of this section requires supervised work experience in eluting generator systems. Many medical facilities no longer elute generators and instead receive unit doses from centralized pharmacies; therefore, training on eluting generators is not available at these facilities. Authorized Nuclear Pharmacists have the T&E to provide the supervised work experience for AUs on the elution of generators.

*Paragraph (c)(2).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under §§ 35.100 and 35.200. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.290.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation must verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*§ 35.300 Use of Unsealed Byproduct Material for Which a Written Directive Is Required*

The introductory paragraph is amended to clarify that a licensee may only use unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) under this section. Currently, § 35.300 states that ''A licensee may use any unsealed byproduct material. . . .'' This change clarifies that a licensee's authorization of the radiopharmaceuticals requiring a WD is only for those types of radiopharmaceuticals for which the AU has documented T&E. An AU may be authorized for one or all of the specific categories described in § 35.390(b)(1)(ii)(G), but not for all unsealed byproduct material.

*Section 35.390 Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required*

*Paragraph (a).* For physicians seeking to be named as AUs of unsealed byproduct material for uses authorized under § 35.300, the requirement to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (b)(1)(ii)(G)(3).* This paragraph is amended to identify a single category of parenteral administrations of radionuclides in which work experience is required for an individual seeking to be an AU for uses under § 35.300.

The current regulations include a broad category for parenteral administrations of ''any other'' radionuclide. This broad category is removed, as any new parenteral administration of radionuclides not listed in this paragraph are regulated under § 35.1000. This approach will allow the NRC to review each new proposed radionuclide for parenteral administration and determine the appropriate T&E for its use.

Current regulations require physicians requesting AU status for administering dosages of radioactive drugs to humans (including parenteral administration) to have work experience with a minimum of three cases in each category for which they are requesting AU status. This requirement is retained in the final rule with regard to all categories in this paragraph.

*Paragraph (b)(2).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as AUs of unsealed byproduct material for uses authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.300.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements, or have experience in administering dosages in the same dosage category or categories as the individual requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the physician requesting AU status, and concurs with the attestation.

Additionally, this paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.392 Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)*

*Paragraph (a).* For physicians seeking to be named as an AU for the oral administration of sodium iodide I–131 requiring a WD in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), the requirement to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (c)(3).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an

AU of unsealed byproduct material for the oral administration of sodium iodide I–131 requiring a WD in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.392.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, or have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation.

Additionally, this paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

*Section 35.394 Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)*

*Paragraph (a).* For physicians seeking to be named as an AU for the oral administration of sodium iodide I–131 requiring a WD in quantities greater than 1.22 gigabecquerels (33 millicuries), the requirement to obtain a written attestation is removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (c)(3).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the oral administration of sodium iodide I–131 requiring a WD in quantities greater than 1.22 gigabecquerels (33 millicuries) authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.394.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, or have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.396 Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive*

Amendments to this section include conforming changes to support the new single category for parenteral administration in § 35.390(b)(1)(ii)(G)(*3*), changes to allow residency program directors to provide written attestations, and a change in the attestation language. Additionally, this section is restructured and renumbered to accommodate the changes.

*Paragraph (a).* This paragraph was restructured to list the physicians who can seek AU status under paragraphs (a)(1), (2), and (3) that were previously listed as paragraphs (a), (b), and (c). Conforming changes are made to support the new single category for parenteral administration in § 35.390(b)(1)(ii)(G)(*3*).

*Paragraph (b).* This paragraph was restructured as paragraphs (b)(1), (2), and (3). These paragraphs describe the T&E required for physicians specified in § 35.396(a)(2) and (a)(3). The provisions within these paragraphs were the previous paragraph (d) in the proposed rule. Conforming changes are made to support the new single category for parenteral administration in § 35.390(b)(1)(ii)(G)(*3*).

*Paragraph (b)(3).* This paragraph is further restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the parenteral administration requiring a WD. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.396.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, or have experience in administering dosages in the same category as the individual requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, and concurs with the attestation. An AU who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category as the individual requesting AU user status.

Additionally, this paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.400 Use of Sources for Manual Brachytherapy*

This section is expanded to allow for sources that are listed in the SSDR for manual brachytherapy to be used for other manual brachytherapy uses that are not explicitly listed in the SSDR.

*Paragraph (a).* This paragraph is amended to allow sources that are listed in the SSDR for manual brachytherapy medical uses to be used for manual

brachytherapy medical uses that are not explicitly listed in the SSDR provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may apply to storage, handling, sterilization, conditions of use, or leak testing of radiation sources.

The NRC recognizes that the medical uses specified in the SSDR may not be all-inclusive. The final rule will permit physicians to use manual brachytherapy sources to treat sites or diseases not listed in the SSDR. For example, the SSDR may specify that the sources are for interstitial uses, but the final rule change allows the physician to use the sources for a topical use. The NRC has determined this flexibility should be afforded to physicians to use their discretion in the practice of medicine.

*Section 35.433 Strontium-90 Sources for Ophthalmic Treatments*

This section title is modified by deleting ''Decay of'' at the beginning of the title. This new title reflects the expanded information and requirements in this section.

*Paragraph (a).* This paragraph is amended and expanded to allow certain individuals who are not AMPs to calculate the activity of strontium-90 (Sr-90) sources that is used to determine the treatment times for ophthalmic treatments. These individuals, defined in § 35.2 as ophthalmic physicists, must meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities. A written attestation will not be required. These requirements are similar to the T&E requirements for an AMP, but include only the requirements related to brachytherapy programs.

*Paragraph (b).* This new paragraph establishes the tasks that individuals qualified under paragraph (a) of this section are required to perform in supporting ophthalmic treatments with Sr-90. The first task is based upon the requirements in § 35.432 for calculating the activity of each Sr-90 source used for ophthalmic treatments. This is not a new requirement, as it is required in the current regulation under § 35.433(a).

The second task is related to the requirements in § 35.41 and is included in this final rule to ensure the safe use of Sr-90 for ophthalmic treatments. Both the AMP and the ophthalmic physicist are required to assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the dose administration is in accordance with the WD. Under this paragraph, the licensee must modify its procedures required under § 35.41 to specify the frequencies at which the AMP or the ophthalmic physicist will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the treatment was administered in accordance with the WD.

*Paragraph (c).* This paragraph is a designation of the recordkeeping requirements in the current regulation under § 35.433(b). The requirements have not changed.

*Section 35.490 Training for Use of Manual Brachytherapy Sources*

*Paragraph (a).* For a physician seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400, the requirement to obtain a written attestation is removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (b)(1)(ii).* This paragraph is amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.400 rather than at a medical institution. The current term ''medical institution'' in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices more than one medical discipline does not ensure that one of the medical disciplines is related to uses authorized under § 35.400. The change will allow individuals to receive work experience at a stand-alone, single-discipline clinic and ensure that the work experience is related to the uses authorized under § 35.400.

*Paragraph (b)(3).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The residency program directors must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.400.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.491 Training for Ophthalmic Use of Strontium-90*

*Paragraph (b)(3).* This paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.500 Use of Sealed Sources and Medical Devices for Diagnosis*

This section is restructured and expanded to include the use of medical devices to allow sealed sources and medical devices that are listed in the SSDR for diagnostic medical uses to be used for diagnostic medical uses that are not explicitly listed in the SSDR, and to allow sealed sources and medical devices to be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. This section title is modified to add ''and medical devices'' because the use of medical devices is added to this section.

*Paragraph (a).* This paragraph is amended to clarify that sealed sources that are not in medical devices for diagnostic medical uses and that are approved in the SSDR can be used for other diagnostic medical uses that are not explicitly listed in an SSDR provided that the sealed sources are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may include storage, handling, sterilization, conditions of use, or leak testing of radiation sources.

*Paragraph (b).* This paragraph is added to allow medical devices containing sealed sources to be used for diagnostic medical uses that are not explicitly listed in an SSDR if both the sealed sources and the medical devices are approved in the SSDR for diagnostic medical uses and provided that the medical devices are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

*Paragraph (c).* This new paragraph allows sealed sources and devices for diagnostic medical uses to be used in research in accordance with an active IDE application accepted by the FDA, provided the requirements of § 35.49(a) are met.

