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# Rules and Regulations

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

The Code of Federal Regulations is sold by the Superintendent of Documents.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2018-0439; Product Identifier 2016-SW-074-AD; Amendment 39-19409; AD 2018-19-09]

RIN 2120-AA64

#### Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

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

**ACTION:** Final rule.

**SUMMARY:** We are superseding Airworthiness Directive (AD) 2017-14-03 for Sikorsky Aircraft Corporation (Sikorsky) Model S-92A helicopters. AD 2017-14-03 required an inspection and reduced the retirement lives of certain landing gear components. This new AD retains the requirements of AD 2017-14-03, reduces the retirement lives of additional landing gear components, and requires repeating the inspection. This AD was prompted by a revised analysis of the fatigue life of the landing gear. The actions of this AD are intended to prevent an unsafe condition on these products.

**DATES:** This AD is effective October 30, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 11, 2017 (82 FR 34838, July 27, 2017).

**ADDRESSES:** For service information identified in this final rule, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1-800-Winged-S or 203-416-4299; email [wcs\\_cust\\_service\\_eng\\_gr-sik@lmco.com](mailto:wcs_cust_service_eng_gr-sik@lmco.com). Operators may also log on to the Sikorsky 360 website at <https://www.sikorsky360.com>. You may view this referenced service

information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0439.

#### Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> in Docket No. FAA-2018-0439; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference information, the economic evaluation, any comments received, and other information. The address for Docket Operations (phone: 800-647-5527) is Docket Operations, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Dorie Resnik, Aviation Safety Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238-7693; email [dorie.resnik@faa.gov](mailto:dorie.resnik@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to remove AD 2017-14-03, Amendment 39-18947 (82 FR 34838, July 27, 2017) (AD 2017-14-03) and add a new AD. AD 2017-14-03 applied to Sikorsky Model S-92A helicopters and required inspecting and reducing the retirement lives of certain landing gear components. AD 2017-14-03 was prompted by Sikorsky's updated fatigue analysis of the nose and main landing gear, which revealed that certain components required a reduced service life and one component required a repetitive visual and ultrasonic inspection. When we issued AD 2017-14-03, we determined that the age of the existing U.S. fleet and the compliance time for the repetitive inspection would allow enough time for notice and public comments on some actions.

The NPRM published in the **Federal Register** on May 17, 2018 (83 FR 22883). The NPRM proposed to retain the

actions in AD 2017-14-03, reduce the life limits of additional components, and require repeating the visual and ultrasonic inspections. These actions are intended to detect and prevent cracks or failure of a landing gear component, which could result in damage and loss of control of the helicopter.

#### Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

#### FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of this same type design and that air safety and the public interest require adopting the AD requirements as proposed.

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

We reviewed Ultrasonic Inspection Technique No. UT 5077, Revision 0, dated July 25, 2014 (UT 5077). UT 5077 contains the inspection method, equipment and materials, calibration, and inspection procedure for performing an ultrasonic inspection of nose gear actuator fitting part number (P/N) 92209-01101-101.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

#### Other Related Service Information

We also reviewed Sikorsky S-92 Helicopter Alert Service Bulletin 92-32-004, Basic Issue, dated January 30, 2015 (ASB). The ASB describes procedures for conducting a visual inspection of the nose landing gear (NLG) airframe fitting assembly and an ultrasonic inspection by following the procedures in UT 5077.

#### Costs of Compliance

We estimate that this AD affects 80 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of \$85 per work-hour:

- Replacing a wheel axle P/N 2392-2334-001 requires 2 work-hours and required parts cost \$22,000, for a cost per helicopter of \$22,170.



- Replacing a main landing gear (MLG) or NLG threaded hinge pin P/N 2392-2311-003 requires 1 work-hour and required parts cost \$3,800, for a cost per helicopter of \$3,885.
- Replacing a NLG cylinder P/N 2392-4006-005 requires 1 work-hour and required parts cost \$27,200, for a cost per helicopter of \$27,285.
- Replacing a NLG hinge pin P/N 2392-4312-003 requires 1 work-hour and required parts cost \$4,400, for a cost per helicopter of \$4,485.
- Replacing a landing gear actuator rod end P/N 2392-0876-901 requires 1 work-hour and required parts cost \$900, for a cost per helicopter of \$985.
- Replacing a MLG cylinder P/N 2392-2006-005 requires 2 work-hours and required parts cost \$33,100, for a cost per helicopter of \$33,270.
- Replacing a MLG pin outboard P/N 2392-2312-003 requires 1 work-hour and required parts cost \$4,300, for a cost per helicopter of \$4,385.
- Replacing a MLG bulkhead left-hand side P/N 92201-08111-105, -107, and -109 requires 70 work-hours and required parts cost \$12,550, for a cost per helicopter of \$18,500.
- Replacing a MLG bulkhead right-hand side P/N 92201-08111-106, -108, and -110 requires 70 work-hours and required parts cost \$12,550, for a cost per helicopter of \$18,500.
- Inspecting the NLG airframe fitting assembly P/N 92209-01101-041 requires 8 work-hours, and required parts cost is minimal, for a cost of \$680 per helicopter and \$54,400 for the U.S. fleet, per inspection cycle.
- If required, replacing a NLG actuator fitting P/N 92209-01101-101 requires 70 work-hours, and required parts cost \$10,000, for a cost per helicopter of \$15,950.

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

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

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

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

**Adoption of the Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2017-14-03, Amendment 39-18947 (82 FR 34838, July 27, 2017), and adding the following new AD:

**2018-19-09 Sikorsky Aircraft Corporation (Sikorsky):** Amendment 39-19409; Docket No. FAA-2018-0439; Product Identifier 2016-SW-074-AD.

**(a) Applicability**

This AD applies to Sikorsky Model S-92A helicopters, certificated in any category.

**(b) Unsafe Condition**

This AD defines the unsafe condition as fatigue failure of the landing gear. This condition could result in failure of the landing gear and subsequent damage to and loss of control of the helicopter.

**(c) Affected ADs**

This AD replaces AD 2017-14-03, Amendment 39-18947 (82 FR 34838, July 27, 2017).

**(d) Effective Date**

This AD becomes effective October 30, 2018.

**(e) Compliance**

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

**(f) Required Actions**

- (1) Before further flight, remove from service any part that has accumulated the number of landing cycles listed in Table 1 to paragraph (f)(1) of this AD. Thereafter, remove from service any part before accumulating the number of landing cycles listed in Table 1 to paragraph (f)(1) of this AD. For purposes of this AD, a landing cycle is counted anytime the helicopter lifts off into the air and then lands again regardless of the duration of the landing and regardless of whether the engine is shut down. If the number of landing cycles is unknown, multiply the number of hours time-in-service by 4.5 to determine the number of landing cycles.

TABLE 1 TO PARAGRAPH (f)(1)

Part name	Part No. (P/N)	Life limit
Main landing gear (MLG) wheel axle .....	2392-2334-001	22,300 landing cycles.
MLG or nose landing gear (NLG) threaded hinge pin .....	2392-2311-003	26,100 landing cycles.
NLG cylinder .....	2392-4006-005	26,300 landing cycles.
NLG hinge pin .....	2392-4312-003	26,700 landing cycles.
Landing gear actuator rod end .....	2392-0876-901	41,700 landing cycles.
MLG cylinder .....	2392-2006-005	76,300 landing cycles.
MLG pin outboard .....	2392-2312-003	50,300 landing cycles.

TABLE 1 TO PARAGRAPH (f)(1)—Continued

Part name	Part No. (P/N)	Life limit
MLG bulkhead (left-hand side) .....	92201-08111-105 92201-08111-107 92201-08111-109	58,400 landing cycles.
MLG bulkhead (right-hand side) .....	92201-08111-106 92201-08111-108 92201-08111-110	58,400 landing cycles.

(2) For helicopters with 31,600 or more landing cycles and an NLG airframe fitting assembly P/N 92209-01101-041 installed, before further flight and thereafter at intervals not to exceed 1,989 landing cycles:

(i) Using a 10X or higher power magnifying glass, inspect each bushing (P/N 92209-01101-102 and P/N 92209-01101-103) and all visible surfaces of mating lug fittings adjacent to each bushing for fretting, corrosion, wear, and scratches. If there is fretting, corrosion, wear, or a scratch more than 0.0005 inch deep, replace the NLG airframe fitting assembly before further flight.

(ii) Ultrasonic inspect each NLG actuator fitting P/N 92209-01101-101 in accordance with Sikorsky Ultrasonic Inspection Technique No. UT 5077, Revision 0, dated July 25, 2014 (UT 5077), except you are not required to report to or contact Sikorsky. If there are any anomalies or suspect indications, replace the NLG actuator fitting before further flight.

**Note 1 to paragraph (f)(2)(ii) of this AD:** A copy of UT 5077 is attached to Sikorsky S-92 Helicopter Alert Service Bulletin 92-32-004, Basic Issue, dated January 30, 2015.

**(g) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Boston ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Dorie Resnik, Aviation Safety Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238-7693; email [dorie.resnik@faa.gov](mailto:dorie.resnik@faa.gov).

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

**(h) Additional Information**

Sikorsky S-92 Helicopter Alert Service Bulletin 92-32-004, Basic Issue, dated January 30, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1-800-Winged-S or 203-416-4299; email [wcs\\_cust\\_service\\_eng.gr-sik@lmco.com](mailto:wcs_cust_service_eng.gr-sik@lmco.com). Operators may also log on to the Sikorsky 360 website at

<https://www.sikorsky360.com>. You may review this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

**(i) Subject**

Joint Aircraft Service Component (JASC) Code: 3200 Main Landing Gear and 3220 Nose Landing Gear.

**(j) Material Incorporated by Reference**

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

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

(3) The following service information was approved for IBR on August 11, 2017 (82 FR 34838, July 27, 2017).

(i) Ultrasonic Inspection Technique No. UT 5077, Revision 0, dated July 25, 2014.

**Note 2 to paragraph (j)(3)(i):** Ultrasonic Inspection Technique No. UT 5077, Revision 0, dated July 25, 2014, is an attachment to Sikorsky S-92 Helicopter Alert Service Bulletin 92-32-004, Basic Issue, dated January 30, 2015, which is not incorporated by reference.

(ii) Reserved.

(4) For Sikorsky service information identified in this AD, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1-800-Winged-S or 203-416-4299; email [wcs\\_cust\\_service\\_eng.gr-sik@lmco.com](mailto:wcs_cust_service_eng.gr-sik@lmco.com). Operators may also log on to the Sikorsky 360 website at <https://www.sikorsky360.com>.

(5) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

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

Issued in Fort Worth, Texas, on September 12, 2018.

**Scott A. Horn,**

*Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2018-20488 Filed 9-24-18; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

**[Docket No. FAA-2017-0867; Product Identifier 2017-CE-021-AD; Amendment 39-19411; AD 2018-19-11]**

**RIN 2120-AA64**

**Airworthiness Directives; Viking Air Limited Airplanes**

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for all Viking Air Limited Models DHC-2 Mk. I, DHC-2 Mk. II, and DHC-2 Mk. III airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracking found in the wing rear spar web at the wing station where the flap outboard hinge is attached. We are issuing this AD to require actions to address the unsafe condition on these products.

**DATES:** This AD is effective October 30, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 30, 2018.

**ADDRESSES:** You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0867; or in person at Document

Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

For service information identified in this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663-8444; fax: (250) 656-0673; email: [technical.support@vikingair.com](mailto:technical.support@vikingair.com); internet: <http://www.vikingair.com/support/service-bulletins>. You may view this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the internet at <http://www.regulations.gov> by searching for Docket No. FAA-2017-0867.

**FOR FURTHER INFORMATION CONTACT:** Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7329; fax: (516) 794-5531; email: [aziz.ahmed@faa.gov](mailto:aziz.ahmed@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Viking Air Limited Models DHC-2 Mk. I, DHC-2 Mk. II, and DHC-2 Mk. III airplanes. The SNPRM published in the **Federal Register** on May 7, 2018 (83 FR 19983). We preceded the SNPRM with a notice of proposed rulemaking (NPRM) that published in the **Federal Register** on September 8, 2017 (82 FR 42489). The NPRM proposed to require inspecting the wing rear spar and flap/aileron support brackets within 400 hours time-in-service (TIS) and reporting the results to the manufacturer. The NPRM was based on mandatory continuing airworthiness information (MCAI) originated by Transport Canada, the aviation authority for Canada. The MCAI states:

It was reported that a crack was found in the wing rear spar web, part number C2W1007, at wing station 123.5 where the flap outboard hinge is attached. An aileron hinge bracket has also been found cracked. Viking Air Ltd. analysis shows that similar cracks may develop on the wing rear spar web and flap/aileron hinge arm support brackets at the other flap/aileron hinge attachment locations.

Undetected cracking of the wing rear spar or flap/aileron hinge bracket may lead to the failure of the component with consequent loss of aeroplane control.

The MCAI requires inspecting the left-hand and right-hand wing rear spar and the flap/aileron hinge air support brackets for cracks, damage, or discrepancies and repairing or replacing any parts with cracks, damage, or discrepancies. The MCAI can be found in the AD docket on the internet at <https://www.regulations.gov/document?D=FAA-2017-0867-0002>.

The SNPRM proposed to revise the compliance times to require the inspections within 400 hours TIS or 6 months, whichever occurs first, to match the compliance times in the MCAI.

**Comments**

We gave the public the opportunity to participate in developing this AD. We received no comments on the SNPRM or on the determination of the cost to the public.

**Conclusion**

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

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

Viking Air Limited has issued Viking DHC-2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017. The service information describes procedures for inspecting the left-hand and right-hand wing rear spars, the flap/aileron hinge brackets, and the exterior store support bracket for cracks, damage, and discrepancies. The service information also specifies repairing or replacing any parts that have cracks, damage, or discrepancies. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

**Interim Action**

We consider this AD interim action. The inspection report required by this AD allows us to obtain better information into the nature, cause, and extent of the damage to the wing rear spars and flap/aileron hinge arm support brackets and to develop final action to address the unsafe condition. After evaluating the inspection results, we may consider further rulemaking.

**Costs of Compliance**

We estimate that this AD will affect 140 products of U.S. registry. We also estimate that it will take about 11 work-hours per product to comply with the basic inspection requirements of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the basic cost of this AD on U.S. operators to be \$130,900, or \$935 per product.

Reporting the inspection findings would require about 5 minutes, for a cost of \$7 per airplane and \$980 for the U.S. operator fleet.

In addition, the following is an estimate of possible necessary follow-on replacement actions. We have no way of determining the number of products that may need these actions.

Part No.	Left-hand (LH) or right-hand (RH) wing	Description	Number per airplane	Parts cost	Number of work-hours to replace
C2W123A .....	Both (one per wing) ..	Hinge bracket LH inboard (flap)/RH outboard (aileron).	2	<sup>2</sup> 288	<sup>2</sup> 12
C2W124A .....	Both (one per wing) ..	Hinge bracket RH inboard (flap)/LH outboard (aileron).	2	<sup>2</sup> 288	<sup>2</sup> 12
C2W143 .....	Both (four per wing) ..	Hinge bracket, flap and aileron (common part—multiple wing stations (WS)).	8	<sup>3</sup> 271	<sup>3</sup> 12
C2W143A (Agricultural Option).	Both (one per wing) ..	Agricultural (optional configuration)—hinge bracket, support arm (IPC PSM 1-2-4 Figure 128, Item 15).	12	<sup>2</sup> 271	<sup>2</sup> 12
C2W63 .....	LH .....	Inboard spar, rear spar .....	.....	277	60

Part No.	Left-hand (LH) or right-hand (RH) wing	Description	Number per airplane	Parts cost	Number of work-hours to replace
C2W64 .....	RH .....	Inboard spar, rear spar .....	.....	277	60
C2W155 .....	Both (one per wing) ..	Intermediate spar .....	2	<sup>2</sup> 563	<sup>2</sup> 60
C2W65A .....	LH .....	Spar WS 89.16 to WS 170.16 .....	* 1	835	60
C2W66A .....	RH .....	Spar WS 89.16 to WS 170.16 .....	* 1	835	60
C2W67A .....	LH .....	Outboard spar, WS 170.16 to WS 245.75 ...	* 1	835	60
C2W68A .....	RH .....	Outboard spar, WS 170.16 to WS 245.75 ...	* 1	835	60

\* To replace any wing spar section takes 60 work-hours. To replace all four wing spar sections per wing takes 240 work-hours.

<sup>1</sup> (If applies).

<sup>2</sup> For both.

<sup>3</sup> For all eight.

**Paperwork Reduction Act**

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

**Authority for This Rulemaking**

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

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

products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

**Regulatory Findings**

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

For the reasons discussed above, I certify this AD:

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

**Examining the AD Docket**

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0867; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the SNPRM, the regulatory evaluation, any

comments received, and other information. The street address for Docket Operations (telephone (800) 647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

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

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

**Adoption of the Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

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

**2018-19-11 Viking Air Limited:**

Amendment 39-19411; Docket No. FAA-2017-0867; Product Identifier 2017-CE-021-AD.

**(a) Effective Date**

This AD becomes effective October 30, 2018.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to Viking Air Limited Models DHC-2 Mk. I, DHC-2 Mk. II, and DHC-2 Mk. III airplanes, all serial numbers, certificated in any category.

**(d) Subject**

Air Transport Association of America (ATA) Code 57: Wings.

**(e) Reason**

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI

describes the unsafe condition as cracking found in the wing rear spar web at the wing station (WS) where the flap outboard hinge is attached. We are issuing this AD to detect and correct cracks in the wing rear spars and the flap/aileron hinge arm support brackets. This condition, if not corrected, could result in structural failure with consequent loss of control of the airplane.

#### (f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (5) of this AD:

(1) Within 400 hours time-in-service (TIS) after October 30, 2018 (the effective date of this AD) or within 6 months after October 30, 2018 (the effective date of this AD), whichever occurs first, visually inspect the left-hand and right-hand wing rear spar and flap/aileron hinge arm support brackets by following the Accomplishment Instructions of Viking DHC-2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017 (SB V2/0009, Revision A).

(2) For airplanes with an agricultural configuration installed (SOO Mod 2/984), within 400 hours TIS after October 30, 2018 (the effective date of this AD) or within 6 months after October 30, 2018 (the effective date of this AD), whichever occurs first, inspect the exterior store support arm bracket at WS 101.24 by following the Accomplishment Instructions of SB V2/0009, Revision A.

(3) If any discrepancies are found during the inspections required in paragraphs (f)(1) and (2) of this AD, before further flight, repair or replace using a method approved by the Manager, New York ACO Branch, FAA; Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Within 30 days after completing the inspections required in paragraphs (f)(1) and (2) of this AD, using the Operator Reply Form on page 7 of SB V2/0009, Revision A, report the inspection results to Viking Air Limited at the address specified in paragraph (i)(3) of this AD.

(5) As of October 30, 2018 (the effective date of this AD), do not install a wing on any airplane affected by this AD unless it has been inspected as specified in paragraphs (f)(1) of this AD and paragraph (f)(2) of this AD, if applicable, and is found free of any discrepancies.

#### (g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7329; fax: (516) 794-5531; email: [aziz.ahmed@faa.gov](mailto:aziz.ahmed@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight

Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements*: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

#### (h) Related Information

Refer to MCAI Transport Canada AD Number CF-2017-17, dated May 18, 2017, for related information. You may examine the MCAI on the internet at <https://www.regulations.gov/document?D=FAA-2017-0867-0002>.

#### (i) Material Incorporated by Reference

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

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

(i) Viking DHC-2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017.

(ii) Reserved.

(3) For Viking DHC-2 Beaver service information identified in this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663-8444; fax: (250) 656-0673; email: [technical.support@vikingair.com](mailto:technical.support@vikingair.com); internet: <http://www.vikingair.com/support/service-Bulletins>.

(4) You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. In addition, you can access this service information on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0867.

[www.regulations.gov](http://www.regulations.gov) by searching for and locating Docket No. FAA-2017-0867.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on September 7, 2018

**Melvin J. Johnson,**

*Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR-601.*

[FR Doc. 2018-20802 Filed 9-24-18; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2018-0438; Product Identifier 2017-SW-062-AD; Amendment 39-19410; AD 2018-19-10]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Helicopters

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, and AS355N helicopters. This AD requires measuring a vibration level in the tail rotor (T/R) drive. This AD was prompted by reports of bearing degradation. The actions of this AD are intended to prevent an unsafe condition on these helicopters.

**DATES:** This AD is effective October 30, 2018.

**ADDRESSES:** For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at [http://www.helicopters.airbus.com/website/en/ref/Technical-Support\\_73.html](http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html). You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

#### Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0438; or in person at Docket Operations

between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Rao Edupuganti, Aviation Safety Engineer, Regulations and Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email [rao.edupuganti@faa.gov](mailto:rao.edupuganti@faa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Discussion**

On May 17, 2018, at 83 FR 22886, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, and AS355N helicopters. The NPRM proposed to require measuring the T/R drive vibration level without balancing, cleaning the fan, and repeating the vibration level measurement. If the difference between the two amplitude values is greater than 0.75 inch per second (ips), the NPRM proposed to require replacing each T/R fan bearing. The proposed requirements were intended to prevent degradation of the main gearbox (MGB) oil cooler fan bearing (bearing), which could result in loss of MGB and engine oil cooling function, loss of the rear transmission, and subsequent loss of control of the helicopter.

The NPRM was prompted by AD No. 2017-0159, dated August 25, 2017, issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, and AS355N helicopters. EASA advises of two occurrences on Model AS355 military helicopters in which the MGB bearing installed on the T/R drive shaft experienced significant degradation. EASA states that while investigation has not determined the cause of the failures, this condition may also occur on other Model AS355 helicopters due to design commonality. According to EASA, this condition, if not detected and corrected, could result in loss of MGB and engine oil cooling function, loss of the rear transmission, and subsequent loss of

control of the helicopter. To address this unsafe condition and as an interim measure, the EASA AD requires two vibration level measurements of the forward portion of the tail rotor drive line, one before and one after cleaning the MGB oil cooler fan, and replacing the bearings if excessive level or level trends are detected. The EASA AD also specifies that after the effective date of the AD, only those MGB oil cooler fan assembly bearings that are new or that have passed the vibration level measurements may be installed.

##### **Comments**

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

##### **FAA's Determination**

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of the same type design and that air safety and the public interest require adopting the AD requirements as proposed.

##### **Interim Action**

We consider this AD to be an interim action. The manufacturer is currently developing a terminating action for the unsafe condition described in this AD. If a terminating action is identified, we may consider further rulemaking then.

##### **Related Service Information**

Airbus Helicopters has issued Alert Service Bulletin No. AS355-05.00.77, Revision 0, dated July 3, 2017, which contains procedures for checking the condition of the fan assembly bearings by measuring the vibration levels of the first section of the T/R drive.

##### **Costs of Compliance**

We estimate that this AD affects 104 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD.

At an average labor rate of \$85 per work-hour, measuring the vibration levels requires about 5 work-hours, for a cost of \$425 per helicopter and \$44,200 for the U.S. fleet. If required, replacing both fan assembly bearings requires about 8 work-hours, and required parts cost \$1,064, for a cost of \$1,744 per helicopter.

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

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

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

##### **Regulatory Findings**

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

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

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

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

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

##### **Adoption of the Amendment**

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

##### **PART 39—AIRWORTHINESS DIRECTIVES**

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

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

### § 39.13 [Amended]

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

#### 2018–19–10 Airbus Helicopters:

Amendment 39–19410; Docket No. FAA–2018–0438; Product Identifier 2017–SW–062–AD.

#### (a) Applicability

This AD applies to Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, and AS355N helicopters, certificated in any category.

#### (b) Unsafe Condition

This AD defines the unsafe condition as degradation of a main gearbox (MGB) oil cooler fan assembly bearing. This condition could result in loss of MGB and engine oil cooling function, loss of the rear transmission, and subsequent loss of control of the helicopter.

#### (c) Effective Date

This AD becomes effective October 30, 2018.

#### (d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

#### (e) Required Actions

(1) Within 165 hours time-in-service (TIS):

(i) Measure the tail rotor (T/R) drive vibration level without balancing the T/R drive, and record the amplitude value.

(ii) Clean the oil cooler fan.

(iii) Measure the T/R drive vibration level without balancing the T/R drive, and record the amplitude value.

(iv) Calculate the difference between the two amplitude values. If the difference is greater than 0.75 inch per second (ips), before further flight, replace each oil cooler fan assembly bearing.

(2) After the effective date of this AD, do not install an oil cooler fan assembly bearing with more than 0 hours TIS unless the requirements of this AD have been accomplished.

#### (f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Rao Edupuganti, Aviation Safety Engineer, Regulations and Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email [9-ASW-FTW-AMOC-Requests@faa.gov](mailto:9-ASW-FTW-AMOC-Requests@faa.gov).

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

#### (g) Additional Information

(1) Airbus Helicopters Alert Service Bulletin No. AS355–05.00.77, Revision 0, dated July 3, 2017, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at [http://www.helicopters.airbus.com/website/en/ref/Technical-Support\\_73.html](http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html). You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2017–0159, dated August 25, 2017. You may view the EASA AD on the internet at <http://www.regulations.gov> in Docket No. FAA–2018–0438.

#### (h) Subject

Joint Aircraft Service Component (JASC) Code: 6510, Tail Rotor Driveshaft.

Issued in Fort Worth, Texas, on September 12, 2018.

#### Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–20487 Filed 9–24–18; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 91

[Docket No.: FAA–2018–0838; Amdt. No. 91–352]

RIN 2120–AL34

#### Amendment of the Prohibition Against Certain Flights in the Pyongyang Flight Information Region (FIR) (ZKKP)

##### Correction

In rule document 2018–20173 appearing on pages 47059–47065 in the issue of September 18, 2018, make the following correction:

On page 47061, in the second column, in the third line, “September 18, 2010” should read “September 18, 2020”.

[FR Doc. C1–2018–20173 Filed 9–24–18; 8:45 am]

BILLING CODE 1301–00–D

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 97

[Docket No. 31213; Amdt. No. 3817]

#### 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 September 25, 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 September 25, 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](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](http://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 September 7, 2018.

**Rick Domingo,**

*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 11 October 2018**

Alton/St Louis, IL, St Louis Rgnl, ILS OR LOC RWY 29, Amdt 12B  
 Alton/St Louis, IL, St Louis Rgnl, RNAV (GPS) RWY 11, Amdt 2B  
 Alton/St Louis, IL, St Louis Rgnl, RNAV (GPS) RWY 17, Amdt 1B  
 Alton/St Louis, IL, St Louis Rgnl, RNAV (GPS) RWY 29, Amdt 1B  
 Peru, IN, Peru Muni, RNAV (GPS) RWY 19, Amdt 1A  
 Peru, IN, Peru Muni, VOR RWY 1, Amdt 8D  
 Marquette, MI, Sawyer Intl, Takeoff Minimums and Obstacle DP, Amdt 1  
 South Haven, MI, South Haven Area Rgnl, RNAV (GPS) RWY 5, Amdt 1E  
 South Haven, MI, South Haven Area Rgnl, RNAV (GPS) RWY 23, Amdt 1E  
 South Haven, MI, South Haven Area Rgnl, VOR RWY 23, Amdt 11B  
 Mankato, MN, Mankato Rgnl, VOR RWY 15, Amdt 7B  
 Chillicothe, MO, Chillicothe Muni, RNAV (GPS) RWY 14, Orig-A  
 Buffalo, NY, Buffalo Niagara Intl, ILS OR LOC RWY 5, Amdt 17A  
 Buffalo, NY, Buffalo Niagara Intl, ILS OR LOC RWY 23, Amdt 32A  
 Buffalo, NY, Buffalo Niagara Intl, ILS OR LOC RWY 32, Amdt 2A  
 Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 16L, Amdt 1A  
 Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 16R, Amdt 1B  
 Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 8R, ILS RWY 8R SA CAT I, ILS RWY 8R SA CAT II, Amdt 26  
 Houston, TX, George Bush Intercontinental/Houston, RNAV (RNP) Y RWY 8R, Amdt 1B  
 Houston, TX, George Bush Intercontinental/Houston, RNAV (RNP) Y RWY 26L, Orig-C



**Effective 8 November 2018**

Fairbanks, AK, Fairbanks Intl, ILS OR LOC RWY 2L, ILS RWY 2L SA CAT I, ILS RWY 2L CAT II, ILS RWY 2L CAT III, Amdt 10B

Fairbanks, AK, Fairbanks Intl, ILS OR LOC RWY 20R, ILS RWY 20R SA CAT I, ILS RWY 20R SA CAT II, Amdt 25B

Fairbanks, AK, Fairbanks Intl, VOR OR TACAN RWY 20R, Orig-B

Palmer, AK, Warren "Bud" Woods Palmer Muni, PALMER FIVE, Graphic DP

Palmer, AK, Warren "Bud" Woods Palmer Muni, RNAV (GPS) RWY 10, Amdt 2

Palmer, AK, Warren "Bud" Woods Palmer Muni, RNAV (GPS)-A, Amdt 1

Palmer, AK, Warren "Bud" Woods Palmer Muni, Takeoff Minimums and Obstacle DP, Amdt 2B

St Mary's, AK, St Mary's, RNAV (GPS) RWY 35, Amdt 2D

Decatur, AL, Pryor Field Rgnl, RNAV (GPS) RWY 36, Amdt 2B

Bentonville, AR, Bentonville Muni/Louise M Thaden Field, RNAV (GPS) RWY 18, Amdt 2

Bentonville, AR, Bentonville Muni/Louise M Thaden Field, RNAV (GPS) RWY 36, Amdt 2

Bentonville, AR, Bentonville Muni/Louise M Thaden Field, VOR-A, Amdt 14

Nogales, AZ, Nogales Intl, NOGALES TWO, Graphic DP

Reedley, CA, Reedley Muni, RNAV (GPS) RWY 16, Orig

Reedley, CA, Reedley Muni, RNAV (GPS) RWY 34, Orig

Reedley, CA, Reedley Muni, Takeoff Minimums and Obstacle DP, Orig

San Luis Obispo, CA, San Luis County Rgnl, Takeoff Minimums and Obstacle DP, Amdt 7

Sebastian, FL, Sebastian Muni, RNAV (GPS) RWY 5, Orig-C, CANCELED

Sebastian, FL, Sebastian Muni, RNAV (GPS) RWY 23, Orig-C, CANCELED

Sebastian, FL, Sebastian Muni, RNAV (GPS)-A, Orig

Sebastian, FL, Sebastian Muni, RNAV (GPS)-B, Orig

Denison, IA, Denison Muni, NDB RWY 30, Amdt 6A, CANCELED

Estherville, IA, Estherville Muni, RNAV (GPS) RWY 16, Amdt 1A

Estherville, IA, Estherville Muni, RNAV (GPS) RWY 34, Amdt 1A

Paynesville, MN, Paynesville Muni, Takeoff Minimums and Obstacle DP, Amdt 1

St Cloud, MN, St Cloud Rgnl, VOR RWY 31, Orig-B

Booneville/Baldwyn, MS, Booneville/Baldwyn, VOR-A, Amdt 1A

Livingston, MT, Mission Field, LIVINGSTON TWO, Graphic DP

Kinston, NC, Kinston Rgnl Jetport at Stallings Fld, VOR RWY 23, Amdt 16, CANCELED