*Section 35.590 Training for Use of Sealed Sources and Medical Devices for Diagnosis*

This section is restructured and expanded to clarify that both diagnostic sealed sources and devices authorized in § 35.500 are included in the T&E requirements of this section.

*Paragraph (a).* This paragraph is revised to reference the redesignated paragraphs (c) and (d).

*Paragraph (b).* This new paragraph recognizes the individuals who are authorized for uses listed in § 35.200, or equivalent Agreement State requirements, for use of diagnostic sealed sources or devices authorized under § 35.500.

*Section 35.600 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit*

This section is amended to separate the uses of photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units from the uses of the sealed sources contained within these units. The amended section allows only sealed sources approved in the SSDR in devices to deliver therapeutic medical treatments as provided for in the SSDR. However, the units containing these sources can be used for therapeutic medical treatments that are not explicitly provided for in the SSDR, provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. The purpose of this amendment is to allow physicians flexibility to exercise their medical judgment and to use these devices for new therapeutic treatments that may not have been anticipated when the devices were registered.

*Paragraph (a).* This paragraph requires that a licensee use only sealed sources approved in the SSDR for therapeutic medical uses in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units as provided for in the SSDR or for research in accordance with an active IDE application accepted by the FDA, provided the requirements of § 35.49(a) are met.

*Paragraph (b).* This paragraph continues to require that a licensee only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or for research in accordance with an active IDE application accepted by the FDA provided the requirements of § 35.49(a) are met. However, this paragraph is amended to provide that these units may be used for medical uses that are not explicitly provided for in the SSDR, provided that these units are used in accordance with the radiation safety conditions and limitations described in the SSDR.

*Section 35.610 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units*

*Paragraph (d)(1).* This paragraph is amended and restructured to add a new training requirement for the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This amendment requires all individuals who operate these units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. This training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the training. This training is also required when software upgrades are made by the vendor or the manufacturer that affect the operation and safety of the unit.

Currently, § 35.610(d) requires that all individuals who operate these units be provided safety instructions initially, and at least annually; however, there is no requirement for these individuals to receive instructions when the unit is upgraded. The amendment requires individuals who operate these new or upgraded units to receive training prior to first use for patient treatment. These individuals include AUs, AMPs, operators, and others that need to know how the units operate.

*Paragraph (d)(2).* This paragraph is restructured and amended to clarify that the training required by this paragraph on the operation and safety of the unit applies to any new staff who will operate the unit or units at the facility. This requirement is added to enhance the safety of patients by eliminating potential delay in training of new staff until the required annual training, which could lead to undertrained individuals operating the unit.

*Paragraph (g).* This paragraph is amended to conform with the restructuring of paragraph (d)(2) of this section.

*Section 35.655 Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units*

This section title is modified to delete ''5-year inspection'' and insert ''Full-inspection servicing'' to more accurately reflect the requirements in this section for inspection and servicing of teletherapy units and gamma stereotactic radiosurgery units.

*Paragraph (a).* This paragraph is amended to extend the full inspection and servicing interval between each full inspection servicing for gamma stereotactic radiosurgery units from 5 years to 7 years to assure proper functioning of the source exposure mechanism. The interval between each full inspection and servicing of teletherapy units remains the same (not to exceed 5 years). For gamma stereotactic radiosurgery units, the full inspection and servicing to assure proper functioning of the source exposure mechanism is performed when the sources are taken out of the unit and before the new sources are placed in the unit (source replacement). Because the cost to replace the decaying sources in a gamma stereotactic radiosurgery unit can be significant, licensees have requested that the intervals between each full inspection servicing for these units be extended beyond 5 years. In support of this extension, the NRC finds that the 6-month routine preventive maintenance that is performed on these units is adequate to ensure the proper functioning of the source exposure mechanisms and, therefore, this final rule extends the full inspection and servicing interval for gamma stereotactic radiosurgery units from 5 years to 7 years.

Additionally, this paragraph requires that the full inspection and servicing of these units be performed during each source replacement regardless of the last time the units were inspected and serviced.

The full inspection and servicing interval of a teletherapy unit has not

been extended from the current interval of 5 years. The current interval of 5 years helps prevent potentially serious radiation exposure of teletherapy operators and patients in the event that the source exposure mechanism fails. The radioactive source contained in a teletherapy unit produces radiation fields on the order of hundreds of rads per minute in areas accessible to patients and operators. In the event of a source exposure mechanism failure, the exposed source could result in overexposure of a patient or operating personnel in a short period of time.

*Section 35.690 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units*

*Paragraph (a).* For a physician seeking to be named as an AU for sealed sources for uses authorized under § 35.600, the requirement to obtain a written attestation is removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section III., Discussion, of this document.

*Paragraph (b)(1)(ii).* This paragraph is amended to require that the work experience required by this section be received at a medical facility authorized to use byproduct materials under § 35.600 rather than at a medical institution. The current term ''medical institution'' in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices more than one medical discipline does not ensure that one of the medical disciplines is related to uses authorized under § 35.600. The change allows the work experience to be received at a stand-alone single discipline clinic for the uses authorized under § 35.600.

*Paragraph (b)(3).* This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600. The residency program directors must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.690.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit(s) for which the individual is requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit(s) for which the individual is requesting AU status and concurs with the attestation.

Additionally, this paragraph is amended to incorporate the new language that the written attestation must verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an AU.

*Section 35.2024 Records of Authority and Responsibilities for Radiation Protection Programs*

*Paragraph (c).* This new paragraph requires the licensee to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. This record must include the written document appointing the ARSO signed by the licensee's management.

*Section 35.2310 Records of Safety Instruction*

This section is amended to conform to the changes made in § 35.610 by adding a requirement to maintain the operational and safety instructions required by § 35.610.

*Section 35.2655 Records of Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units*

This section title is modified to delete ''5-year inspection'' and insert ''full-inspection servicing'' to reflect the changes to § 35.655 requiring full inspection and servicing of teletherapy units and gamma stereotactic radiosurgery units.

*Section 35.3045 Report and Notification of a Medical Event*

*Paragraph (a).* This paragraph is restructured and amended to provide separate specific criteria for reporting an ME involving permanent implant brachytherapy. These new criteria are different from the criteria for reporting an ME for other administrations. The paragraph retains the current introductory sentence, ''A licensee shall report any event as a medical event, except for an event that results from patient intervention. . .'' The introductory sentence of § 35.3045(a), published in the proposed rule in July 21, 2014, provided that ''A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention. . . .'' The phrase ''requiring a written directive'' is removed from this sentence in the final rule. This revision in the final rule maintains the current requirement that all events that meet the ME criteria be reported, not just those that require a WD.

*Paragraph (a)(1).* This new paragraph contains criteria for reporting an ME for all administrations other than permanent implant brachytherapy administrations. Criteria for reporting an ME involving permanent implant brachytherapy are in the new paragraph (a)(2) in this section. The criteria used to determine if an ME has occurred for all administrations, except permanent implant brachytherapy, are unchanged except (1) the current paragraph (a)(3) related to the dose to the skin or an organ or tissue other than the treatment site is restructured for clarity as the new paragraph (a)(1)(iii); and (2) a criterion is added in the new paragraph (a)(1)(ii)(A) of this section for reporting an administration involving the wrong radionuclide for a brachytherapy procedure as an ME.

*Paragraph (a)(2).* This new paragraph is added to establish separate criteria for reporting MEs involving permanent implant brachytherapy. These new criteria are designed to ensure reporting of situations where harm or potential harm to the patient may occur. The new criteria for reporting an ME involving permanent implant brachytherapy are:

(1) The total source strength administered differs by 20 percent or more from the total source strength documented in the post-implantation portion of the WD. An example of a situation that meets this criterion is a situation in which the sealed sources that were implanted had a different source strength than what was intended. This situation could occur because the licensee ordered, or the vendor shipped, sealed sources with the wrong activity;

(2) The total source strength administered outside of the treatment site exceeds 20 percent of the total source strength documented in the post-implantation portion of the WD. An example of a situation that meets this criterion is a situation in which the

sealed sources are unintentionally implanted outside of the treatment site. This situation would be identified by the licensee when determinations are made pursuant to § 35.41;

(3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; sealed source, or sources, implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the WD; or a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue. Only the criteria for a leaking sealed source retains the dose threshold in current regulations because the NRC determined the leaking sealed source delivering a dose below this threshold does not need to be reported as an ME. Several situations that will meet this criterion are self-evident, *i.e.,* the wrong patient, the wrong treatment site, or a leaking sealed source. Three criteria published in the proposed rule on July 21, 2014, have been deleted in the final rule: (1) The criterion related to absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside the treatment site; (2) the criterion related to absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site; and (3) the criterion related to an error of 20 percent or more in calculating the total source strength. These deletions are based on the comments received on the proposed rule and is discussed in Section V., Public Comment Analysis, of this document.

*Section 35.3204 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations*

This new section requires reporting and notification of an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator that exceeds the regulatory requirements in §§ 30.34 and 35.204(a). Further discussion of this requirement can be found in Section III., Discussion, of this document.

*Paragraph (a).* This new paragraph requires a licensee to notify both the NRC Operations Center and the distributor, which also may sometimes be the manufacturer, of the generator by telephone within 7 calendar days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). This notification must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

*Paragraph (b).* This new paragraph requires a licensee to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The report must be submitted by an appropriate method listed in § 30.6(a). The report must include the action taken by the licensee; patient dose assessments; the methodology used in making the patient dose assessment if the eluate was administered to patients or human research subjects; probable cause and assessment of failure in the licensee's equipment; procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.

## VII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This final rule affects a number of ''small entities'' as defined by the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810). However, as indicated in the regulatory analysis available as indicated in Section XXIII, ''Availability of Documents'' section of this document, these amendments do not have a significant economic impact on the affected small entities. The NRC requested comment on the proposed rule and accompanying draft regulatory analysis on the impact of the proposed rule on small entities. The NRC received no comment submissions from an identified small entity.

## VIII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The regulatory analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in Section XXIII., Availability of Documents, of this document.

## IX. Backfitting and Issue Finality

The backfit rule and issue finality provisions of 10 CFR part 52 (which are found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52) do not apply to this final rule. Parts 30, 32, and 35 of 10 CFR do not contain a backfitting provision. Therefore, a backfitting analysis is not required.

## X. Cumulative Effects of Regulation

Cumulative effects of regulation (CER) describes the challenges that licensees, certificate holders, States, or other entities may encounter while implementing new regulatory requirements (*e.g.,* rules, generic letters, orders, inspection findings). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. The NRC specifically requested comments on the cumulative effects of this rulemaking in the proposed rule published on July 21, 2014, and received three comments on the CER. Two Agreement States stated that with steady accretion of regulations, there are always unintended consequences, in that the additional costs impact decisions on functions of the State radiation control program. With regard to the NRC's cost/benefit analysis in the draft Regulatory Analysis, these commenters stated that the NRC's cost/benefit analysis appeared to support the rule. One of the commenters expressed concern that there is the potential for applying rules in a manner in which they were not intended based on the permanent implant brachytherapy language in § 35.40(b)(6). The commenter was concerned about the specification of dose to the normal tissues, located within the treatment site, in the proposed rule in § 35.40(b)(6)(i). Based on these comments and other public comments, § 35.40(b)(6)(i) in the final rule does not require the AU to specify dose to the normal tissues located within the treatment site. The comments are discussed in Section V., Public Comment Analysis, of this document.

## XI. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883).

## XII. Environmental Impact: Categorical Exclusion

The NRC has determined that the following actions in this final rule are the types of actions described in categorical exclusions in § 51.22(c)(2) and (c)(3)(i–v):

(1) The amendments to the general administrative requirements and general technical requirements meet the categorical exclusion criteria under § 51.22(c)(2).

(2) The amendments to sealed sources usage provide clarifications to the current regulations and meet the categorical exclusion criteria under § 51.22(c)(2).

(3) The amendments to the requirements for reporting MEs and reporting failed generator tests meet the categorical exclusion criteria under § 51.22(c)(3)(iii).

(4) The amendments related to the record-keeping requirements meet the categorical exclusion criteria under § 51.22(c)(3)(ii).

(5) The amendments related to the T&E requirements meet the categorical exclusion criteria under § 51.22(c)(3)(iv).

There are two amendments that do not meet the categorical exclusion criteria in § 51.22. Therefore, an environmental assessment has been prepared for this rule for the two amendments that do not meet the categorical exclusion criteria in § 51.22. The environmental assessment is discussed in Section XIII., Environmental Assessment and Final Finding of No Significant Environmental Impact, of this document. The amendments that do not meet the categorical exclusions in § 51.22 are: (1) The increase in the frequency of Mo–99 measurement tests required in § 35.204, and (2) the increase in the full inspection time interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years in § 35.655.

## XIII. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in Subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and; therefore, an environmental impact statement is not required. The amendments that were the subject of the Environmental Assessment establish more frequent measuring of Mo–99 and increase the inspection interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years. The amendments are procedural in nature. It is expected that this rule will not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

The NRC requested the views of the States and State Liaison Officers on the environmental assessment for this rule. The NRC did not receive any comments on the environmental assessment from the States or State Liaison Officers.

The determination of the environmental assessment is that this rule would have no significant impact on the quality of the human environment. The environmental assessment is available as indicated in Section XXIII, Availability of Documents, of this document.

## XIV. Paperwork Reduction Act Statement

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information were approved by the Office of Management and Budget, control number 3150–0010.

The burden to the public for the information collection(s) is estimated to average 2.52 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collection is being conducted to provide the NRC the information it needs to effectively evaluate license applications, applications for amendments, licensee operations, and significant safety events for protection of public health and safety. The information will be used by the NRC in evaluating compliance with licensing requirements. The NRC will assess the adequacy of an applicant's or licensee's physical location, equipment, organization, training, experience, procedures and plans for protection of public health and safety. The NRC review and the findings derived there form the basis of NRC licensing and inspection decisions. The NRC uses reports of significant safety events in evaluating the protective actions required to avoid exposures to patients and the public that could exceed regulatory limits, and therefore impact public health and safety and the environment. Responses to the information collection requirements at §§ 32.72 and 35.12 are mandatory or are required to obtain or retain a benefit. All other information collection requirements in this final rule are mandatory. Section 161b of the AEA authorizes the NRC to impose these information collections.

You may submit comments on any aspect of the information collection(s), including suggestions for reducing the burden, by the following methods:

- *Federal rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0175.
- *Mail comments to:* FOIA, Privacy, and Information Collections Branch, Office of Information Services, Mail Stop: T–5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or to Matthew Oreska, Desk Officer, Office of Information and Regulatory Affairs (3150–0010), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–9593, email: *oira_submission@omb.eop.gov*.

*Public Protection Notification*

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

## XV. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5. U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

## XVI. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this final rule that amends 10 CFR parts 30, 32, and 35 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule will be subject to criminal enforcement.

## XVII. Coordination With NRC Agreement States

The NRC has coordinated with the Agreement States throughout the development of this final rule. Agreement State representatives have served on the rulemaking working group that developed the proposed and final amendments to 10 CFR part 35 and on the steering committee for the rulemaking.

Through an All Agreement State Letter (FSME–11–044, dated May 20, 2011), the Agreement States were notified of the availability of preliminary rule text for comments

posted on *www.regulations.gov* and noticed in the **Federal Register** (76 FR 29171; May 20, 2011). The **Federal Register** notice also invited the Agreement States to participate at the two public workshops that were held in New York City, New York, and Houston, Texas, during the summer of 2011.