Lincolnton, NC, Lincolnton-Lincoln County Rgnl, NDB RWY 23, Amdt 3B, CANCELED

West Creek, NJ, Eagles Nest, Takeoff Minimums and Obstacle DP, Amdt 1

Tucumcari, NM, Tucumcari Muni, Takeoff Minimums and Obstacle DP, Amdt 2B

Las Vegas, NV, North Las Vegas, Takeoff Minimums and Obstacle DP, Amdt 3A

Springfield, OH, Springfield-Beckley Muni, ILS OR LOC RWY 24, Amdt 2, CANCELED

Springfield, OH, Springfield-Beckley Muni, VOR RWY 6, Amdt 11, CANCELED

Springfield, OH, Springfield-Beckley Muni, VOR/DME RWY 33, Orig, CANCELED

Versailles, OH, Darke County, RNAV (GPS) RWY 9, Amdt 1

Versailles, OH, Darke County, RNAV (GPS) RWY 27, Amdt 1

Versailles, OH, Darke County, Takeoff Minimums and Obstacle DP, Amdt 3

Wadsworth, OH, Wadsworth Muni, Takeoff Minimums and Obstacle DP, Amdt 2

Creswell, OR, Hobby Field, HOBBY ONE, Graphic DP

Creswell, OR, Hobby Field, RNAV (GPS) RWY 16, Orig

Creswell, OR, Hobby Field, Takeoff Minimums and Obstacle DP, Orig

Tyler, TX, Tyler Pounds Rgnl, ILS OR LOC RWY 13, Amdt 22

Tyler, TX, Tyler Pounds Rgnl, RNAV (GPS) RWY 13, Amdt 3

Tyler, TX, Tyler Pounds Rgnl, RNAV (GPS) RWY 17, Amdt 1

Tyler, TX, Tyler Pounds Rgnl, RNAV (GPS) RWY 22, Amdt 3

Tyler, TX, Tyler Pounds Rgnl, RNAV (GPS) RWY 31, Amdt 3

Tyler, TX, Tyler Pounds Rgnl, RNAV (GPS) RWY 35, Amdt 1

Tyler, TX, Tyler Pounds Rgnl, VOR RWY 4, Amdt 5

Tyler, TX, Tyler Pounds Rgnl, VOR RWY 31, Amdt 3

Suffolk, VA, Suffolk Executive, LOC RWY 4, Amdt 6

Suffolk, VA, Suffolk Executive, RNAV (GPS) RWY 4, Amdt 4A

Vancouver, WA, Pearson Field, Takeoff Minimums and Obstacle DP, Amdt 4

Ashland, WI, John F Kennedy Memorial, LOC RWY 2, Amdt 1B

Ashland, WI, John F Kennedy Memorial, RNAV (GPS) RWY 20, Amdt 1B

[FR Doc. 2018-20396 Filed 9-24-18; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 97****[Docket No. 31214; Amdt. No. 3818]****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 September 25, 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 September 25, 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](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](http://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 September 7, 2018.

**Rick Domingo**

*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:

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
11-Oct-18 .....	GA	Greensboro .....	Greene County Rgnl ...	8/2255	8/21/18	This NOTAM, published in TL 18–21, is hereby rescinded in its entirety.
11-Oct-18 .....	OR	Redmond .....	Roberts Field .....	8/7158	8/21/18	This NOTAM, published in TL 18–21, is hereby rescinded in its entirety.
11-Oct-18 .....	OK	Guymon .....	Guymon Muni .....	8/8036	8/21/18	This NOTAM, published in TL 18–21, is hereby rescinded in its entirety.
11-Oct-18 .....	RI	Block Island .....	Block Island State .....	8/1641	8/31/18	VOR/DME RWY 10, Amdt 5C.
11-Oct-18 .....	AR	Little Rock .....	Bill and Hillary Clinton National/Adams Field.	8/2663	8/22/18	RNAV (GPS) RWY 4L, Amdt 1D.
11-Oct-18 .....	AR	Little Rock .....	Bill and Hillary Clinton National/Adams Field.	8/2664	8/22/18	RNAV (GPS) RWY 4R, Amdt 1D.
11-Oct-18 .....	AR	Little Rock .....	Bill and Hillary Clinton National/Adams Field.	8/2665	8/22/18	RNAV (GPS) RWY 18, Amdt 1E.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/2666	8/22/18	RNAV (GPS) RWY 22L, Amdt 1D.
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/2667	8/22/18	RNAV (GPS) RWY 36, Orig-C.
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/2668	8/22/18	VOR-A, Orig-C.
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/2671	8/22/18	ILS OR LOC RWY 4L, Amdt 26A.
11-Oct-18	LA	Baton Rouge	Baton Rouge Metropolitan, Ryan Field.	8/2672	8/23/18	RNAV (GPS) RWY 31, Amdt 2.
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/3166	8/22/18	ILS OR LOC RWY 4R, Amdt 2D.
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/3169	8/22/18	ILS OR LOC RWY 22L, Orig-D.
11-Oct-18	AR	Little Rock	Bill and Hillary Clinton National/Adams Field.	8/3170	8/22/18	RNAV (GPS) RWY 22R, Amdt 1C.
11-Oct-18	PA	Towanda	Bradford County	8/4682	8/22/18	Takeoff Minimums and Obstacle DP, Amdt 2.
11-Oct-18	NE	Seward	Seward Muni	8/5764	8/28/18	RNAV (GPS) RWY 16, Orig.
11-Oct-18	PA	State College	University Park	8/6359	8/29/18	VOR-B, Amdt 11.
11-Oct-18	PA	State College	University Park	8/6361	8/29/18	ILS OR LOC RWY 24, Amdt 9B.
11-Oct-18	PA	State College	University Park	8/6363	8/29/18	RNAV (GPS) RWY 6, Amdt 2.
11-Oct-18	PA	State College	University Park	8/6368	8/29/18	RNAV (GPS) RWY 24, Amdt 1.
11-Oct-18	MN	Willmar	Willmar Muni-John L Rice Field.	8/7156	8/31/18	ILS OR LOC RWY 13, Orig.
11-Oct-18	MN	Willmar	Willmar Muni-John L Rice Field.	8/7159	8/31/18	RNAV (GPS) RWY 13, Orig-A.
11-Oct-18	MN	Willmar	Willmar Muni-John L Rice Field.	8/7161	8/31/18	RNAV (GPS) RWY 31, Amdt 1A.
11-Oct-18	MN	Willmar	Willmar Muni-John L Rice Field.	8/7162	8/31/18	VOR RWY 31, Orig-A.
11-Oct-18	KS	Concordia	Blosser Muni	8/7179	8/28/18	RNAV (GPS) RWY 17, Orig-A.
11-Oct-18	IA	Emmetsburg	Emmetsburg Muni	8/7181	8/28/18	NDB RWY 31, Amdt 3A.
11-Oct-18	IA	Emmetsburg	Emmetsburg Muni	8/7182	8/28/18	NDB RWY 13, Amdt 3A.
11-Oct-18	IA	Emmetsburg	Emmetsburg Muni	8/7183	8/28/18	RNAV (GPS) RWY 31, Orig-A.
11-Oct-18	IA	Emmetsburg	Emmetsburg Muni	8/7184	8/28/18	RNAV (GPS) RWY 13, Orig-A.
11-Oct-18	NJ	Manville	Central Jersey Rgnl	8/7538	8/22/18	RNAV (GPS) RWY 7, Amdt 1B.
11-Oct-18	MI	Mount Pleasant	Mount Pleasant Muni	8/7841	8/29/18	RNAV (GPS) RWY 27, Orig-A.
11-Oct-18	VA	Norfolk	Chesapeake Rgnl	8/9780	8/9/18	RNAV (GPS) RWY 5, Amdt 1A.
11-Oct-18	VA	Norfolk	Chesapeake Rgnl	8/9800	8/9/18	ILS OR LOC RWY 5, Amdt 1A.

[FR Doc. 2018-20394 Filed 9-24-18; 8:45 am]

BILLING CODE 4910-13-P

**TENNESSEE VALLEY AUTHORITY**

**18 CFR Part 1301**

**Tennessee Valley Authority Procedures for the Protection of National Security Classified Information**

**AGENCY:** Tennessee Valley Authority.

**ACTION:** Final rule.

**SUMMARY:** The Tennessee Valley Authority is amending its regulation which contain TVA’s procedure for the Protection of National Security Classified Information. These amendments reflect changes in position

titles and addresses; conform the references to Protection of National Security Classified Information to the most current publication of TVA’s Protection of National Security Classified Information Notices in the **Federal Register**.

**DATES:** *Effective date:* September 25, 2018.

**FOR FURTHER INFORMATION CONTACT:** Glenn Alan Spencer, Employment & Government Law Attorney, Tennessee Valley Authority, 400 W Summit Hill Dr. (WT6), Knoxville, Tennessee 37902-1401; telephone (865) 632-6255 or by email at *gaspencer@tva.gov*.

**SUPPLEMENTARY INFORMATION:** Section 1301.63(a) currently states that Executive Order 13526 requires that each agency that originates or handles classified information designate a senior

agency official to direct and administer its information security program. TVA’s senior agency official is currently the Director, Enterprise Information Security & Policy. TVA is revising § 1301.63(a) to align with organizational and personnel changes within the agency.

Section 1301.67(c) currently states that requests shall be in writing, and shall be sent to: Director, Enterprise Information Security & Policy, Tennessee Valley Authority, 1101 Market St., Chattanooga, TN 37402. TVA is revising § 1301.67(c) to align with organizational and personnel changes within the agency.

TVA considers this rule to be a procedural rule which is exempt from notice and comment under 5 U.S.C. 533(b)(3)(A). This rule is not a

significant rule for purposes of Executive Order 13526 and has not been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, TVA certifies that these regulatory amendments will not have a significant impact on small business entities. Since this rule is non-substantive, it is being made effective September 25, 2018.

**List of Subjects in 18 CFR Part 1301**

Freedom of information, Government in the sunshine, Privacy, Protection of national security classified information.

For the reasons stated in the preamble, TVA amends 18 CFR part 1301 as follows:

**PART 1301—PROCEDURES**

■ 1. The authority citation for part 1301 continues to read as follows:

**Authority:** 5 U.S.C. 552 and 552a; 16 U.S.C. 831–831dd.

**Subpart E—Protection of National Security Classified Information**

■ 2. In § 1301.63, revise paragraph (a) to read as follows:

**§ 1301.63 Senior agency official.**

(a) The Executive Order requires that each agency that originates or handles classified information designate a senior agency official to direct and administer its information security program. TVA’s senior agency official is the Director, TVA Police & Emergency Management.

\* \* \* \* \*

■ 3. In § 1301.67, revise paragraph (c) to read as follows:

**§ 1301.67 Mandatory review for declassification.**

\* \* \* \* \*

(c) Requests shall be in writing, and shall be sent to: Director, TVA Police & Emergency Management, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, TN 37902.

**Todd M. Peney,**

*Director, TVA Police & Emergency Management, Tennessee Valley Authority.*

[FR Doc. 2018–20828 Filed 9–24–18; 8:45 am]

**BILLING CODE 8120–08–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 74**

[Docket No. FDA–2017–C–2902]

**Listing of Color Additives Subject to Certification; D&C Yellow No. 8**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution. We are taking this action in response to a color additive petition submitted by Glo Eyes, LLC.

**DATES:** This rule is effective October 26, 2018. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by October 25, 2018.

**ADDRESSES:** You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before October 25, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 25, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic objections in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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

objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2017–C–2902 for “Listing of Color Additives Subject to Certification; D&C Yellow No. 8.” Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or with the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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 our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the 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.

**FOR FURTHER INFORMATION CONTACT:** Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1075.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

In a document published in the **Federal Register** of May 31, 2017 (82 FR 24912), we announced that we filed a color additive petition (CAP 7C0311) submitted by Glo Eyes, LLC (petitioner), 5501 Highway 199, suite 202, Fort Worth, TX 76114. The petition proposed to amend the color additive regulations in 21 CFR part 74, *Listing of Color Additives Subject to Certification* by expanding the permitted uses of D&C Yellow No. 8 (principally the disodium salt of fluorescein) to include use in coloring contact lens solution at a level not to exceed 0.044 percent in the contact lens solution. Because the colored contact lens solution is intended for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses and because D&C Yellow No. 8 in these colored contact lenses will come into direct contact with the user's eyes for a significant amount of time, this color additive is subject to section 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e).

##### II. Background

D&C Yellow No. 8 is currently approved under § 74.1708 (21 CFR 74.1708) for coloring externally applied drugs in amounts consistent with good manufacturing practice (GMP). D&C Yellow No. 8 is also approved under § 74.2708 (21 CFR 74.2708) for coloring externally applied cosmetics in amounts consistent with GMP. The regulations for D&C Yellow No. 8 require that all batches of the color additive be certified in accordance with regulations in part 80.

D&C Yellow No. 8 (CAS 518-47-8) is principally the disodium salt of

fluorescein. In the subject petition, D&C Yellow No. 8 is proposed for use as a color additive in contact lens solution intended for soaking disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses for up to 12 hours. The treated lenses are to be used one time and then discarded. The treated contact lenses, when exposed to ultraviolet light, fluoresce a yellow-green color for cosmetic purposes. The treated color contact lenses are expected to be used for limited, celebratory, and special occasions, and not every day. The maximum intended use level of D&C Yellow No. 8 in the contact lens solution is 0.044 percent. The contact lens solution colored with D&C Yellow No. 8 is intended for distribution by prescription only and for use in accordance with the directions supplied. Based on data and information provided in the petition on the identity, properties, manufacturing process, and composition of the color additive, we have determined that the color additive meets the specifications for D&C Yellow No. 8 in § 74.1708 (Ref. 1).

##### III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act (21 U.S.C. 379e(b)(4)), a color additive may not be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. Our color additive regulations at § 70.3(i) (21 CFR 70.3(i)) define "safe" to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive.

As part of our safety evaluation of the color additive, we considered the projected human exposure to D&C Yellow No. 8 and any impurities resulting from the petitioned use of the color additive. We also considered results from ocular irritation, skin sensitization, oral mucosal irritation, acute systemic toxicity, and cytotoxicity studies that tested extracts from contact lenses soaked in contact lens solution colored with D&C Yellow No. 8.

###### A. Exposure Estimate

During our safety assessment of the use of D&C Yellow No. 8 in contact lens solution, we considered the estimated exposure to D&C Yellow No. 8 that would result from the petitioned use in amounts not to exceed 0.044 percent in contact lens solution. The petitioner determined that the theoretical maximum amount of D&C Yellow No. 8 that could be absorbed by, and potentially extracted from, a contact lens is 17 micrograms per lens ( $\mu\text{g}/\text{lens}$ ).

The petitioner considers 17  $\mu\text{g}/\text{lens}$  or 34  $\mu\text{g}/\text{person}/\text{day}$  (p/d) (for two lenses) to be a conservative estimate of the exposure to the color additive under the proposed use conditions (Ref. 1). FDA agrees with the petitioner's estimate. We note that the estimated exposure (17  $\mu\text{g}/\text{lens}$  or 34  $\mu\text{g}/\text{p}/\text{d}$ ) represents a theoretical maximum amount of the color additive per use and is based on the worst-case assumption that all the water in the hydrogel-based soft contact lens is displaced by the colored contact lens solution. However, this exposure estimate is not an estimate of chronic daily exposure since the treated contact lenses are for occasional wear and not for everyday use. Furthermore, the actual exposure to D&C Yellow No. 8 from the petitioned use is expected to be lower than 17  $\mu\text{g}/\text{lens}$  or 34  $\mu\text{g}/\text{p}/\text{d}$  based on the amount of color additive extracted from the contact lenses soaked in the colored contact lens solution as indicated in the instructions for use (Ref. 1).

###### B. Safety of Petitioned Use of Color Additive

To establish that D&C Yellow No. 8 is safe for use in a contact lens solution intended for soaking disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses, the petitioner submitted toxicity studies including an ocular irritation test in rabbits, a Guinea pig maximization sensitization test, an oral mucosal irritation study in hamsters, an acute systemic toxicity test in mice, and a cytotoxicity test that tested extracts from representative contact lenses soaked in contact lens solution colored with D&C Yellow No. 8. The results of these studies indicate that the color additive is not an irritant to the skin, eyes or oral mucosa, is not a sensitizer, is not cytotoxic, and shows no systemic toxicity (Ref. 2). Therefore, we conclude that the available toxicology data are sufficient to support the safety of the proposed expanded safe use of D&C Yellow No. 8.