In February 2013, the NRC provided the preliminary draft proposed rule to the Agreement States for a 30-day review. The Agreement States provided comments on the preliminary draft proposed rule. Several comments resulted in revisions to the discussion section of the proposed rule to provide additional emphasis or clarity. A summary of the Agreement States comments and the NRC staff responses to the comments is contained in Enclosure 6 to SECY–13–0084.

Through an All Agreement State Letter (FSME–14–078, dated August 15, 2014), the Agreement States were notified of the availability of the proposed rule noticed in the **Federal Register** (79 FR 42410; July 21, 2014). The Agreement States also had an opportunity to comment on the draft final rule. In preparing both the proposed rule and the final rule, the rulemaking working group considered the comments provided by the Agreement States.

## XVIII. Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into Compatibility Categories A, B, C, D, NRC, or adequacy category Health and Safety (H&S). Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and, therefore do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the AEA or NRC rules. These program elements should not be adopted by the Agreement States. Adequacy Category H&S are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

The final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. Discussion on the Compatibility Category for § 35.3045, Report and notification of a medical event, can be found in Section V., Public Comment Analysis, of this document. The compatibility categories are designated in the following table:

COMPATIBILITY TABLE

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| **Part 30** | | | | |
| 30.34(g) | Amend | Terms and conditions of licenses | B | B |
| **Part 32** | | | | |
| 32.72(a)(4) | Amend | Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35. | B | B |
| 32.72(b)(5)(i) | Amend | Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35. | B | B |
| 32.72(d) | New | Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35. | ..... | B |
| **Part 35** | | | | |
| 35.2 | New | Definitions—Associate Radiation Safety Officer | ..... | B |
| 35.2 | New | Definitions—Ophthalmic physicist | ..... | B |
| 35.2 | Amend | Definitions—Preceptor | D | D |
| 35.12(b)(1) | Amend | Application for license, amendment, or renewal | D | D |
| 35.12(c)(1) | Amend | Application for license, amendment, or renewal | D | D |
| 35.12(c)(1)(ii) | Amend | Application for license, amendment, or renewal | D | D |
| 35.12(d) | Amend | Application for license, amendment, or renewal | D | D |
| 35.12(d)(1) | New | Application for license, amendment, or renewal | ..... | D |
| 35.12(d)(2) | New | Application for license, amendment, or renewal | ..... | D |
| 35.12(d)(3) | New | Application for license, amendment, or renewal | ..... | D |
| 35.12(d)(4) | Amend | Application for license, amendment, or renewal | D | D |
| 35.13(b) | Amend | License amendments | D | D |

COMPATIBILITY TABLE—Continued

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| 35.13(d) | New | License amendments | | D |
| 35.13(i) | New | License amendments | | D |
| 35.14(a) | Amend | Notifications | D | D |
| 35.14(b)(1) | Amend | Notifications | D | D |
| 35.14(b)(2) | Amend | Notifications | D | D |
| 35.14(b)(6) | New | Notifications | | D |
| 35.15(c) and (e) | Amend | Exemptions regarding Type A specific licenses of broad scope. | D | D |
| 35.24(b) | Amend | Authority and responsibilities for the radiation protection program. | H&S | H&S |
| 35.24(c) | Amend | Authority and responsibilities for the radiation protection program. | D | D |
| 35.40(b)(6) | Amend | Written directives | H&S | H&S |
| 35.40(b)(7) | Amend Redesignated | Written directives | H&S | H&S |
| 35.41(b)(5) | New | Procedures for administrations requiring a written directive | | H&S |
| 35.41(b)(6) | New | Procedures for administrations requiring a written directive | | H&S |
| 35.50 | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.50(a) | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.50(a)(2)(ii)(B) | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.50(b)(1)(ii) | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.50(b)(2) | New | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | | B |
| 35.50(c)(1) | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.50(c)(2) | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.50(c)(3) | New | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | | B |
| 35.50(d) | Amend | Training for Radiation Safety Officer and Associate Radiation Safety Officer. | B | B |
| 35.51(a) | Amend | Training for an authorized medical physicist | B | B |
| 35.51(a)(2)(i) | Amend | Training for an authorized medical physicist | B | B |
| 35.51(b)(2) | Amend | Training for an authorized medical physicist | B | B |
| 35.55(a) | Amend | Training for an authorized nuclear pharmacist | B | B |
| 35.55(b)(2) | Amend | Training for an authorized nuclear pharmacist | B | B |
| 35.57(a)(1) | Amend | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | B | B |
| 35.57(a)(2) | New | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | | B |
| 35.57(a)(3) | New | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | | B |
| 35.57(a)(4) | Redesignated | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | D | D |
| 35.57(b)(1) | Amend | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | B | B |
| 35.57(b)(2) | Amend | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | B | B |
| 35.57(b)(2)(i) | New | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | | B |

COMPATIBILITY TABLE—Continued

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| 35.57(b)(2)(ii) | New | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | | B |
| 35.57(b)(2)(iii) | New | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | | B |
| 35.57(b)(2)(iv) | New | Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. | | B |
| 35.65(a)(1)–(5) | Redesignated | Authorization for calibration, transmission, and reference sources. | D | D |
| 35.65(b) | New | Authorization for calibration, transmission, and reference sources. | | D |
| 35.65(b)(1) | New | Authorization for calibration, transmission, and reference sources. | | D |
| 35.65(b)(2) | New | Authorization for calibration, transmission, and reference sources. | | D |
| 35.65(c) | New | Authorization for calibration, transmission, and reference sources. | | D |
| 35.190(a) | Amend | Training for uptake, dilution, and excretion studies | B | B |
| 35.190(c)(2) | Amend | Training for uptake, dilution, and excretion studies | B | B |
| 35.190(c)(2)(i) | New | Training for uptake, dilution, and excretion studies | | B |
| 35.190(c)(2)(ii) | New | Training for uptake, dilution, and excretion studies | | B |
| 35.204(b) | Amend | Permissible molybdenum-99, strontium-82, and strontium-85 concentrations. | H&S | H&S |
| 35.204(e) | New | Permissible molybdenum-99, strontium-82, and strontium-85 concentrations. | | H&S |
| 35.290(a) | Amend | Training for imaging and localization studies | B | B |
| 35.290(c)(1)(ii) | Amend | Training for imaging and localization studies | B | B |
| 35.290(c)(2) | Amend | Training for imaging and localization studies | B | B |
| 35.290(c)(2)(i) | New | Training for imaging and localization studies | | B |
| 35.290(c)(2)(ii) | New | Training for imaging and localization studies | | B |
| 35.300 | Amend | Use of unsealed byproduct material for which a written directive is required. | B | B |
| 35.390(a) | Amend | Training for use of unsealed byproduct material for which a written directive is required. | B | B |
| 35.390(b)(1)(ii) (G)(*3*) | Amend | Training for use of unsealed byproduct material for which a written directive is required. | B | B |
| 35.390(b)(2) | Amend | Training for use of unsealed byproduct material for which a written directive is required. | B | B |
| 35.390(b)(2)(i) | New | Training for use of unsealed byproduct material for which a written directive is required. | | B |
| 35.390(b)(2)(ii) | New | Training for use of unsealed byproduct material for which a written directive is required. | | B |
| 35.392(a) | Amend | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). | B | B |
| 35.392(c)(3) | Amend | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). | B | B |
| 35.392(c)(3)(i) | New | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). | | B |
| 35.392(c)(3)(ii) | New | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). | | B |
| 35.394(a) | Amend | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). | B | B |
| 35.394(c)(3) | Amend | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). | B | B |
| 35.394(c)(3)(i) | New | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). | | B |

COMPATIBILITY TABLE—Continued

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| 35.394(c)(3)(ii) | New | Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). | | B |
| 35.396(a)(1) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(a)(2) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(a)(3) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(b)(1) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(b)(2) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(b)(2)(vi) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(b)(3) | Amend Redesignated | Training for the parenteral administration of unsealed by-product material requiring a written directive. | B | B |
| 35.396(b)(3)(i) | New | Training for the parenteral administration of unsealed by-product material requiring a written directive. | | B |
| 35.396(b)(3)(ii) | New | Training for the parenteral administration of unsealed by-product material requiring a written directive. | | B |
| 35.400(a) | Amend | Use of sources for manual brachytherapy | C | C |
| 35.400(b) | Amend | Use of sources for manual brachytherapy | C | C |
| 35.433(a) | Amend | Strontium-90 sources for ophthalmic treatments | H&S | B |
| 35.433(b) | New | Strontium-90 sources for ophthalmic treatments | | H&S |
| 35.433(b)(1) | New | Strontium-90 sources for ophthalmic treatments | | H&S |
| 35.433(b)(2) | New | Strontium-90 sources for ophthalmic treatments | | H&S |
| 35.433(c) | Redesignated | Strontium-90 sources for ophthalmic treatments (Previously 35.433(b)). | D | D |
| 35.490(a) | Amend | Training for use of manual brachytherapy sources | B | B |
| 35.490(b)(1)(ii) | Amend | Training for use of manual brachytherapy sources | B | B |
| 35.490(b)(3) | Amend | Training for use of manual brachytherapy sources | B | B |
| 35.490(b)(3)(i) | New | Training for use of manual brachytherapy sources | | B |
| 35.490(b)(3)(ii) | New | Training for use of manual brachytherapy sources | | B |
| 35.491(b)(3) | Amend | Training for ophthalmic use of strontium-90 | B | B |
| 35.500(a) | Amend | Use of sealed sources and medical devices for diagnosis (Previously 35.500). | [C] | C |
| 35.500(b) | New | Use of sealed sources and medical devices for diagnosis | | C |
| 35.500(c) | New | Use of sealed sources and medical devices for diagnosis | | C |
| 35.590 (a) | Amend | Training for use of sealed sources for diagnosis | B | B |
| 35.590 (b) | New | Training for use of sealed sources for diagnosis | | B |
| 35.590 (c) | Redesignated | Training for use of sealed sources for diagnosis (Previously 35.590(b)). | B | B |
| 35.590 (d) | Redesignated | Training for use of sealed sources for diagnosis (Previously 35.590(c)). | B | B |
| 35.600(a) | Amend | Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. | C | C |
| 35.600(b) | Amend | Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. | C | C |
| 35.610(d)(1) | New | Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | | H&S |
| 35.610(d)(2) | Amend | Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | H&S | H&S |
| 35.610(g) | Amend | Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | H&S | H&S |
| 35.655(a) | Amend | Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units. | H&S | H&S |
| 35.690(a) | Amend | Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | B | B |
| 35.690(b)(1)(ii) | Amend | Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | B | B |
| 35.690(b)(3) | Amend | Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | B | B |
| 35.690(b)(3)(i) | New | Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | | B |
| 35.690(b)(3)(ii) | New | Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. | | B |

COMPATIBILITY TABLE—Continued

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| 35.2024(c) | New | Records of authority and responsibilities for radiation protection programs. | | D |
| 35.2024(c)(1) | New | Records of authority and responsibilities for radiation protection programs. | | D |
| 35.2024(c)(2) | New | Records of authority and responsibilities for radiation protection programs. | | D |
| 35.2310 | Amend | Records of safety instruction | D | D |
| 35.2655(a) | Amend | Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units. | D | D |
| 35.3045(a)(1) | Amend | Report and notification of a medical event | C | C |
| 35.3045(a)(2) | New | Report and notification of a medical event for permanent implant brachytherapy. | | C |
| 35.3204(a) | New | Report and notification of an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations. | | C |
| 35.3204(b) | New | Written report of an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations. | | C |

**XIX. Coordination With the Advisory Committee on the Medical Uses of Isotopes**

The NRC staff consults with the ACMUI whenever it identifies an issue with implementation of 10 CFR part 35 regulations. Accordingly, issues addressed by this rule have been discussed at ACMUI meetings over the last several years. The ACMUI meetings are transcribed. Full transcripts of the ACMUI meetings can be found online in the NRC Library at *http://www.nrc.gov/reading-rm/doc-collections/acmui/tr*. In addition, in the SRM to SECY–10–0062, the Commission specifically directed the NRC staff to engage the ACMUI in developing the ME definition criterion for permanent implant brachytherapy. Further, the amendments that revise T&E requirements to eliminate preceptor attestation for board-certified individuals, change the language of the attestation, and allow a residency director to provide preceptor attestations were initiated by the ACMUI in its briefing to the Commission held on April 29, 2008 (discussed in detail in Item b, Section III., Discussion, of this document). Similarly, the issue of naming more than one RSO was initiated by the ACMUI at the June 2007 ACMUI meeting (discussed in detail in Item d in Section III., Discussion, of this document). Finally, the entire ACMUI meeting held on April 20–21, 2011, was devoted to discussion of the rulemaking issues addressed in the proposed rule, so that the NRC staff would be better able to understand ACMUI's position and views on the issues raised.

In December 2012, the NRC provided the preliminary draft proposed rule to the ACMUI for a 90-day review. The draft proposed rule was made public to facilitate the ACMUI review in a public forum. The ACMUI discussed the draft proposed rule at two publicly held teleconferences on March 5 and March 12, 2013. The ACMUI provided a final report, ''Advisory Committee on the Medical Uses of Isotopes Sub-Committee on Proposed Rule,'' dated April 5, 2013, to the NRC on April 9, 2013.

While the ACMUI was supportive of most of the proposed amendments, it expressed concerns on some issues and provided its recommendations on those issues. Several comments resulted in revisions to the discussion section of the proposed rule to provide additional emphasis or clarity. However, the NRC did not accept all of the ACMUI recommendations. The recommendations that the NRC staff did not accept were discussed in a document entitled, ''NRC Staff Responses to the ACMUI Comments on the Draft Part 35 Proposed Rule,'' Enclosure 5, to SECY–13–0084.

In addition, the ACMUI recommended that for permanent implant brachytherapy procedures, licensees be allowed to use total source strength as a substitute for total dose for determining MEs until the 10 CFR part 35 rulemaking is completed. In response, on July 9, 2013, the Commission issued an interim enforcement policy (78 FR 41125) that addressed this issue.

On October 6, 2015, the NRC provided the preliminary draft final rule to the ACMUI for a 90-day review. The ACMUI held a public teleconference on January 6, 2016, and provided a final report, ''Advisory Committee on the Medical Uses of Isotopes Sub-Committee on Draft Final Rule, 10 CFR parts 30, 32, and 35,'' dated January 6, 2016, to the NRC on January 6, 2016. The NRC prepared a response to the ACMUI recommendations and the response is listed in the list of available documents, in Section XXIII., ''Availability of Documents.''

**XX. Consistency With Medical Policy Statement**

The amendments to 10 CFR part 35 are consistent with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654). This rule is consistent with the Commission's statement because it balances the interests of the patient with the flexibility needed by the AU to take the actions that he or she deems medically necessary, while continuing to enable the NRC to detect deficiencies in processes, procedures, and training, as well as any misapplication of byproduct materials.

**XXI. Voluntary Consensus Standards**

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its medical use regulations related to ME definitions for permanent implant brachytherapy; T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; completing action on PRM–35–20 to ''grandfather'' certain experienced individuals; measuring Mo-99 contamination for each elution and

reporting of failed breakthrough tests; naming ARSOs on a medical license; and making several minor clarifications. This action does not constitute the establishment of a standard that contains generally applicable requirements.

## XXII. Availability of Guidance

Published elsewhere in this issue of the **Federal Register**, the NRC is issuing new guidance, ''Guidance for the Final Rule 'Medical Use of Byproduct Material—Medical Events, Definitions, Training and Experience, and Clarifying Amendments,'' (NRC–2014–0030), for the implementation of the requirements in this final rule.