##### IV. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of D&C Yellow No. 8 for coloring contact lens solution intended for soaking disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses is safe. We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Consequently, we are amending the color additive regulations in 21 CFR part 74 as set forth in this document. We also conclude that batch certification of

D&C Yellow No. 8 continues to be necessary to protect the public health.

#### V. Public Disclosure

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **ADDRESSES**). As provided in § 71.15(b), we will delete from the documents any materials that are not available for public disclosure.

#### VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the May 31, 2017, **Federal Register** notice of filing for CAP 7C0311 (82 FR 24912). We stated that we had determined, under 21 CFR 25.32(I), that this action “is of a type that does not individually or cumulatively have a significant effect on the human environment” such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

#### VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VIII. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file electronic objections to this docket at <https://www.regulations.gov>, or written objections with the Dockets Management Staff (see **ADDRESSES**). You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a

description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>. We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

#### IX. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. Memorandum from H. Lee, Chemistry Review Team, Division of Petition Review, Office of Food Additive Safety (OFAS), CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, July 3, 2018.
2. Memorandum from A. Khan, Toxicology Team, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, July 12, 2018.

#### List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 74 is amended as follows:

#### PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

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

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

- 2. Add § 74.3708 to subpart D to read as follows:

#### § 74.3708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* (1) D&C Yellow No. 8 may be safely used for coloring contact lens solution for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses at a level not to exceed 0.044 percent in the contact lens solution. Following excitation by ultraviolet light, the colored contact

lenses fluoresce a yellow-green color. The contact lens solution colored with D&C Yellow No. 8 is distributed by prescription only and used in accordance with the supplied directions for use. Contact lens solutions containing D&C Yellow No. 8 are intended for use only for coloring contact lenses that are worn for infrequent, celebratory occasions, and not for regular or daily use.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens solution in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: September 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–20767 Filed 9–24–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2018–0619]

RIN 1625–AA00

#### Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Lower Mississippi River. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters near New Orleans, LA, during a fireworks display on October 6, 2018. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative.

**DATES:** This rule is effective from 9 p.m. through 10 p.m. on October 6, 2018.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>

[www.regulations.gov](http://www.regulations.gov), type USCG–2018–0619 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rulemaking, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email [Benjamin.P.Morgan@uscg.mil](mailto:Benjamin.P.Morgan@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
 COTP Captain of the Port Sector New Orleans  
 DHS Department of Homeland Security  
 FR Federal Register  
 MM Mile marker  
 NPRM Notice of proposed rulemaking  
 § Section  
 U.S.C. United States Code

##### II. Background, Purpose, and Legal Basis

The Coast Guard was notified that Zito Company, LLC would be conducting a fireworks display from 9 p.m. through 10 p.m. on October 6, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate mile marker (MM) 94.5, above Head of Passes, off Algiers Point, New Orleans, LA. Hazards from firework displays include discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks display will be a safety concern for anyone within a one-mile stretch of the river.

In response, on July 19, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled *Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA* (83 FR 34092). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended August 20, 2018 we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the fireworks display.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector New Orleans (COTP) is establishing a temporary safety zone from 9 p.m. through 10 p.m. on October 6, 2018. The safety zone covers all navigable waters of the Lower Mississippi River between MM 94 and MM 95, above Head of Passes. The duration of the zone is intended to ensure the safety of persons, vessels, and the marine environment on these navigable waters before, during, and after the scheduled fireworks display.

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

As noted above, we received no comments on our NPRM published on July 19, 2018. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 9 p.m. to 10 p.m. on October 6, 2018. The safety zone covers all navigable waters of the Lower Mississippi River between MM 94 and MM 95, above Head of Passes. The duration of the zone is intended to ensure the safety of persons, vessels, and the marine environment on these navigable waters before, during, and after the scheduled fireworks display.

No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans. Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative. The COTP or a designated representative would inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

##### V. Regulatory Analyses

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

##### A. Regulatory Planning and Review

Executive Orders 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). This regulatory action determination is based on the size and short duration of the safety zone, which would impact a one-mile stretch of the Lower Mississippi River for one hour on one evening. In addition, vessel traffic seeking to transit the area may seek permission from the COTP or a designated representative to do so.

##### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant

economic impact on a substantial number of small entities.

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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

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

#### C. Collection of Information

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

#### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism

principles and preemption requirements described in Executive Order 13132.

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

#### E. Unfunded Mandates Reform Act

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

#### F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting one hour that would prohibit entry on one-mile stretch of the Lower Mississippi River. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

#### G. Protest Activities

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

#### List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0619 to read as follows:

#### § 165.T08–0619 Safety Zone; Lower Mississippi River, Mile Markers 94 to 95, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River between mile marker (MM) 94 and MM 95 above Head of Passes, New Orleans, LA.

(b) *Effective period.* This section is effective from 9 p.m. through 10 p.m. on October 6, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

Dated: September 19, 2018.

**K.M. Luttrell,**

*Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.*

[FR Doc. 2018–20794 Filed 9–24–18; 8:45 am]

**BILLING CODE 9110–04–P**



**DEPARTMENT OF THE INTERIOR****National Park Service****36 CFR Part 7**

[Docket ID: NPS–2018–0004; NPS–PERI–25774; PPMWPERIS0 PPMSPD1Z.YM0000]

RIN 1024–AE41

**Special Regulations, Areas of the National Park System, Pea Ridge National Military Park; Bicycles****AGENCY:** National Park Service, Interior.**ACTION:** Final rule.

**SUMMARY:** The National Park Service promulgates special regulations for Pea Ridge National Military Park to allow bicycle use on two multi-use trails located within the park. One trail will be approximately 0.55 miles in length and the other will be approximately 1.17 miles in length. Both trails will require trail construction activities to accommodate bicycles and are therefore considered new trails that will be opened to bicycles. National Park Service regulations require promulgation of a special regulation to designate new trails for bicycle use off park roads and outside developed areas.

**DATES:** This rule is effective on October 25, 2018.

**ADDRESSES:** The comments received on the proposed rule and an economic analysis are available on [www.regulations.gov](http://www.regulations.gov) in Docket ID: NPS–2018–0004.

**FOR FURTHER INFORMATION CONTACT:** Lee Terzis, NPS Denver Service Center Transportation Division, 1155 E Pearl St., Monticello, FL 32344. Phone (850) 997–9972. Email: [lee\\_terzis@nps.gov](mailto:lee_terzis@nps.gov).

**SUPPLEMENTARY INFORMATION:****Background**

Pea Ridge National Military Park (the park), established in 1956 and opened to the public in 1963, preserves and commemorates the site of the March 1862 Civil War battle that helped Union forces maintain physical and political control of the State of Missouri. Administered by the National Park Service (NPS), the 4,300-acre battlefield is situated in the foothills of the Ozark Mountains 10 miles north of Rogers, Arkansas, just off of U.S. Highway 62. The park is divided into two sections: The main portion of the park is located north of U.S. Highway 62 and encompasses a majority of the historic battleground. The main portion consists of a dedicated series of soft surface trails for equestrians and pedestrians, as well as the tour road, which bicyclists share with vehicle users. The second, smaller

portion is located to the south of U.S. Highway 62 along the bluffs of Little Sugar Creek and contains the Federal Trenches of the Union troops. This non-contiguous section is currently accessible from a small parking lot along Sugar Creek Road, which intersects with US Highway 62, with a trail leading to the trenches.

The park contains a portion of the northern route of the Trail of Tears that is one of the few places the Trail of Tears passes through Arkansas. Eleven Cherokee Removal contingents used this route from 1837 to 1839. Through the park, the Trail of Tears generally followed the route of Telegraph Road, which is eligible for the National Register of Historic Places.

**Road and Trail System in the Park**

The park contains an existing road and trail system (including the Federal Trenches trail) that provides pedestrians, hikers, bicyclists, and equestrians with interpretive and recreational opportunities. This system consists of a total of 32 miles of trail, including 7.6 miles of asphalt trail, 13.9 miles of off-road hiking trail, and 10.8 miles of horse trail. Bicycles are allowed on roads but not on trails within the park.

The area surrounding the park—including local communities such as Pea Ridge, Garfield, Bentonville, Rogers, Springdale, and Fayetteville—has experienced dynamic population growth in recent years. Increased visitation to the park has created a need to improve the existing road and trail system to better accommodate travel through the park by various methods (*e.g.*, automobile, pedestrian, equestrian, bicycle). In addition to enhancing interpretive and recreational opportunities, an improved road and trail system will generate operational efficiencies. There are opportunities to combine trails or locate trails adjacent to other trail types or facilities (*e.g.*, water, restrooms, phones) to maximize the efficiency of performing park maintenance. By removing duplicative trails and infrastructure, the NPS can reduce overall maintenance costs.

**Trail Plan/Environmental Assessment**

In November 2017, the NPS published the Pea Ridge National Military Park Trail Master Plan/Environmental Assessment (EA). The EA evaluates two action alternatives that are designed to improve visitor access to the park's historical and interpretive sites while avoiding or minimizing impacts to these sites by consolidating and restructuring the existing trail network. These alternatives also seek to improve multi-

modal trail connections within the park while linking to a regional trail network outside of the park. Under both action alternatives, the NPS would expand and enhance opportunities for pedestrian trail interpretation, construct additional trailheads, modify trail loops for simplicity and interpretive value, construct additional ADA-accessible trails, install signage for the Trail of Tears, improve multi-use trails, and improve equestrian trails to avoid erosion-prone areas. These actions will meet the increasing recreational needs of the area while protecting the cultural and natural resources within the park.

The EA identifies one of the action alternatives as the NPS preferred alternative. This alternative would allow bicycle use on two multi-use trails that would require trail construction activities. The first would be a 0.55-mile trail from U.S. Highway 62 to the visitor center. The second would be a 1.17-mile trail from Arkansas Highway 72 to the Sugar Creek Greenway on the western edge of the park. Bicycles would also be allowed on Ford Road, which is closed to motor vehicle use by the public, but open to motor vehicle use for administrative purposes. Bicycles would also be allowed on segments of the Tour Road, which is paved and open to motor vehicle use by the public.

With respect to the bike trails, the EA evaluates (i) the suitability of the trails for bicycle use; and (ii) life cycle maintenance costs, safety considerations, methods to prevent or minimize user conflict, and methods to protect natural and cultural resources and mitigate impacts associated with bicycle use on the trails. After a public review period, the Regional Director of the Midwest Region signed a Finding of No Significant Impact (FONSI) in June 2018 that identified the preferred alternative (Alternative 3) in the EA as the selected action. At the same time, the Regional Director signed a written determination that bicycle use on the two trails is consistent with the protection of the park area's natural, scenic, and aesthetic values; safety considerations and management objectives; and will not disturb wildlife or park resources.

The EA, FONSI and written determination, which contain a full description of the purpose and need for taking action, scoping, the alternatives considered, maps, and the environmental impacts associated with the project, may be viewed on the park's planning website at <http://parkplanning.nps.gov/peri>, by clicking on the link entitled "Trail Master Plan/Environmental Assessment" and then

clicking on the link entitled “Document List.”

### Final Rule

This rule implements the selected action in the FONSI and authorizes the Superintendent to designate bicycle use on the two trails described above. In order to accommodate bicycles, both trails will require construction activities that will be conducted in accordance with sustainable trail design principles and guidelines. NPS regulations at 36 CFR 4.30 require a special rule to designate these trails for bicycles use because they are located outside of developed areas. Bicycle use will not be authorized by the Superintendent until the trail construction activities are completed.

The rule adds a new section 7.95 to 36 CFR part 7—Special Regulations, Areas of the National Park System for the park. The rule requires the Superintendent to notify the public of trail designation for bicycle use and identify the designation on maps available in the office of the Superintendent and other places convenient to the public. The rule authorizes the Superintendent to establish closures, conditions, or restrictions for bicycle use on designated trails in accordance with 36 CFR 4.30. After notifying the public, the Superintendent may take these actions for reasons of public health and safety, natural and cultural resource protection, and other management activities and objectives.

### Summary of Public Comments

The NPS published a proposed rule in the **Federal Register** on March 13, 2018 (83 FR 11650). The NPS accepted comments on the proposed rule through the mail, hand delivery, and through the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). Comments were accepted through May 15, 2018. A summary of the pertinent issues raised in the comments and NPS responses are provided below. After considering the public comments and after additional review, the NPS did not make any changes to the rule.

**1. Comment:** One commenter suggested that the trails should be experienced in ways—such as hiking and walking—that are less destructive to the environment and more conducive to their short length.

**NPS Response:** The NPS determined in the FONSI that bicycle use on the trails will not have a significant impact on the environment. A more detailed discussion of the environmental impacts of bicycle use on these trails can be found in the EA, FONSI, and written

determination. With respect to the length of the trails, the segments of trail within the park will connect to the regional trail network identified in the Northwest Arkansas Regional Bicycle and Pedestrian Master Plan. The length of the larger network of trails is conducive to bicycling, as are the segments within the park that the NPS expects will be used by bicyclists as a new way of experiencing the historical and cultural resources within the park. The rolling topography of the park will lengthen the amount of time it will take a visitor to travel by bicycle, making the trails more conducive to this form of transportation.

**2. Comment:** One commenter asked the NPS to provide evidence for the statement in the proposed rule that population growth in the areas surrounding the park support the need for providing increased recreational opportunities such as bicycling.

**NPS Response:** U.S. Census Bureau data from 2016 show that the Northwest Arkansas metro area accounted for most of the state’s population growth in the previous five years. The Northwest Arkansas Council’s recent analysis of new U.S. Census Bureau population estimates indicate the region will be listed in the Top 100 largest metropolitan areas by 2019. More information can be found online at <http://www.nwacouncil.org/news/2018/3/22/analysis-northwest-bentonville-fayetteville-arkansas-census-top-100-population>.

**3. Comment:** One commenter requested more information about the construction activities that the NPS will undertake to accommodate bicycles on the trails. In particular, the commenter raised concerns about impacts to soil in erosion-prone areas. This commenter also asked for more information about the sustainable trail design principles and guidelines that will govern the construction activities.

**NPS Response:** The trail alignments identified in the EA primarily use established road beds that have suitable soil compaction for bicycle use. The selected action includes the removal of redundant trail alignments and relocation of existing pedestrian and equestrian trails that are currently experiencing extensive erosion in order to minimize impacts to natural and cultural resources. The EA identifies applicable mitigation measures to minimize impacts caused by construction activities. Section 9.2.2 of NPS Management Policies (2006) requires that all trails be carefully situated, designed and managed to protect park resources. The NPS will design and construct the trails to avoid

or minimize disturbance to sensitive resources and will incorporate design techniques to reduce the likelihood and presence of social trailing.

### Compliance With Other Laws, Executive Orders and Department Policy Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this rule in a manner consistent with these requirements.

### Reducing Regulation and Controlling Regulatory Costs (Executive Order 13771)

Enabling regulations are considered deregulatory under guidance implementing E.O. 13771 (M–17–21). This rule authorizes the Superintendent to allow a recreational activity for the public to enjoy and experience certain areas within the National Park System that would otherwise be prohibited.

### Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based on information contained in the economic analyses found in the report entitled “Benefit-Cost and Regulatory Flexibility Threshold Analyses: Bicycle Trails at Pea Ridge National Military Park” which is available on [www.regulations.gov](http://www.regulations.gov) in Docket ID: NPS–2018–0004.

**Small Business Regulatory Enforcement Fairness Act**

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

- (a) Does not have an annual effect on the economy of \$100 million or more.
- (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

**Unfunded Mandates Reform Act**

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. It addresses public use of national park lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

**Takings (Executive Order 12630)**

This rule does not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

**Federalism (Executive Order 13132)**

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This rule only affects use of federally-administered lands and waters. It has no outside effects on other areas. A Federalism summary impact statement is not required.