## XXIII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

| Date | Document | ADAMS accession No. |
|---|---|---|
| 03/01/2004 | 03/01/2004 Transcript of Advisory Committee on the Medical Uses of Isotopes Meeting in Rockville MD, Pages 1–194. | ML040780651 |
| 06/28/2005 | Transcript of the Advisory Committee on the Medical Uses of Isotopes Medical Event Subcommittee Meeting. | ML052360415 |
| 12/27/2005 | SECY–05–0234, ''Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public''. | ML053180408 |
| 02/15/2006 | SRM–SECY–05–0234, ''Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public''. | ML060460594 |
| 09/10/2006 | PRM–35–20, ''AAPM Petition for Rulemaking to Amend 10 CFR 35.57, Training for Experience Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist,'' filed by E. Russell Ritenour. | ML062620129 |
| 06/12/2007 | Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, June 12, 2007, Pages 1–325. | ML072340094 |
| 04/29/2008 | M080429—Commission Meeting with the Advisory Committee on the Medical Uses of Isotopes, Transcript | ML081270628 |
| 05/15/2008 | SRM–M080429, Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI) 1:30 p.m., Tuesday, April 29, 2008. | ML081360319 |
| 11/20/2008 | SECY–08–0179, ''Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material''. | ML083170176 |
| 01/16/2009 | SRM–SECY–08–0179, ''Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material''. | ML090160275 |
| 05/18/2010 | SECY–10–0062, ''Reproposed Rule: Medical Use of Byproduct Material—Amendments/Medical Event Definitions''. | ML100890121 |
| 07/08/2010 | M100708B—Commission Briefing on ''Proposed Rule on Part 35 Medical Events Definitions—Permanent Implant Brachytherapy,'' Transcript. | ML101930532 |
| 08/10/2010 | SRM–SECY–10–0062, ''Reproposed Rule: Medical Use of Byproduct Material—Amendments/Medical Event Definitions (RIN 3150–AI26)''. | ML102220233 |
| 10/20/2010 | Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, Open Session, October 20, 2010, Pages 1–168. | ML103350657 |
| 10/20/2010 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Interim Report. | ML103540385 |
| 04/11/2011 | Final Transcript of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, April 11, 2011, Pages 1–226. | ML11174A070 |
| 05/16/2011 | Part 35 Preliminary Draft Proposed Rule Language, provided for ACMUI review | ML111390420 |
| 05/20/2011 | FSME–11–044, ''Opportunity to Comment on Preliminary Proposed Rule Language for Medical Use Regulations''. | ML111400231 |
| 06/20/2011 | Public Meeting Summary for Part 35 Medical Workshop, June 20–21, 2011 | ML111930470 |
| 08/11/2011 | Transcript of Public Workshop for Discussion of Topics Related to NRC's Medical Regulations, August 11, 2011, Pages 1–240. | ML112900103 |
| 08/12/2011 | Transcript of Public Workshop for Discussion of Topics Related to NRC's Medical Regulations, August 12, 2011, Pages 1–192. | ML112900185 |
| 10/18/2011 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Final Report. | ML11292A139 |
| 10/18/2011 | Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, October 18, 2011, Pages 1–77. | ML12062A275 |
| 11/30/2011 | The American Society for Radiation Oncology (ASTRO) letter to the Chairman of the ACMUI | ML11341A051 |
| 02/07/2012 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Revised Final Report. | ML12038A279 |
| 02/07/2012 | Final Transcript of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, February 7, 2012, Pages 1–85. | ML12242A101 |
| 02/13/2012 | ASTRO letter to the Chairman of the ACMUI | ML12044A358 |
| 04/05/2012 | SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs''. | ML12072A306 |
| 04/24/2012 | Transcript of Commission Meeting April 24, 2012, before Commission vote on SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs''. | ML12116A294 |
| 08/13/2012 | SRM–SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs''. | ML122260211 |
| 01/14/2013 | Part 35 Preliminary Draft Proposed Rule **Federal Register** Notice, provided for ACMUI review | ML13014A487 |
| 03/05/2013 | Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, March 5, 2013, Pages 1–111. | ML13175A030 |
| 03/12/2013 | Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, March 12, 2013, Pages 1–115. | ML13175A028 |
| 03/28/2013 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Comments on the Proposed Rule, 10 CFR parts 30, 32 and 35, Final Report. | ML13071A690 |

| Date | Document | ADAMS accession No. |
|---|---|---|
| 08/08/2013 | SECY–13–0084, ''Proposed Rule: Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150–AI63)''. | ML13179A068 |
| 08/08/2013 | SECY–13–0085, Enclosure 5, ''NRC Staff Responses to the ACMUI Comments on the Draft Part 35 Proposed Rule''. | ML13179A073 |
| 01/06/2014 | SRM–SECY–13–0084, ''Proposed Rule: Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150–AI63)''. | ML14007A044 |
| 07/23/2014 | Draft Environmental Assessment: Proposed Rule Amending 10 CFR parts 30, 32, and 35—Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments. | ML14184A621 |
| 07/23/2014 | Draft Regulatory Analysis: Proposed Rule: Amendments to Medical Use of Byproduct Material Regulations, 10 CFR parts 30, 32, and 35. | ML14184A620 |
| 08/15/2014 | FSME–14–078, ''Opportunity to Comment on Proposed Amendments to Medical Use of Byproduct Material Regulations, 10 CFR 30, 32, and 35 and Notification of October 8, 2014 Public Meeting''. | ML14226A319 |
| 10/08/2014 | Part 35 Proposed Rule Public Meeting Transcript, Pages 1–171, October 8, 2014 | ML15026A317 |
| 02/12/2015 | Meeting Summary: Public Meeting Between Spectrum Pharmaceuticals, Inc., and the Nuclear Regulatory Commission (NRC) Regarding Modification of the Training and Experiences Requirements for Beta Emitter Products. | ML15054A215 |
| 06/16/2015 | Final Transcript of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, June 16, 2015, Pages 1–109. | ML15285A016 |
| 09/21/2015 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience for Authorized Users of Alpha and Beta Emitters Draft Subcommittee Report. | ML15271A124 |
| 10/08/2015 | Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, October 8, 2015, Open Session, Pages 1–255. | ML15357A551 |
| 10/09/2015 | Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, October 9, 2015, Open Session, Pages 1–262. | ML15357A552 |
| 01/06/2016 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Comments on the Draft Final Rule, 10 CFR parts 30, 32 and 35, Final Report. | ML16007A771 |
| 03/16/2016 | Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience for Authorized Users of Alpha and Beta Emitters under 10 CFR 35.390, Final Report. | ML16089A271 |
| June 2016 | Final Environmental Assessment | ML16124B050 |
| June 2016 | Final Regulatory Analysis | ML16124B034 |
| June 2016 | NRC Staff Response to the Advisory Committee on the Medical Uses of Isotopes' Part 35 Draft Final Rule—Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments; Final Comments.''. | ML16124B068 |
| June 2016 | Summary of Specific Agreement State and Organization of Agreement States Comments on the Draft Final Rule and Staff Response. | ML16124B069 |
| December 2016 | Final Implementing Guidance | ML16126A441 |

**List of Subjects**

*10 CFR Part 30*

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

*10 CFR Part 32*

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

*10 CFR Part 35*

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Labeling, Medical devices, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 30, 32, and 35:

## PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

■ 1. The authority citation for part 30 continues to read as follows:

**Authority:** Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

■ 2. In § 30.34, add a third sentence to paragraph (g) to read as follows:

**§ 30.34 Terms and conditions of licenses.**

* * * * *

(g) * * * The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter.

* * * * *

## PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

■ 3. The authority citation for part 32 continues to read as follows:

**Authority:** Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note.

■ 4. In § 32.72:

■ a. Revise paragraphs (a)(4) introductory text and (b)(5)(i);

■ b. Redesignate paragraph (d) as paragraph (e); and

■ c. Add new paragraph (d).

The revisions and addition read as follows:

**§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.**

(a) * * *

(4) The applicant commits to the following labeling requirements:

* * * * *

(b) * * *

(5) * * *

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or

* * * * *

(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.