**Civil Justice Reform (Executive Order 12988)**

This rule complies with the requirements of Executive Order 12988. This rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

**Consultation With Indian Tribes (Executive Order 13175 and Department Policy)**

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. The NPS has evaluated this rule under the criteria in Executive Order 13175 and under the Department's tribal consultation policy and has determined that tribal consultation is not required because the rule will have no substantial direct effect on federally recognized Indian tribes.

Nevertheless, the NPS recognizes that the park contains significant archeological sites and the Trail of Tears, which are considered very important to the following tribes: Absentee Shawnee Tribe, Cherokee Nation of Oklahoma, Jena Band of the Choctaw Indians, The Osage Nation, Shawnee Tribe of Oklahoma, Quapaw Tribe of Oklahoma, United Keetoowah Band of Cherokee Indians, The Chickasaw Nation, Caddo Nation, and the Muscogee (Creek) Nation. The park consulted with these tribes throughout the development of the EA and incorporated comments by adjusting trails to mitigate or avoid impacts to these areas of interest.

**Paperwork Reduction Act**

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. The NPS may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

**National Environmental Policy Act**

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required because the NPS reached a Finding of No Significant Impact. A copy of the EA and FONSI can be found online at <http://parkplanning.nps.gov/peri>, by clicking on the link entitled "Trail Master Plan/Environmental Assessment" and then clicking on the link entitled "Document List."

**Effects on the Energy Supply (Executive Order 13211)**

This rule is not a significant energy action under the definition in Executive

Order 13211. A Statement of Energy Effects is not required.

**List of Subjects in 36 CFR Part 7**

District of Columbia, National parks, Reporting and Recordkeeping requirements.

In consideration of the foregoing, the National Park Service amends 36 CFR part 7 as set forth below:

**PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM**

- 1. The authority citation for part 7 continues to read as follows:

**Authority:** 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under DC Code 10-137 and DC Code 50-2201.07.

- 2. Add § 7.95 to read as follows:

**§ 7.95 Pea Ridge National Military Park.**

(a) *Bicycle use.* (1) The Superintendent may designate all or portions of the following trails as open to bicycle use:

(i) A trail from U.S. Highway 62 to the visitor center (approximately 0.55 miles).

(ii) A trail from Arkansas Highway 72 to the Sugar Creek Greenway on the western edge of the park (approximately 1.17 miles).

(2) A map showing trails open to bicycle use will be available at park visitor centers and posted on the park website. The Superintendent will provide notice of all bicycle route designations in accordance with § 1.7 of this chapter. The Superintendent may limit, restrict, or impose conditions on bicycle use, or close any trail to bicycle use, or terminate such conditions, closures, limits, or restrictions in accordance with § 4.30 of this chapter.

(b) [Reserved]

**Andrea Travnicek,**

*Principal Deputy Assistant Secretary—Water and Science, Exercising the Authority of the Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2018-20693 Filed 9-24-18; 8:45 am]

**BILLING CODE 4310-EJ-P**

**DEPARTMENT OF VETERANS AFFAIRS****38 CFR Part 17**

**RIN 2900-AP00**

**Definition of Domiciliary Care**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) adopts as final, with no

changes, a proposed rule amending the definition of domiciliary care to encompass VA's Mental Health Residential Rehabilitation Treatment Program (MH RRTP). This rule aligns regulations with VA's administrative decision in 2005 to designate MH RRTP as a type of domiciliary care. We also proposed clarifying that domiciliary care provides temporary, not permanent, residence to affected veterans. We provided a 60-day comment period on this proposed rule and received 4 comments, all of which were generally supportive of the proposed changes. We make no changes based on public comments and adopt the proposed rule as final.

**DATES:** *Effective Date:* This rule is effective on October 25, 2018.

**FOR FURTHER INFORMATION CONTACT:** Jamie R. Ploppert, National Director, Mental Health Residential Treatment Programs (10P4M), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; (757) 722-9991 extension 1123. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** Title 38, United States Code, section 1710(b)(2) authorizes VA to provide needed domiciliary care to veterans whose annual income does not exceed the applicable maximum annual rate of VA pension and to veterans who have no adequate means of support. Prior to the proposed changes to the definition "domiciliary care" was defined at 38 CFR 17.30(b) as the furnishing of a home to a veteran, embracing the furnishing of shelter, food, clothing and other comforts of home, including necessary medical services, as well as travel and incidental expenses pursuant to 38 CFR 70.10. Veterans eligible for domiciliary care include only: Those whose annual income does not exceed the maximum annual rate of pension payable to a veteran in need of regular aid and attendance; or those who have no adequate means of support, as this phrase is defined in 38 CFR 17.47(b)(2), who can perform the activities specified in 38 CFR 17.46(b) but who suffer from a chronic disability, disease, or defect that results in the veteran being unable to earn a living for a prospective period. See 38 CFR 17.47(b)(2) and (c).

The domiciliary program is authorized to provide eligible veterans with a home and coordinated ambulatory medical care as needed. Typically, domiciliaries are co-located with VA medical centers or exist as designated bed-settings within the centers.

While the above-referenced statutory definitions and eligibility criteria still apply as do the regulatory criteria of §§ 17.46(b) and 17.47(b)(2), the scope of services furnished under the program has evolved significantly, requiring revision of §§ 17.30(b) and 17.47(c). We proposed to amend the definition of domiciliary care to reflect that change.

The scope of clinical services available to VA domiciliary residents has necessarily become specialized over time due to the characteristics of the patient populations served by the residential rehabilitation treatment model. In 2005, VA's supervision of domiciliary care facilities was moved from the Office of Geriatrics and Extended Care to the Office of Mental Health Services. In 2010, VA merged domiciliary care facilities and RRTPs (which began in 1995) into one system of residential care under the MH RRTP designation to fully integrate mental health residential rehabilitation and treatment and domiciliary care. MH RRTPs provide comprehensive supervised treatment and rehabilitative services to veterans with mental health or substance use disorders, and coexisting medical or psychosocial needs such as homelessness and unemployment. MH RRTPs identify and address goals of rehabilitation, recovery, health maintenance, improved quality of life, and community integration in addition to specific treatment of medical conditions, mental illnesses, addictive disorders, and homelessness. These services are intended to restore, to the maximum extent possible, the physical, mental, and psychological functioning of veterans receiving residential rehabilitation treatment. VA domiciliaries are used currently for VA's Domiciliary Residential Rehabilitation Treatment Programs; Domiciliary Care for Homeless Veterans Program, Health Maintenance Domiciliary beds program; General Domiciliary or Psychosocial Residential Rehabilitation Treatment Program; Domiciliary Substance Abuse programs; and Domiciliary Post-Traumatic Stress Disorder (PTSD) programs.

On April 6, 2018, we proposed amending the definition of domiciliary care in § 17.30(b) to also include MH RRTP. (83 FR 14804). We also proposed clarifying in both §§ 17.30(b) and 17.47(c) that domiciliary care provides a temporary home, not permanent. This clarification is consistent with VA's long-standing practice of providing domiciliary care as a non-permanent living arrangement for eligible veterans.

We provided a 60-day period in which the public had the opportunity to submit comments on the proposed rule.

The comment period ended on June 5, 2018, and we received 4 comments, all of which were generally supportive of the proposed changes. One commenter stated that he supported the effort to provide clear and concise rules regarding the scope of domiciliary care. Another commenter stated that providing domiciliary care consistent with the proposed rule supports the services that homeless veterans need such as mental health, counseling, and substance treatment while providing a chance to implement change in their life and creating realistic timelines to facilitate progress.

We appreciate the comments and believe that the MH RRTP provides important and necessary support to those veterans requiring such services. We make no changes based on public comments.

Based on the rationale set forth in the proposed rule and in this document, VA adopts the proposed rule as final, with no changes.

#### **Effect of Rulemaking**

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

#### **Paperwork Reduction Act**

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

#### **Regulatory Flexibility Act**

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

#### **Executive Orders 12866, 13563, and 13771**

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.” VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and determined that the action is not a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s website at <http://www.va.gov/orpm> by following the link for VA Regulations Published from FY 2004 through FYTD. This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

#### Unfunded Mandates

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

#### Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.005—Grants to States for Construction of State Home Facilities; 64.008—Veterans Domiciliary Care; 64.011—Veterans Dental Care; 64.012—Veterans Prescription Service; 64.013—Veterans Prosthetic Appliances; 64.014—Veterans State Domiciliary Care; 64.015—Veterans State Nursing Home Care; 64.024—VA Homeless Providers Grant and Per Diem Program; 64.026—Veterans State Adult Day Health Care; 64.033—VA Supportive Services for Veteran Families Program; 64.035—Veterans Transportation Program; 64.040—VHA Inpatient Medicine; 64.041—VHA Outpatient Specialty Care; 64.042—VHA Inpatient Surgery; 64.043—VHA Mental Health Residential; 64.044—VHA Home Care; 64.045—VHA Outpatient Ancillary Services; 64.046—VHA Inpatient Psychiatry; 64.047—VHA Primary Care; 64.048—VHA Mental Health clinics; 64.049—VHA Community Living Center; 64.050—VHA Diagnostic Care; 64.054—Research and Development.

#### List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

#### Signing Authority

The Secretary of Veterans Affairs 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. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on September 19, 2018, for publication.

Dated: September 19, 2018.

#### Consuela Benjamin,

*Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

For the reasons stated in the preamble, Department of Veterans Affairs amends 38 CFR part 17 as follows:

#### PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 38 U.S.C. 501, and as noted in specific sections.

Section 17.35 is also issued under 38 U.S.C. 1724.

Section 17.38 is also issued under 38 U.S.C. 101, 501, 1701, 1705, 1710, 1710A, 1721, 1722, 1782, and 1786.

Section 17.125 is also issued under 38 U.S.C. 7304.

Section 17.169 is also issued under 38 U.S.C. 1712C.

Sections 17.380, 17.390 and 17.412 are also issued under sec. 260, Public Law 114–223, 130 Stat. 857.

Section 17.410 is also issued under 38 U.S.C. 1787.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

Section 17.417 also issued under 38 U.S.C. 1701 (note), 1709A, 1712A (note), 1722B, 7301, 7330A, 7401–7403, 7406 (note).

Sections 17.640 and 17.647 are also issued under sec. 4, Public Law 114–2, 129 Stat. 30.

Sections 17.641 through 17.646 are also issued under 38 U.S.C. 501(a) and sec. 4, Public Law 114–2, 129 Stat. 30.

Section 17.655 also issued under 38 U.S.C. 501(a), 7304, 7405.

■ 2. Amend § 17.30 by revising paragraph (b) to read as follows:

#### § 17.30 Definitions.

\* \* \* \* \*

(b) *Domiciliary care.* The term domiciliary care—

(1) Means the furnishing of:

(i) A temporary home to a veteran, embracing the furnishing of shelter, food, clothing and other comforts of home, including necessary medical services; or

(ii) A day hospital program consisting of intensive supervised rehabilitation and treatment provided in a therapeutic residential setting for residents with mental health or substance use disorders, and co-occurring medical or psychosocial needs such as homelessness and unemployment.

(2) Includes travel and incidental expenses pursuant to § 70.10.

(Authority: 38 U.S.C. 1701(4))

#### § 17.47 [Amended]

■ 3. Amend § 17.47(c) by removing the word “home” and adding in its place the words “temporary home”.

[FR Doc. 2018–20707 Filed 9–24–18; 8:45 am]

BILLING CODE 8320–01–P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[EPA-R04-OAR-2018-0020; FRL-9984-23—Region 4]

**Air Plan Approval; North Carolina; Inspection and Maintenance Program****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 North Carolina on November 17, 2017, through the North Carolina Department of Environmental Quality, Division of Air Quality (DAQ), for the purpose of removing 26 counties from North Carolina's expanded inspection and maintenance (I/M) program, which was previously approved into the SIP for use as a component of the State's Nitrogen Oxides (NO<sub>x</sub>) Budget and Allowance Trading Program. The EPA has determined that North Carolina's November 17, 2017, SIP revision is approvable because it is consistent with the Clean Air Act (CAA or Act) and with the EPA's regulations.

**DATES:** This rule will be effective September 25, 2018.

**ADDRESSES:** The EPA has established a docket for this action under Docket Identification No. EPA-R04-OAR-2018-0020. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) website. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Kelly Sheckler, Air Regulatory

Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9222. Ms. Sheckler can also be reached via electronic mail at [sheckler.kelly@epa.gov](mailto:sheckler.kelly@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

On November 17, 2017, DAQ submitted a SIP revision seeking to remove 26 counties from the expanded I/M program contained in the North Carolina SIP. This removal consequently removes reliance on the I/M reduction credits gained from the 26 counties' participation in the expanded I/M program from the State's NO<sub>x</sub> emissions budget—a component of the State's response to the NO<sub>x</sub> SIP Call. North Carolina indicated that it no longer needs these reduction credits in order to meet its obligations under the NO<sub>x</sub> SIP Call. In addition, North Carolina provided a technical demonstration showing that removing the 26 counties from the expanded I/M program will not interfere with North Carolina's attainment or maintenance of any National Ambient Air Quality Standard (NAAQS) or with any other applicable requirement of the CAA.

The EPA published a proposed rulemaking on July 26, 2018 (83 FR 35444), proposing to approve this SIP revision. The proposed approval was based on the EPA's proposed findings that the removal of the 26 counties from the State's expanded I/M program will not interfere with North Carolina's obligations under the NO<sub>x</sub> SIP Call and will not interfere with North Carolina's attainment or maintenance of any NAAQS or with any other applicable requirement of the CAA. The details of North Carolina's submittal and the rationale for the EPA's action are explained in the proposed rulemaking. The comment period for this proposed rulemaking closed on August 27, 2018. The EPA received two comments supporting the proposed action. The remaining comments received were not relevant.

**II. Final Action**

The EPA is taking final action to approve the November 17, 2017, revision to the North Carolina SIP. Specifically, the EPA is approving the removal of Brunswick, Burke, Caldwell, Carteret, Catawba, Chatham, Cleveland, Craven, Edgecombe, Granville, Harnett, Haywood, Henderson, Lenoir, Moore, Nash, Orange, Pitt, Robeson, Rutherford, Stanly, Stokes, Surry, Wayne, Wilkes,

and Wilson counties from the SIP-approved expanded I/M program. Additionally, the EPA is finding that North Carolina's removal of the 26 counties from the SIP-approved expanded I/M program (and the removal of reliance on the I/M emissions reductions generated from those counties as part of the "credits" in North Carolina's NO<sub>x</sub> emissions budget) will not interfere with the State's obligations under the NO<sub>x</sub> SIP Call to meet its Statewide NO<sub>x</sub> emissions budget. The EPA is also finding that the removal of the 26 counties from the SIP-approved I/M program will not interfere with continued attainment or maintenance of any applicable NAAQS or with any other applicable requirement of the CAA, and that North Carolina has satisfied the requirements of section 110(l) of the CAA.

The EPA has determined that this action is effective immediately upon publication under the authority of 5 U.S.C. 553(d)(1). The purpose of the 30-day waiting period prescribed in section 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Section 553(d)(1) allows an effective date less than 30 days after publication if a substantive rule "relieves a restriction." This action qualifies for the exception under section 553(d)(1) because it relieves the 26 counties identified above from the requirements of North Carolina's SIP-approved expanded I/M program.

**III. Statutory and Executive Order Reviews**

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. 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 the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian

country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 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 may not

be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

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

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

Dated: September 11, 2018.

**Onis “Trey” Glenn, III,**  
*Regional Administrator, Region 4.*

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 II—North Carolina**

■ 2. In § 52.1770, the table in paragraph (e) is amended by adding the entry “North Carolina Removal of 26 Counties from Inspection and Maintenance Program and 110(l) Non-Interference Demonstration” at the end of the table to read as follows:

**§ 52.1770 Identification of plan.**

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

**EPA-APPROVED NORTH CAROLINA NON-REGULATORY PROVISIONS**

Provision	State effective date	EPA approval date	Federal Register citation	Explanation
* * * * * North Carolina Removal of 26 Counties from Inspection and Maintenance Program and 110(l) Non-Interference Demonstration.	11/17/2017	9/25/2018	[insert <b>Federal Register</b> citation].	*

[FR Doc. 2018-20748 Filed 9-24-18; 8:45 am]  
BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[Docket No. EPA-R02-OAR-2018-0622; FRL-9984-35—Region 2]

**Adequacy Status of Motor Vehicle Emissions Budgets for the New Jersey Portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT 2008 8-hour Ozone Nonattainment Area**

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

**ACTION:** Notification of adequacy.

**SUMMARY:** In this document, the Environmental Protection Agency (“EPA” or “Agency”) is notifying the public that the Agency has found that the 2017 motor vehicle emissions budgets (“budgets”) for volatile organic compounds (“VOCs”) and nitrogen oxides (“NO<sub>x</sub>”) submitted by the New Jersey Department of Environmental Protection for the 2008 national ambient air quality standard (“NAAQS”) for ozone are adequate for transportation conformity purposes for the New Jersey portions of the New York-Northern New

Jersey-Long Island, NY-NJ-CT 8-hour ozone nonattainment area. The transportation conformity rule) requires that the EPA conduct a public process and make an affirmative decision on the adequacy of these budgets before they can be used by metropolitan planning organizations in conformity determinations. As a result of this finding, upon the effective date of this notification of adequacy, the North Jersey Transportation Planning Authority must use these budgets in future transportation conformity determinations. The budgets are contained in New Jersey's December 22, 2017, state implementation plan submittal for the 2008 8-hour ozone NAAQS and are associated with the reasonable further progress milestone demonstration.

**DATES:** This finding is effective October 10, 2018.

**FOR FURTHER INFORMATION CONTACT:**

Reema Loutan, Environmental Protection Agency Region 2, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007-1866; (212) 637-3760, [loutan.reema@epa.gov](mailto:loutan.reema@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Throughout this document, whenever "we," "us," or "our" is used, we mean the EPA.

This document is simply an announcement of a finding that we have already made. EPA Region 2 sent a letter to the New Jersey Department of Environmental Protection on August 16, 2018, stating that the 2017 motor vehicle emissions budgets ("budgets") in the submitted state implementation plan ("SIP") for the 2008 national ambient air quality standard for ozone for the New Jersey portions of the New York-Northern New Jersey-Long Island, NY-NJ-CT 8-hour ozone nonattainment area are adequate for transportation conformity purposes. These budgets are associated with the SIP's reasonable further progress milestone demonstration and must apply to future transportation conformity determinations conducted by the North Jersey Transportation Planning Authority ("NJTPA").

On December 22, 2017, the New Jersey Department of Environmental Protection submitted a SIP revision for the New Jersey portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT 2008 8-hour ozone nonattainment area. This revision to the SIP included 2017 summer day volatile organic compound ("VOC") and nitrogen oxides ("NO<sub>x</sub>") motor vehicle emissions budgets associated with the SIP's reasonable further progress

demonstration. We announced availability of the plan and related budgets on the EPA's transportation conformity website on February 8, 2018, requesting comments by March 12, 2018. We received no comments in response to the adequacy review posting.

This finding will also be available at the EPA's conformity website: <https://www.epa.gov/state-and-local-transportation/conformity-adequacy-review-region-2>.

The motor vehicle emissions budgets are provided in Table 1 below.

TABLE 1—2017 MOTOR VEHICLE EMISSIONS BUDGETS FOR NJTPA  
[Tons per day]

Year	NO <sub>x</sub>	VOC
2017 .....	103.22	48.69

Transportation conformity is required by Clean Air Act section 176(c). The EPA's conformity rule requires that long-range transportation plans, transportation improvement programs, and transportation projects conform to a state's air quality SIP and establishes the criteria and procedures for determining whether or not they conform. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS.

The criteria the EPA uses to determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). We have further described our process for determining the adequacy of submitted SIP budgets in 40 CFR 93.118(f), and we followed this rule in making our adequacy determination. Please note that an adequacy review is separate from the EPA's completeness review and should not be used to prejudge the EPA's ultimate action on the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

Pursuant to 40 CFR 93.104(e), within 2 years of the effective date of this document, NJTPA and the U.S. Department of Transportation will need to demonstrate conformity to the new budgets. For demonstrating conformity to the budgets in this plan, the on-road motor vehicle emissions from implementation of the long-range transportation plan should be projected consistently with the budgets in this plan.

**Authority:** 42 U.S.C. 7401-7671q.

Dated: September 5, 2018.

**Peter D. Lopez,**

*Regional Administrator, Region 2.*

[FR Doc. 2018-20738 Filed 9-24-18; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R01-OAR-2016-0398; FRL-9983-99—Region 1]

**Air Plan Approval; New Hampshire; Updates to Enhanced Motor Vehicle Inspection and Maintenance Program Regulation**

**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 New Hampshire. This revision includes an amended regulation for the enhanced motor vehicle inspection and maintenance (I/M) program in New Hampshire. New Hampshire continues to implement a test and repair network for an on-board diagnostic (OBD2) testing program. The submitted New Hampshire regulation updates and clarifies the implementation of the New Hampshire I/M program. The intended effect of this action is to approve the updated I/M program regulation into the New Hampshire SIP. This action is being taken in accordance with the Clean Air Act.

**DATES:** This rule is effective on October 25, 2018.

**ADDRESSES:** EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2016-0398. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, 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 at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to



schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Ariel Garcia, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA Region 1 Regional Office, 5 Post Office Square, Suite 100 (Mail code: OEP05-2), Boston, MA 02109-3912, telephone number: (617) 918-1660, email: [garcia.ariel@epa.gov](mailto:garcia.ariel@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document whenever "we," "us," or "our" is used, we mean EPA.

## Table of Contents

- I. Background and Purpose
- II. Response to Comments
- III. Final Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

### I. Background and Purpose

On August 3, 2018 (83 FR 38102), the EPA published a Notice of Proposed Rulemaking (NPRM) for the State of New Hampshire. The NPRM proposed approval of New Hampshire's amended regulation for the New Hampshire motor vehicle inspection and maintenance (I/M) program. The formal SIP revision was submitted by New Hampshire on June 7, 2016. The rationale for the EPA's proposed action is explained in the NPRM and will not be restated here.

### II. Response to Comments

The EPA received one comment during the comment period, which discussed subjects outside the scope of this SIP action, does not explain (or provide a legal basis for) how the proposed action should differ in any way, and makes no specific mention of the proposed action. As such, the comment is not germane and does not require further response to finalize the action as proposed.

### III. Final Action

The EPA is approving New Hampshire's amended I/M regulation as a revision to the New Hampshire SIP.

### IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the amended New Hampshire Code of Administrative Rules Chapter Saf-C 3200 entitled, "Official Motor Vehicle Inspection Requirements," described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and

will continue to make, these documents generally available through <https://www.regulations.gov> and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the State implementation plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.<sup>1</sup>

### V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- This action is not an Executive Order 13771 regulatory action because this action is not significant 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 (Public Law 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 Clean Air Act; and

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 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 may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide,

<sup>1</sup> 62 FR 27968 (May 22, 1997).

Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 17, 2018.

**Alexandra Dunn,**

*Regional Administrator, EPA Region 1.*

Part 52 of chapter I, title 40 of the Code of Federal Regulations 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 EE—New Hampshire**

■ 2. In § 52.1520, the table in paragraph (c) is amended by revising the entry for “Saf-C 3200” to read as follows:

**§ 52.1520 Identification of plan.**

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

**EPA-APPROVED NEW HAMPSHIRE REGULATIONS**

State citation	Title/subject	State effective date	EPA approval date <sup>1</sup>	Explanations
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Saf-C 3200 .....	Official Motor Vehicle Inspection Requirements.	01/06/2016	9/25/2018, [Insert <b>Federal Register</b> citation].	Amends Saf-C sections 3202, 3203, 3204, 3205, 3206.04, 3207.01, 3209, 3210, 3218, 3220, 3222, and 3248; and approves Saf-C 3219.
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

<sup>1</sup> In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

\* \* \* \* \*  
[FR Doc. 2018–20743 Filed 9–24–18; 8:45 am]  
BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA–R04–OAR–2016–0334; FRL–9984–36—Region 4]

**Air Plan Approval; AL, FL, GA, KY, MS, NC, SC, TN; Interstate Transport for the 2012 PM<sub>2.5</sub> NAAQS**

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to approve portions of State Implementation Plan (SIP) submissions from Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee addressing the Clean Air Act (CAA or Act) interstate transport infrastructure SIP requirements for the 2012 Fine Particulate Matter (PM<sub>2.5</sub>) National Ambient Air Quality Standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, commonly referred to as an “infrastructure SIP.” EPA is taking final action to approve the interstate transport portions of these

infrastructure SIPs for the aforementioned states as demonstrating that air emissions in the states do not significantly contribute to nonattainment or interfere with maintenance of the 2012 PM<sub>2.5</sub> NAAQS in any other state.

**DATES:** This rule will be effective October 25, 2018.

**ADDRESSES:** EPA has established a docket for these actions under Docket Identification No. EPA–R04–OAR–2016–0334. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) website. Although listed in the index, some information may not be publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office’s official hours of business are Monday

through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Wong can be reached by telephone at (404) 562–8726 or via electronic mail at [wong.richard@epa.gov](mailto:wong.richard@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On December 14, 2012, EPA revised the primary Annual PM<sub>2.5</sub> NAAQS to 12.0 micrograms per cubic meter (µg/m<sup>3</sup>). See 78 FR 3086 (January 15, 2013). An area meets the standard if the three-year average of its annual average PM<sub>2.5</sub> concentration (at each monitoring site in the area) is less than or equal to 12.0 µg/m<sup>3</sup>. States were required to submit infrastructure SIP submissions for the 2012 Annual PM<sub>2.5</sub> NAAQS to EPA no later than December 14, 2015.

CAA section 110(a)(1) requires states to submit SIP revisions within three years after promulgation of a new or revised NAAQS in order to provide for the implementation, maintenance, and enforcement of the new or revised NAAQS. CAA section 110(a)(2) outlines the applicable requirements of such SIP submissions, which EPA has historically referred to as “infrastructure SIP” submissions. Section 110(a)(2)

requires states to address basic SIP elements such as monitoring, basic program requirements (e.g., permitting), and legal authority that are designed to assure attainment and maintenance of the newly established or revised NAAQS. Thus, section 110(a)(1) provides the procedural and timing requirements for infrastructure SIPs, and section 110(a)(2) lists specific elements that states must meet for the infrastructure SIP requirements related to a newly established or revised NAAQS. The contents of an infrastructure SIP submission may vary depending upon the data and analytical tools available to the state, as well as the provisions already contained in the state's implementation plan at the time in which the state develops and submits the submission for a new or revised NAAQS.

Section 110(a)(2)(D) has two subsections: 110(a)(2)(D)(i) and 110(a)(2)(D)(ii). Section 110(a)(2)(D)(i) includes four distinct components, commonly referred to as "prongs," that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), require plans to prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (prong 1) and from interfering with maintenance of the NAAQS in another state (prong 2). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state (prong 3) or from interfering with measures to protect visibility in another state (prong 4). Section 110(a)(2)(D)(ii) requires SIPs to include provisions insuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement.<sup>1</sup>

In a notice of proposed rulemaking (NPRM) published on August 9, 2018 (83 FR 39387), EPA proposed to approve the prong 1 and prong 2 portions of infrastructure SIP submissions transmitted under cover letter by:

<sup>1</sup> EPA highlighted the statutory requirement to submit infrastructure SIPs within three years of promulgation of a new NAAQS in an October 2, 2007, guidance document entitled "Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and PM<sub>2.5</sub> National Ambient Air Quality Standards." EPA has issued additional guidance documents and memoranda, including a September 13, 2013, guidance document entitled "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)."

Alabama (dated December 9, 2015); Florida (dated December 14, 2015); Georgia (dated December 14, 2015); Kentucky (dated February 8, 2016); Mississippi (dated December 8, 2015); North Carolina (dated December 4, 2015); South Carolina (dated December 14, 2015); and Tennessee (dated December 16, 2015), as demonstrating that these states do not significantly contribute to nonattainment or interfere with maintenance of the 2012 Annual PM<sub>2.5</sub> NAAQS in any other state.<sup>2</sup> All other applicable infrastructure SIP requirements for these SIP submissions have been or will be addressed in separate rulemakings. The specific details of the SIP submissions and the rationale for EPA's actions on prongs 1 and 2 are discussed in the NPRM. Comments on the proposed rulemaking were due on or before August 30, 2018. EPA received three comments that are not relevant to the proposed actions and one comment in support of the proposed actions. These comments can be found in the docket for these actions.

## II. Final Action

EPA is taking final action to approve the portions of the infrastructure SIP submissions transmitted under cover letter by: Alabama (dated December 9, 2015); Florida (dated December 14, 2015); Georgia (dated December 14, 2015); Kentucky (dated February 8, 2016); Mississippi (dated December 8, 2015); North Carolina (dated December 4, 2015); South Carolina (dated December 14, 2015); and Tennessee (dated December 16, 2015) addressing prongs 1 and 2 of section 110(a)(2)(D)(i)(I) for the 2012 Annual PM<sub>2.5</sub> NAAQS. EPA is taking final action to approve section 110(a)(2)(D)(i)(I) for the aforementioned infrastructure SIP submissions for the 2012 Annual PM<sub>2.5</sub> NAAQS because the submissions are consistent with section 110 of the CAA.

## III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. See 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. These actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those

<sup>2</sup> EPA notes that the Agency may not have received the submissions until after the date of the cover letter.

imposed by state law. For that reason, these actions:

- Are not significant regulatory actions 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);
  - Are not Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory actions because SIP approvals are exempted under Executive Order 12866;
  - Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
  - Are 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.*);
  - Do 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);
  - Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
  - Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
  - Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
  - Are 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
  - Do 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 SIPs subject to these actions, with the exception of the South Carolina SIP, are not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law. With respect to the South Carolina SIP, EPA notes that the Catawba Indian Nation Reservation is located within South Carolina, and pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27-16-120, "all state and local environmental

laws and regulations apply to the Catawba Indian Nation and Reservation and are fully enforceable by all relevant state and local agencies and authorities.” Thus, the South Carolina SIP applies to the Catawba Reservation; however, because the action related to South Carolina is not approving any specific rule into the South Carolina SIP, but rather finding that the State’s already approved SIP meets certain CAA requirements, EPA has determined that there are no substantial direct effects on the Catawba Indian Nation. EPA has also determined that the action related to South Carolina’s SIP will not impose any substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a

report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 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 may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

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

Environmental protection, Air pollution control, Carbon monoxide,

Incorporation by reference, Intergovernmental relations, Particulate matter, Volatile organic compounds.

Dated: September 13, 2018.