* * * * *

## PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

■ 5. The authority citation for part 35 continues to read as follows:

**Authority:** Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 6. In § 35.2, add in alphabetical order definitions for *Associate Radiation Safety Officer* and *Ophthalmic physicist* and revise the definition of *Preceptor* to read as follows:

### § 35.2 Definitions.

* * * * *

*Associate Radiation Safety Officer* means an individual who—

(1) Meets the requirements in §§ 35.50 and 35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on—

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

* * * * *

*Ophthalmic physicist* means an individual who—

(1) Meets the requirements in §§ 35.433(a)(2) and 35.59; and

(2) Is identified as an ophthalmic physicist on a—

(i) Specific medical use license issued by the Commission or an Agreement State;

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

* * * * *

*Preceptor* means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

* * * * *

■ 7. In § 35.8, revise paragraph (b) to read as follows:

### § 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35.3067, and 35.3204.

* * * * *

■ 8. In § 35.12, revise paragraphs (b)(1), (c)(1) introductory text, (c)(1)(ii), and (d) to read as follows:

### § 35.12 Application for license, amendment, or renewal.

* * * * *

(b) * * *

(1) Filing an original NRC Form 313, ''Application for Material License,'' that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

* * * * *

(c) * * *

(1) Submitting an original of either—

* * * * *

(ii) A letter containing all information required by NRC Form 313; and

* * * * *

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include:

(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

(2) Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific § 35.1000 medical use;

(3) Any additional specific information on—

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) Any other information requested by the Commission in its review of the application.

* * * * *

■ 9. In § 35.13:

■ a. Revise paragraph (b);

■ b. Redesignate paragraphs (d) through (g) as paragraphs (e) through (h);

■ c. Add new paragraph (d);

■ c. Revise newly redesignated paragraphs (g) and (h); and

■ d. Add paragraph (i).

The revisions and additions read as follows:

### § 35.13 License amendments.

* * * * *

(b) Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist—

* * * * *

(d) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

* * * * *

(g) Before it changes the address(es) of use identified in the application or on the license;

(h) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety; and

(i) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

■ 10. In § 35.14, revise paragraphs (a) and (b) to read as follows:

**§ 35.14 Notifications.**

(a) A licensee shall provide the Commission, no later than 30 days after the date that the licensee permits an individual to work under the provisions of § 35.13(b) as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist—

(1) A copy of the board certification and, as appropriate, verification of completion of:

(i) Training for the authorized medical physicist under § 35.51(c);

(ii) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300; or

(iii) Device specific training in § 35.690(c) for the authorized user under § 35.600; or

(2) A copy of the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

(b) A licensee shall notify the Commission no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c);

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter;

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in § 35.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

* * * * *

■ 11. In § 35.15, revise paragraphs (c) and (e) to read as follows:

**§ 35.15 Exemptions regarding Type A specific licenses of broad scope.**

* * * * *

(c) The provisions of § 35.13(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

* * * * *

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;

* * * * *

■ 12. In § 35.24, revise paragraphs (b) and (c) to read as follows:

**§ 35.24 Authority and responsibilities for the radiation protection program.**

* * * * *

(b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

* * * * *

■ 13. In § 35.40:

■ a. Revise paragraph (b)(5);

■ b. Redesignate paragraph (b)(6) as paragraph (b)(7);

■ c. Add new paragraph (b)(6);

■ d. Revise newly redesignated paragraph (b)(7);

■ e. Redesignate paragraph (c) introductory text as paragraph (c)(1); and

■ f. Redesignate paragraph (c)(1) as paragraph (c)(2).

The revisions and addition read as follows:

**§ 35.40 Written directives.**

* * * * *

(b) * * *

(5) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: The treatment site, radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: The radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date.

* * * * *

■ 14. In § 35.41, revise paragraphs (b)(3) and (4) and add paragraphs (b)(5) and (6) to read as follows:

**§ 35.41 Procedures for administrations requiring a written directive.**

* * * * *

(b) * * *

(3) Checking both manual and computer-generated dose calculations;

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;

(5) Determining if a medical event, as defined in § 35.3045, has occurred; and

(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

* * * * *

■ 15. Revise § 35.50 to read as follows:

**§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.**

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to: (1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or an Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or an Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety

Officer, and meets the requirements in paragraph (d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in paragraph (d) of this section.

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

■ 16. In § 35.51, revise paragraphs (a) introductory text, (a)(2)(i), and (b)(2) to read as follows:

**§ 35.51 Training for an authorized medical physicist.**

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(2) * * *

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or

* * * * *

(b) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, § 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

* * * * *

■ 17. In § 35.55, revise paragraphs (a) introductory text and (b)(2) to read as follows:

**§ 35.55 Training for an authorized nuclear pharmacist.**

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b) * * *

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

■ 18. In § 35.57, revise paragraphs (a) and (b) to read as follows:

**§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.**

(a)(1) An individual identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of § 35.50, § 35.51, or § 35.55, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of § 35.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in § 35.51, for those materials and uses that these individuals performed on or before October 24, 2005.

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 35.50, § 35.51 or § 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master

material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(i) For uses authorized under § 35.100 or § 35.200, or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under § 35.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under § 35.400 or § 35.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British ''Fellow of the Faculty of Radiology'' or ''Fellow of the Royal College of Radiology''; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under § 35.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

* * * * *

■ 19. Revise § 35.65 to read as follows:

**§ 35.65 Authorization for calibration, transmission, and reference sources.**

(a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCI) or 1000 times the quantities in appendix B of part 30 of this chapter; or

(5) Technetium-99m in amounts as needed.

(b) Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in § 35.2 except in accordance with the requirements in § 35.500; or

(2) Combined (*i.e.,* bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph (a) or (b) of this section need not list these sources on a specific medical use license.

■ 20. In § 35.190, revise paragraphs (a) introductory text and (c)(2) to read as follows:

**§ 35.190 Training for uptake, dilution, and excretion studies.**

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(c) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.190, § 35.290, or § 35.390, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.190, § 35.290, or § 35.390, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the

Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

■ 21. In § 35.204, revise paragraph (b) and add paragraph (e) to read as follows:

**§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

* * * * *

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (a) of this section.

* * * * *

(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204.

■ 22. In § 35.290, revise paragraphs (a) introductory text, (c)(1)(ii) introductory text, and (c)(2) to read as follows:

**§ 35.290 Training for imaging and localization studies.**

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(c)(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in § 35.55 or § 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve—

* * * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

■ 23. In § 35.300, revise the introductory text to read as follows:

**§ 35.300 Use of unsealed byproduct material for which a written directive is required.**

A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—

* * * * *

■ 24. In § 35.390, revise paragraphs (a) introductory text, (b)(1)(ii)(G), and (b)(2) to read as follows:

**§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.**

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) * * *

(G) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under § 35.1000. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(*1*) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

(*2*) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131; [2]

(*3*) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association

[2] Experience with at least three cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

and must include training and experience specified in paragraph (b)(1) of this section.

* * * * *

■ 25. In § 35.392, revise paragraphs (a) and (c)(3) to read as follows:

**§ 35.392 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).**

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (2) of this section and whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.392, § 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.390, § 35.392, § 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.

■ 26. In § 35.394, revise paragraphs (a) and (c)(3) to read as follows:

**§ 35.394 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).**

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (2) of this section, and whose certification has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.390, § 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.

■ 27. Revise § 35.396 to read as follows:

**§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.**

(a) Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(1) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(3), or equivalent Agreement State requirements; or

(2) Is an authorized user under § 35.490, § 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraph (b) of this section; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.490 or § 35.690, and who meets the requirements in paragraph (b) of this section.