**Onis “Trey” Glenn, III,**  
*Regional Administrator, Region 4.*

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 B—Alabama**

■ 2. Section 52.50(e) is amended by adding the entry “110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.50 Identification of plan.**

\* \* \* \* \*

(e) \* \* \*

**EPA-APPROVED ALABAMA NON-REGULATORY PROVISIONS**

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	Alabama .....	12/9/2015	9/25/2018, [Insert citation of publication].	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

**Subpart K—Florida**

■ 3. Section 52.520(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.520 Identification of plan.**

\* \* \* \* \*

(e) \* \* \*

**EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS**

Provision	State effective date	EPA approval date	Federal Register notice	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	10/15/2015 .....	9/25/2018	[Insert citation of publication]	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

**Subpart L—Georgia**

■ 4. Section 52.570(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.570 Identification of plan.**

\* \* \* \* \*

(e) \* \* \*

EPA-APPROVED GEORGIA NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	Georgia .....	12/14/2015	9/25/2018, [Insert citation of publication].	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

**Subpart S—Kentucky**

■ 5. Section 52.920(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.920 Identification of plan.**  
\* \* \* \* \*  
(e) \* \* \*

EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanations
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	Kentucky .....	2/8/2016	9/25/2018, [Insert citation of publication].	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

\* \* \* \* \*

**Subpart Z—Mississippi**

■ 6. Section 52.1270(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.1270 Identification of plan.**  
\* \* \* \* \*  
(e) \* \* \*

EPA-APPROVED MISSISSIPPI NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	Mississippi .....	12/8/2015	9/25/2018, [Insert citation of publication].	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

**Subpart II—North Carolina**

■ 7. Section 52.1770(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.1770 Identification of plan.**  
\* \* \* \* \*  
(e) \* \* \*

EPA-APPROVED NORTH CAROLINA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	Federal Register citation	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	12/4/2015 .....	9/25/2018	[Insert citation of publication]	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

**Subpart PP—South Carolina**

■ 8. Section 52.2120(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.2120 Identification of plan.**  
\* \* \* \* \*  
(e) \* \* \*

Provision	State effective date	EPA approval date	Explanation
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	12/14/2015	9/25/2018, [Insert citation of publication].	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

**Subpart RR—Tennessee**

■ 9. Section 52.2220(e) is amended by adding the entry “110(a)(1) and (2)

Infrastructure Requirements for the 2012 Annual PM<sub>2.5</sub> NAAQS” at the end of the table to read as follows:

**§ 52.2220 Identification of plan.**  
 \* \* \* \* \*  
 (e) \* \* \*

**EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS**

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM <sub>2.5</sub> NAAQS.	Tennessee	11/19/2015	9/25/2018, [Insert citation of publication].	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

[FR Doc. 2018–20728 Filed 9–24–18; 8:45 am]  
**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[EPA–HQ–SFUND–2002–0001; FRL–9984–46–Region 8]

**National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Eureka Mills Superfund Site**

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 8 announces the deletion of the Eureka Mills Superfund Site (Site) located in Eureka, Utah, from the National Priorities List (NPL). 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). The EPA and the State of Utah, through the Utah Department of Environmental Quality (UDEQ), have determined that all appropriate response actions under CERCLA, other than operation and maintenance and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** This action is effective September 25, 2018.

**ADDRESSES:** *Docket:* EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–2002–0001. 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, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form.

Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at: Eureka City Hall, 255 W Main Street, Eureka, UT 84628; Phone: 435–433–6915; Hours: M–Fri: 8:30 a.m.–5:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Armando Saenz, Remedial Project Manager, U.S. Environmental Protection Agency, Region 8, EPA–SR, Denver, CO 80202, (303) 312–6559, email: [saenz.armando@epa.gov](mailto:saenz.armando@epa.gov).

**SUPPLEMENTARY INFORMATION:** The site to be deleted from the NPL is: Eureka Mills Superfund Site, Eureka, Utah. A Notice of Intent to Delete for this Site was published in the **Federal Register** (83 FR 38672–38675) on August 7, 2018.

The closing date for comments on the Notice of Intent to Delete was September 6, 2018. Two comments were received. One comment discusses air pollution and air monitoring in China and India. The other comment is about

air travel. These comments are not germane to the proposed ruling. A responsiveness summary was prepared and placed in both the docket, EPA–HQ–SFUND–2002–0001, on [www.regulations.gov](http://www.regulations.gov), and in the local repositories listed above.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. 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. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

**List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 17, 2018.

**Douglas H. Benevento,**  
*Regional Administrator, Region 8.*

For reasons set out in the preamble, 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 removing “UT”, “Eureka Mills”, “Eureka”.

[FR Doc. 2018–20855 Filed 9–24–18; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[EPA–HQ–SFUND–2000–0003; FRL–9984–45–Region 4]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Davis Timber Company Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 4 announces the deletion of the Davis Timber Company Superfund Site (Site) located in Hattiesburg, Lamar County, Mississippi, from the National Priorities List (NPL). 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). The EPA and the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ), have determined that all appropriate response actions under CERCLA, other than operation and maintenance, and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** This action is effective September 25, 2018.

**ADDRESSES:** *Docket:* EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–2000–0003. 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, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

(1) USEPA Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960, Monday–Friday 7:30 a.m.–4:30 p.m., Contact Tina Terrell 404–562–8835; and

(2) Oak Grove Public Library (in the Reference Section), 4958 Old Highway 11, Hattiesburg, Mississippi, 39402, Monday–Friday 9:00 a.m.–6:00 p.m.; and Saturdays 10:00 a.m. to 2:00 p.m.; Phone: 601–296–1620.

#### FOR FURTHER INFORMATION CONTACT:

Scott Martin, Remedial Project Manager, Superfund Restoration and Sustainability Branch, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960, (404) 562–8916, email: [martin.scott@epa.gov](mailto:martin.scott@epa.gov).

**SUPPLEMENTARY INFORMATION:** The site to be deleted from the NPL is: Davis Timber Company Superfund Site (Site) located in Hattiesburg, Lamar County, Mississippi. A Notice of Intent to Delete for this Site was published in the **Federal Register** 83 FR 33182 on July 17, 2018.

The closing date for comments on the Notice of Intent to Delete was August 16, 2018. One public comment was received and it does not address the rule-making or deletion. Since the comment was not related to the deletion of this Site, EPA believes the deletion action is appropriate. A responsiveness summary was prepared and placed in both the docket, EPA–HQ–SFUND–2000–0003, on [www.regulations.gov](http://www.regulations.gov), and in the local repositories listed above.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. 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. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

#### 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: September 11, 2018.

Onis “Trey” Glenn, III,  
Regional Administrator, Region 4.

For reasons set out in the preamble, 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 removing the listing under Mississippi for “Davis Timber Company”.

[FR Doc. 2018–20838 Filed 9–24–18; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[EPA–HQ–SFUND–2002–0001; FRL–9984–44–Region 4]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Reasor Chemical Company Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 4 announces the deletion of the Reasor Chemical Company Superfund Site (Site) located in Castle Hayne, North Carolina, from the National Priorities List (NPL). 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). The EPA and the State of North Carolina, through the North Carolina Department of Environmental Quality, have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** This action is effective September 25, 2018.

**ADDRESSES:** *Docket:* EPA has established a docket for this action under Docket Identification No. EPA-HQ-SFUND-2002-0001. 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, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

- U.S. EPA Record Center, attention: Ms. Tina Terrell, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. Phone: 404-562-8835. Hours: 8 a.m.-4 p.m., Monday through Friday by appointment only; and
- New Hanover County Library, 201 Chestnut Street, Wilmington, North Carolina 28401. Phone: 910-798-6391. Hours: 9 a.m.-5 p.m., Monday through Saturday.

**FOR FURTHER INFORMATION CONTACT:** Samantha Urquhart-Foster, Remedial Project Manager, Remediation and Site Evaluation Branch, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. Phone: 404-562-8760, email: [urquhart-foster.samantha@epa.gov](mailto:urquhart-foster.samantha@epa.gov).

**SUPPLEMENTARY INFORMATION:** The site to be deleted from the NPL is: Reasor Chemical Company Site in Castle Hayne, North Carolina. A Notice of Intent to Delete for this Site was published in the **Federal Register** (83 FR 36844) on July 31, 2018.

The closing date for comments on the Notice of Intent to Delete was August 30, 2018. One public comment was received. EPA believes this is not a site-specific adverse comment opposing the rule-making. EPA believes it is still appropriate to delete the site, and will proceed with the deletion action. A responsiveness summary was prepared and placed in both the docket, EPA-HQ-SFUND-2002-0001, on [www.regulations.gov](http://www.regulations.gov), and in the local repositories listed above.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial

action. 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. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

#### 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: September 10, 2018.

**Onis "Trey" Glenn, III,**

*Regional Administrator, Region 4.*

For reasons set out in the preamble, 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 removing the listing under North Carolina for "Reasor Chemical Company".

[FR Doc. 2018-20839 Filed 9-24-18; 8:45 am]

**BILLING CODE 6560-50-P**

### DEPARTMENT OF TRANSPORTATION

#### Pipeline and Hazardous Materials Safety Administration

#### 49 CFR Parts 174 and 179

[Docket No. PHMSA-2017-0102 (HM-251F)]

RIN 2137-AF35

#### Hazardous Materials: Removal of Electronically Controlled Pneumatic Brake System Requirements for High Hazard Flammable Unit Trains

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** The Pipeline and Hazardous Materials Safety Administration, in

coordination with the Federal Railroad Administration, is issuing this final rule to remove requirements pertaining to electronically controlled pneumatic brake systems on high-hazard flammable unit trains. This final action is based on the Department of Transportation's determination that the requirements are not economically justified.

**DATES:** *Effective Date:* This rule is effective September 25, 2018.

**ADDRESSES:** *Docket:* You may view the public docket online at <http://www.regulations.gov> or in person at Dockets Operations, M-30, Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001 between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** For regulatory impact analysis-related questions, please contact Mark Johnson, Senior Economist, PHMSA, by telephone at 202-366-4495 or by email at [mark.johnson@dot.gov](mailto:mark.johnson@dot.gov), or Marc Fuller, Staff Director, RRS-21, FRA, by telephone at 202-366-9335 or by email at [marc.fuller@dot.gov](mailto:marc.fuller@dot.gov). For rulemaking related questions, please contact Candace Casey, Transportation Specialist, PHMSA, by telephone at 202-366-8579 or by email at [candace.casey@dot.gov](mailto:candace.casey@dot.gov).

#### SUPPLEMENTARY INFORMATION:

#### Abbreviations and Terms

AAR Association of American Railroads  
 APA Administrative Procedure Act  
 CFR Code of Federal Regulations  
 CPC Casualty Prevention Circular  
 DOT Department of Transportation  
 DP system Distributive Power  
 EA Environmental Assessment  
 ECP Electronically Controlled Pneumatic  
 EOT End-of-Train  
 FAST Act Fixing America's Surface Transportation Act of 2015  
 FR Federal Register  
 FRA Federal Railroad Administration  
 GAO Government Accountability Office  
 HHFT High-Hazard Flammable Train  
 HHFUT High-Hazard Flammable Unit Train  
 HMR Hazardous Materials Regulations  
 HMT Hazardous Materials Table  
 NEPA National Environmental Policy Act  
 NPRM Notice of Proposed Rulemaking  
 NPV Net Present Value  
 NTSB National Transportation Safety Board  
 OMB Office of Management and Budget  
 PG Packing Group  
 PV Present Value  
 PHMSA Pipeline and Hazardous Materials Safety Administration  
 RFA Regulatory Flexibility Act  
 RIA Regulatory Impact Analysis  
 RIN Regulation Identifier Number  
 RSAC Railroad Safety Advisory Council  
 RSI Railway Supply Institute  
 TDG Transportation of Dangerous Goods  
 U.S.C. United States Code



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**I. Background**

On May 8, 2015, in collaboration with the Federal Railroad Administration (FRA), PHMSA published the final rule “Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains” (hereafter referred to as “HM–251 final rule”). The HM–251 final rule was an integral part of the Department’s comprehensive approach to ensuring the safe transportation of energy products by rail. Many provisions in HM–251, including those pertaining to advanced brake systems, were the culmination of industry-led efforts to improve tank car safety in anticipation of increased crude oil shipments by rail, which began in 2008.

In September of 2007, FRA published a notice of proposed rulemaking (NPRM) proposing to revise FRA power brake regulations “to provide for and encourage the safe implementation and use of ECP brake system technologies” (72 FR 50820). The rulemaking was initiated following a joint petition by BNSF Railway (BNSF) and Norfolk Southern (NS) to FRA for a waiver from existing brake power requirements to allow those railroads to operate ECP brake pilot trains.<sup>1</sup> The NPRM proposed incorporating by reference the Association of American Railroad’s (AAR) existing ECP brake system standards. In December of 2008, FRA published a final rule adopting updated AAR ECP brake standards and granting regulatory relief from certain

requirements tied to traditional power brakes (e.g. extended the distance between brake inspections for train operations using ECP brakes), which added regulatory flexibility by allowing the use of ECP brakes without the need to apply for a waiver.

In 2011, FRA and the Railway Supply Institute (RSI) met to discuss improvements to tank cars used for the transportation of crude oil in unit trains. The main intent of the meeting was to spur discussion about innovative ways to improve tank car safety for potential future changes in the hazardous materials transportation supply chain. The meeting resulted in the RSI members offering to develop an industry standard (non-regulatory in nature) in collaboration with the AAR, the Renewable Fuels Association (RFA), Growth Energy, and the American Petroleum Institute (API). This collaborative effort was conducted through AAR’s Tank Car Committee Task Force, T87.6.<sup>2</sup> The T87.6 Task Force carried out technical analyses and generated information for tank car safety improvements, including findings on alternative brake signal propagation systems (i.e., “brake systems”). The advanced brake systems considered in the T87.6 Task Force meetings included conventional air brake systems, ECP brake systems, distributive power (DP) systems, and two-way end-of-train (EOT) devices.

On September 6, 2013, PHMSA published an Advance Notice of Proposed Rulemaking (ANPRM) titled, “Hazardous Materials: Rail Petitions and Recommendations To Improve the Safety of Railroad Tank Car Transportation” (78 FR 54849), specifically requesting comments pertaining to the use of these advanced brake propagation systems to reduce the kinetic energy associated with a derailment based on the understanding that a reduction in kinetic energy would, on average, reduce the number of tank cars involved in the derailment. Similarly, FRA and the Railroad Safety Advisory Committee (RSAC) considered and evaluated the usefulness of advanced brake systems. On August 1, 2014, PHMSA issued an NPRM titled “Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains” (79 FR 45016). In the NPRM, PHMSA and

FRA considered comments submitted to the ANPRM and, where relevant, proposed to adopt revisions based on the comments. Additionally, in the NPRM, PHMSA requested additional comments pertaining to advanced brake systems.

On May 8, 2015, PHMSA issued the HM–251 final rule (80 FR 26644). In the final rule, PHMSA amended the Hazardous Materials Regulations (HMR; 49 CFR parts 171 through 180) by codifying new definitions for trains carrying large volumes of flammable liquids, “high-hazard flammable trains” (HHFTs) and “high-hazard flammable unit trains” (HHFUTs),<sup>3</sup> and by implementing additional operational restrictions (e.g., requirements related to speed, braking systems, and routing) for such trains. Specifically, as it relates to this final rule, HM–251 included amendments requiring all tank cars in HHFUTs operating under certain conditions to be equipped with ECP brake systems.

On December 4, 2015, President Barack Obama signed the Fixing America’s Surface Transportation Act of 2015 (FAST Act) into law. Title VII of the FAST Act, called the Hazardous Materials Transportation Safety Improvement Act of 2015, outlines several requirements pertaining to the HMR. Section 7311 specifically mandates the study and testing of ECP brake systems, focusing on requirements that were promulgated under the HM–251 final rule. Furthermore, the FAST Act instructs the Department of Transportation to incorporate the results of the Government Accountability Office’s (GAO) evaluations and the testing of ECP brake systems by the National Academy of Sciences into an updated regulatory impact analysis (RIA) of the ECP brake system requirements, and to solicit public comment on the updated RIA. Additionally, the FAST Act required that within two years of the mandate, the DOT must determine, based on the updated RIA, whether the ECP brake system requirements in the HM–251 final rule were justified.

In October 2016, GAO submitted a report<sup>4</sup> with four major recommendations concerning the ECP

<sup>3</sup> A high-hazard flammable train is a single train comprised of 20 or more loaded tank cars containing a Class 3 flammable liquid in a continuous block, or 35 or more loaded tank cars containing a Class 3 flammable liquid across the entire train. A high-hazard flammable unit train is a train comprised of 70 or more loaded tank cars containing Class 3 flammable liquids.

<sup>4</sup> DOT’s Rulemaking on Electronically Controlled Pneumatic Brakes Could Benefit from Additional Data and Transparency, GAO–17–122, Oct. 12, 2016.