(b) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). A supervising authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include

at least three cases of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(*3*); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

■ 28. Revise § 35.400 to read as follows:

**§ 35.400 Use of sources for manual brachytherapy.**

A licensee must use only brachytherapy sources:

(a) Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

■ 29. Revise § 35.433 to read as follows:

**§ 35.433 Strontium-90 sources for ophthalmic treatments.**

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(A) The creation, modification, and completion of written directives;

(B) Procedures for administrations requiring a written directive; and

(C) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

(b) The individuals who are identified in paragraph (a) of this section must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

■ 30. In § 35.490, revise paragraphs (a) introductory text, (b)(1)(ii) introductory text, and (b)(3) to read as follows:

**§ 35.490 Training for use of manual brachytherapy sources.**

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.490, or equivalent Agreement State requirements, at a medical facility authorized to use byproduct materials under § 35.400, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.490, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.490, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

■ 31. In § 35.491, revise paragraph (b)(3) to read as follows:

**§ 35.491 Training for ophthalmic use of strontium-90.**

* * * * *

(b) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.57, § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

■ 32. Revise § 35.500 to read as follows:

**§ 35.500 Use of sealed sources and medical devices for diagnosis.**

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

■ 33. Revise § 35.590 to read as follows:

**§ 35.590 Training for use of sealed sources and medical devices for diagnosis.**

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (c) and (d) of this section and whose certification has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

(b) Is an authorized user for uses listed in § 35.200 or equivalent Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

■ 34. Revise § 35.600 to read as follows:

**§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.**

(a) A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

■ 35. In § 35.610, revise paragraphs (d) and (g) to read as follows:

**§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

* * * * *

(d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—

(i) The procedures identified in paragraph (a)(4) of this section; and

(ii) The operating procedures for the unit.

* * * * *

(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.

■ 36. In § 35.655, revise the section heading and paragraph (a) to read as follows:

**§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.**

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

* * * * *

■ 37. In § 35.690, revise paragraphs (a) introductory text, (b)(1)(ii) introductory text, and (b)(3) to read as follows:

**§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized,

a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.690, or equivalent Agreement State requirements, at a medical facility that is authorized to use byproduct materials in § 35.600, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) and (c) of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.690, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

* * * * *

■ 38. In § 35.2024, add paragraph (c) to read as follows:

**§ 35.2024 Records of authority and responsibilities for radiation protection programs.**

* * * * *

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

■ 39. Revise § 35.2310 to read as follows:

**§ 35.2310 Records of safety instruction.**

A licensee shall maintain a record of safety instructions required by §§ 35.310 and 35.410 and the operational and safety instructions required by § 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

■ 40. In § 35.2655, revise the section heading and paragraph (a) to read as follows:

**§ 35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.**

(a) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the use of the unit.

* * * * *

■ 41. In § 35.3045, revise paragraph (a) to read as follows:

**§ 35.3045 Report and notification of a medical event.**

(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

* * * * *

■ 42. Add § 35.3204 to subpart M to read as follows:

**§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

(a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator

within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.

Dated at Rockville, Maryland, this 6th day of July 2018.

For the Nuclear Regulatory Commission.

**Russell E. Chazell,**

*Acting Secretary of the Commission.*

[FR Doc. 2018–14852 Filed 7–13–18; 8:45 am]

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# FEDERAL REGISTER

Vol. 83 Monday,

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Part V

## The President

Executive Order 13844—Establishment of the Task Force on Market Integrity and Consumer Fraud

Federal Register
Vol. 83, No. 136
Monday, July 16, 2018

# Presidential Documents

**Title 3—**

## The President

**Executive Order 13844 of July 11, 2018**

## Establishment of the Task Force on Market Integrity and Consumer Fraud

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to strengthen the efforts of the Department of Justice and Federal, State, local, and tribal agencies to investigate and prosecute crimes of fraud committed against the U.S. Government or the American people, recover the proceeds of such crimes, and ensure just and effective punishment of those who perpetrate crimes of fraud, it is hereby ordered as follows:

**Section 1**. *Establishment.* The Attorney General shall establish within the Department of Justice a Task Force on Market Integrity and Consumer Fraud (Task Force).

**Sec. 2**. *Membership and Operation.* (a) The Task Force shall include the following members:

(i) the Deputy Attorney General, who shall serve as the Chair;

(ii) the Associate Attorney General, who shall serve as the Vice Chair;

(iii) the Assistant Attorney General (Criminal Division);

(iv) the Assistant Attorney General (Civil Division);

(v) the Assistant Attorney General (Tax Division);

(vi) the Assistant Attorney General (Antitrust Division);

(vii) the Director of the Federal Bureau of Investigation;

(viii) United States Attorneys designated by the Attorney General; and

(ix) such other officers or employees of the Department of Justice as the Attorney General may from time to time designate.

(b) The Deputy Attorney General shall convene and direct the work of the Task Force in fulfilling its functions under this order. The Deputy Attorney General may permit, when appropriate, the designee of a member of the Task Force, including participants invited under section 3 of this order, to participate in lieu of the member or participant. The Deputy Attorney General shall convene the Task Force at such times as the Deputy Attorney General deems appropriate.

**Sec. 3**. *Additional Participation for Specified Functions.* In the Task Force's performance of the functions set forth in subsection 4(a) and (c) of this order, and to the extent permitted by law, the Attorney General, or the Deputy Attorney General as his designee, shall periodically convene meetings and shall invite participation from the following senior officials from executive departments and agencies (agencies), or their designees, as well as such other officials of the Federal Government as the Attorney General or Deputy Attorney General deems appropriate:

(a) the Secretary of the Treasury;

(b) the Secretary of Defense;

(c) the Secretary of Health and Human Services;

(d) the Secretary of Housing and Urban Development;

(e) the Secretary of Energy;

(f) the Secretary of Education;

(g) the Secretary of Veterans Affairs;

(h) the Secretary of Homeland Security;

(i) the Administrator of the Small Business Administration;

(j) the Chairman of the Board of Governors of the Federal Reserve System;

(k) the Commissioner of Social Security;

(l) the Administrator of the United States Agency for International Development;

(m) the Director of the Bureau of Consumer Financial Protection;

(n) the Chairman of the Federal Trade Commission;

(o) the Chairman of the Securities and Exchange Commission;

(p) the Administrator of General Services;

(q) the Chairman of the National Credit Union Administration;

(r) the Chairman of the Commodity Futures Trading Commission;

(s) the Chairperson of the Board of Directors of the Federal Deposit Insurance Corporation;

(t) the Director of the Federal Housing Finance Agency;

(u) the Comptroller of the Currency; and

(v) the Chief Postal Inspector for the Postal Inspection Service.

**Sec. 4**. *Functions.* Consistent with the authorities assigned to the Attorney General by law, and other applicable law, the Task Force shall:

(a) provide guidance for the investigation and prosecution of cases involving fraud on the government, the financial markets, and consumers, including cyber-fraud and other fraud targeting the elderly, service members and veterans, and other members of the public; procurement and grant fraud; securities and commodities fraud, as well as other corporate fraud, with particular attention to fraud affecting the general public; digital currency fraud; money laundering, including the recovery of proceeds; health care fraud; tax fraud; and other financial crimes;

(b) provide recommendations to the Attorney General on fraud enforcement initiatives across the Department of Justice and on any matters the Task Force determines from time to time to be important in the investigation and prosecution of fraud and other financial crimes; and

(c) make recommendations to the President, through the Attorney General for:

(i) action to enhance cooperation among agencies in the investigation and prosecution of fraud and other financial crimes;

(ii) action to enhance cooperation among Federal, State, local, and tribal authorities in connection with the detection, investigation, and prosecution of fraud and other financial crimes; and

(iii) changes in rules, regulations, or policy, or recommendations to the Congress regarding legislative measures, to improve the effective investigation and prosecution of fraud and other financial crimes.

**Sec. 5**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

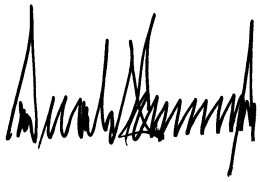
(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This Task Force shall replace the Financial Fraud Enforcement Task Force created by Executive Order 13519 of November 17, 2009 (Establishment of the Financial Fraud Enforcement Task Force). The Financial Fraud Enforcement Task Force is hereby terminated pursuant to section 8 of Executive Order 13519 and that order is hereby revoked.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

**Sec. 6**. *Termination.* The Task Force shall terminate when directed by the President or, with the approval of the President, by the Attorney General.



THE WHITE HOUSE,
*July 11, 2018.*

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# Reader Aids

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## CUSTOMER SERVICE AND INFORMATION

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