<sup>1</sup> The joint waiver petition was handled in a separate proceeding than FRA’s ECP brake rulemaking. See Docket No. FRA–2006–26435 at <https://www.regulations.gov/docket?D=FRA-2006-26435>.

<sup>2</sup> On July 20, 2011, at the summer AAR Tank Car Committee meeting, Docket T87.6 was created with a dual charge: (1) To develop an industry standard for tank cars used to transport crude oil, denatured alcohol, and ethanol/gasoline mixtures; and (2) to consider operating requirements to reduce the risk of derailment of tank cars carrying crude oil classified as Packing Group I and II, and ethanol.

brake system requirements. GAO recommended that DOT: (1) When updating the RIA, take into account potential uncertainty in key variables and assumptions (e.g., fuel prices and future rail traffic of crude oil and ethanol), discuss this uncertainty, and present ranges of possible scenarios; (2) create a plan to collect data from railroads' ongoing and future operational experiences using ECP brake systems; (3) require freight railroads to collect and provide data to FRA on their ongoing operational experience with ECP brake systems if a new requirement were adopted; and (4) publish information that would allow a third party to fully assess and replicate the analysis used in support of the HM-251 final rule. In May 2017, GAO produced a separate report<sup>5</sup> in response to a congressional inquiry, which further indicated that DOT's forecasted values for some of the variables associated with the transportation by rail of crude oil and ethanol (such as the forecasted number of tank cars used to ship crude oil and ethanol, derailment rate, average amount of product lost per derailment, and number of injuries and deaths) may be higher than values realized in 2015 and 2016 based on preliminary data.

In October 2017, PHMSA and FRA published a notice of availability and request for comments (82 FR 48006) on a revised RIA updating the original RIA associated with the ECP brake provisions. As mandated by the FAST Act, DOT updated the RIA and made a determination regarding whether the applicable ECP brake system requirements are economically justified.

Based on that revised analysis, the Department determined that the expected benefits, including safety benefits, of implementing ECP brake system requirements do not exceed the associated costs of equipping tank cars with ECP brake systems, and therefore are not economically justified. For this reason, PHMSA is issuing this final rule to remove the ECP brake system requirements from the HMR.

The estimated costs and benefits for the 20-year analysis used in the final revised RIA are presented in Table 1 (below) in three different scenarios labeled "high," "low," and "sensitivity." The three scenarios are based on various levels of future crude oil shipped by rail, to reflect uncertainty regarding those future volumes and to evaluate the ECP brake system requirements over a reasonably wide range of scenarios to determine whether the cost-benefit ratio would be affected by varying levels of crude oil transportation by rail.

The scenario labeled "high" describes a projection in which the highest crude oil by rail volumes of the three scenarios were produced. The "high" scenario was derived from an analysis by linear regression of crude oil carloads on crude oil production volumes using data from 2010 through 2016. A similar model was run comparing volumes of ethanol shipped by rail to ethanol production volumes. The forecasted streams of rail carloads from both models were then added to obtain the total forecast carload volume as presented in Table 8.2a of the docketed RIA.

The "low" scenario presents a crude oil volume forecast that is essentially

flat at the 5-year average at a lower volume than that produced by the linear forecast described above. The "low" scenario used the linear forecast model for ethanol as described above to forecast ethanol carload volumes and used an average of the most recent 5 years for which data is complete (2012–2016) to forecast crude oil volumes into the future. These years coincide with the emergence of high crude oil by rail volumes (volumes in excess of 100,000 carloads per year). The carload figures for this forecast are also presented in Table 8.2a of the docketed RIA.

Finally, DOT examined a third scenario which forecast crude oil by rail volumes to continue their recent decline for a few more years and bottom out at 120,000 carloads per year, which were added to the linear ethanol forecast volumes as described above in the "high" scenario description. This scenario was presented in the sensitivity analysis section, and hence was labeled "sensitivity" in the table. It produced the lowest volume crude oil by rail forecast of the three scenarios, and was intended to capture the potential impacts of increased pipeline capacity or other factors that might lead to further declines in crude oil by rail volumes. These scenarios capture a wide range of future flammable liquids by rail volumes, over which the ECP brake requirements were evaluated. As can be seen below, and as reflected in the final updated RIA, the ECP brake system requirements are not expected to be cost-beneficial under any scenario assessed.

TABLE 1—COSTS AND BENEFITS OVER 20 YEARS  
[Millions of dollars]

	7 Percent			3 Percent		
	Low	High	Sensitivity	Low	High	Sensitivity
Tank Cars .....	\$237.76	\$318.49	\$165.00	\$256.18	\$341.52	\$178.39
Locomotives .....	105.03	140.42	77.13	110.79	147.39	81.84
Asset Management .....	0.52	0.52	0.52	0.52	0.52	0.52
Training .....	32.29	32.29	32.29	34.62	34.62	34.62
Total Costs .....	375.60	491.72	274.95	402.11	524.05	295.37
Damage Mitigation .....	48.16	78.19	37.36	67.19	109.44	52.41
Set Out Reliefs .....	5.87	7.46	3.56	8.24	10.55	4.97
Class IA Brake Test .....	27.54	46.04	21.68	45.07	65.12	30.24
Wheel Savings .....	26.77	37.40	17.87	36.08	52.90	24.93
Fuel Savings .....	22.70	28.85	13.79	31.90	40.81	19.23
Total Benefits .....	131.03	197.95	94.27	188.49	278.81	131.78
Net Benefits .....	-244.57	-293.78	-180.68	-213.63	-245.24	-163.59

<sup>5</sup> 2015 Electronically Controlled Pneumatic Brake Rule: Comparison of DOT Forecasts for Selected

Data Points for 2015 and 2016 to Preliminary Data for Those Years, GAO-17-567R, May 31, 2017.

## II. Good Cause Justification

PHMSA is issuing this final rule without providing an opportunity for public notice and comment as is normally provided under the Administrative Procedure Act (APA; 5 U.S.C. 553). The APA authorizes agencies to dispense with certain notice and comment procedures if the agency finds good cause that notice and public procedures thereon are impracticable, unnecessary, or contrary to the public interest. *See* 5 U.S.C. 553(b)(3)(B). Good cause exists because PHMSA and FRA are following the procedures established in section 7311 of the FAST Act, which requires DOT to prepare a draft updated RIA, seek public comment on the draft updated RIA, prepare a final updated RIA, and make a determination whether the ECP brake system provisions for HHFUTs were justified, based on the costs and the benefits. On December 4, 2017, the Department determined that the ECP brake system provisions in the HM-251 final rule were not justified. This rulemaking action codifies that determination. The public was afforded an opportunity to comment on the revised RIA that formed the basis for determination of whether the ECP brake system requirements would be removed from the HMR. (*See* Section I of this revised final rule.) In this sense, the public has had an opportunity to provide useful information related to this regulatory action. However, having come to its determination that the ECP brake system requirement is not economically justified, PHMSA's adoption of this rule is non-discretionary.

This final rule addresses a Congressional mandate instructing the Department to make a determination on whether the ECP brake provisions in the HM-251 final rule were justified by December 4, 2017. Section 7311 of the FAST Act established a clearly defined procedure for making that determination. PHMSA's actions in this final rule merely codify the Department's determination in the HMR.<sup>6</sup> Publishing a notice of proposed rulemaking and seeking comment on the proposal would unnecessarily impede the due and timely execution of PHMSA's regulatory functions by delaying the codification of a non-discretionary regulatory action. In making these ministerial amendments to give effect to the Department's determination, PHMSA is not exercising discretion in a way that could be informed by public comment. As such,

notice and comment procedures are "impracticable, unnecessary, or contrary to the public interest" within the meaning of the APA (5 U.S.C. 553(b)(3)(B)).

Furthermore, this final rule is effective on the day of publication in the **Federal Register**. The APA requires agencies to delay the effective date of regulations for 30 days after publication, unless the agency finds good cause to make the regulations effective sooner. *See* 5 U.S.C. 553(d). As previously discussed, PHMSA finds that good cause exists to publish this rulemaking without a notice of proposed rulemaking and opportunity for public comment and to make the regulations effective prior to 30 days after publication. This rule simply implements the determination of the Department, which was made in accordance with the specific process designated in section 7311 of the FAST Act; therefore, PHMSA would be unable to adjust the text of the rule to account for any public comment.

## III. Section-by-Section Review

### Part 174

#### Section 174.310

Section 174.310 outlines additional safety requirements, such as routing, speed restrictions, and brake system requirements specific to HHFTs and HHFUTs. A rail carrier must comply with these additional requirements if they operate an HHFT or HHFUT as defined in § 171.8. Section 174.310(a)(3) requires advanced brake systems (*e.g.*, two-way end-of-train devices, distributive power, and ECP brake systems) for HHFTs and HHFUTs transporting hazardous materials under certain conditions. Specifically, § 174.310(a)(3)(ii) requires that HHFUTs comprised of at least one tank car that is loaded with a Packing Group (PG) I material and operating at speeds exceeding 30 mph be equipped with ECP brakes after January 1, 2021. Similarly, paragraph (a)(3)(iii) requires that all other HHFUTs not described in paragraph (a)(3)(ii) be equipped with ECP brakes after May 1, 2023, if operating at speeds exceeding 30 mph. Paragraph (a)(3)(iv) states that each buffer car in an HHFUT that is not equipped with ECP brakes will be counted in determining the percentage of cars with effective and operative brakes, as required under 49 CFR 232.609, which requires that a train have a minimum percentage of operative brakes. Since the ECP brake system requirements are being removed, we are removing this accounting provision as it no longer applies. Lastly,

paragraph (a)(3)(v) allows the use of an alternative brake system with approval from FRA in accordance with the processes and procedures outlined in 49 CFR part 232, subpart F. The approval provision is also being removed, as we have determined that restating this option is superfluous, given that approval provisions for new rail brake system technology are outlined in 49 CFR part 232, subpart F.

Further, § 174.310(a)(5) outlines requirements for retrofit reporting by owners of non-jacketed DOT-111 tank cars in PG I service in an HHFUT. Specifically, paragraph (a)(5)(v) requires owners to report the number of tank cars built or retrofitted to a DOT-117, 117R, or 117P specification that are ECP brake-ready or ECP brake-equipped. Because we are removing the ECP brake system requirements, we are also deleting the requirement to report those tank cars that are ECP brake system ready or equipped.

Therefore, as mandated by section 7311 of the FAST Act and based on our determination that ECP brake system requirements are not justified, PHMSA is removing the requirements in § 174.310 for high-hazard flammable unit trains to be equipped with ECP brake systems, for approval of the use of alternative brake systems, and for retrofit status reports on ECP brake system readiness and use.

### Part 179

Subpart D of title 49, part 179 outlines DOT specification requirements for non-pressure tank cars including DOT-117s added under the HM-251 final rule.

#### Section 179.102-10

Section 179.102-10 outlines ECP brake system capability requirements consistent with § 174.310 for DOT-117 specification tank cars. Paragraph (a) requires each rail carrier operating an HHFUT that is comprised of at least one tank car loaded with a PG I material must ensure that the train meets the ECP braking capability requirements by January 1, 2021. Paragraph (b) requires each rail carrier operating an HHFUT that is not described in paragraph (a) to ensure that the train meets the ECP braking capability requirements by May 1, 2023. Paragraph (c) allows the use of an alternative brake system with approval from FRA. As mandated by the FAST Act and based on the Department's determination that ECP brake system requirements are not justified, PHMSA is removing the requirements to ensure that HHFUTs meet the ECP braking capability requirements. Additionally, the provision for approval of alternate brake

<sup>6</sup> The Secretary has delegated this authority to PHMSA. *See* 49 CFR 1.97.

systems is being removed, as reference to 49 CFR part 232, subpart F, is superfluous in the absence of the ECP brake system requirements.

#### Section 179.202–12

Section 179.202–12 prescribes the performance standard requirements for DOT–117P tank cars. Paragraph (g)(1) requires rail carriers operating an HHFUT that is comprised of at least one tank car loaded with a PG I material to ensure that the train meets the ECP braking capability requirements by January 1, 2021. Paragraph (g)(2) requires rail carriers operating an HHFUT not described in paragraph (g)(1) to ensure that the train meets the ECP braking capability requirements by May 1, 2023. Paragraph (g)(3) allows the use of an alternative brake system with approval from FRA. Therefore, as mandated by the FAST Act and based on the Department's determination that ECP brake system requirements are not justified, PHMSA is removing the requirements to ensure that HHFUTs meet the ECP braking capability requirements. Additionally, the approval provision for alternate brake systems is being removed, as reference to 49 CFR part 232, subpart F, is superfluous in the absence of the ECP brake system requirements.

#### Section 179.202–13

Section 179.202–13 prescribes retrofit standards for existing non-pressure DOT–117 tank cars. Paragraph (i)(1) requires rail carriers operating an HHFUT that is comprised of at least one tank car loaded with a PG I material to ensure the train meets the ECP braking capability requirements specified in § 174.310 by January 1, 2021. Paragraph (i)(2) requires rail carriers operating HHFUTs not described in paragraph (i)(1) to ensure the train meets the ECP braking capability requirements in § 174.310 by May 1, 2023. Paragraph (i)(3) allows the use of an alternative brake system with approval from FRA.

As mandated by the FAST Act and based on the Department's determination that ECP brake system requirements are not justified, PHMSA is deleting the requirements to ensure that HHFUTs meet the ECP braking capability requirements. Additionally, the approval provision for alternative brake systems is being removed, as reference to 49 CFR part 232, subpart F, is superfluous in the absence of the ECP brake system requirements.

## IV. Regulatory Analyses and Notices

### A. Statutory/Legal Authority for This Rulemaking

This final rule is published under the authority of Federal Hazardous Materials Transportation Law (Federal Hazmat Law; 49 U.S.C. 5101 *et seq.*), and the Federal Railroad Safety Laws (49 U.S.C. ch. 201–213). Section 5103(b) of the Federal Hazmat Law authorizes the Secretary to prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce. Section 20103 of the Federal Railroad Safety Laws, authorizes the Secretary to prescribe regulations and issue orders for every area of railroad safety.

### B. Executive Order 12866, Executive Order 13563, Executive Order 13610, and DOT Regulatory Policies and Procedures

#### 1. Background

As previously discussed, the HM–251 final rule amended the HMR by adopting heightened brake system requirements for HHFUTs. Specifically, it required an HHFUT meeting certain operational and train makeup conditions to be equipped with and operate an ECP brake system. These trains were subject to a two-staged implementation schedule. The first stage required that certain HHFUTs be equipped and operate an ECP brake system by January 1, 2021. The second stage required remaining trains be equipped and operate an ECP brake system by May 1, 2023.

The FAST Act instructed GAO to conduct an independent evaluation of ECP brake systems and DOT to contract with the National Academy of Sciences (NAS) to conduct testing and analysis on ECP brake systems to help assess the costs and benefits of the ECP brake system requirements adopted in the HM–251 final rule. Based on the updated regulatory impact analysis, which incorporates the findings of GAO and NAS, PHMSA is removing the ECP brake system requirements for HHFUTs in this final rule.

#### 2. Executive Orders

This final rule is not a significant regulatory action within the meaning of Executive Order 12866 (E.O. 12866) and DOT policies and procedures. See 44 FR 11034 (Feb. 26, 1979). DOT made this determination by finding that the economic effects of this regulatory action will not have an effect on the economy that exceeds the \$100 million annual threshold defined by E.O. 12866

and that the regulatory action is not otherwise significant.

In December 2017, DOT prepared and placed an updated Regulatory Impact Analysis (RIA) in the docket (Docket no. PHMSA–2017–0102–0035) updating the economic impact of the ECP brake system provisions in the May 8, 2015, final rule titled “Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains.” (See 80 FR 26644; HM–251.) The RIA estimated the costs and benefits of the ECP provisions that were likely to be incurred over a twenty-year period. DOT estimated the costs and benefits of the final rule using discount rates of 3 percent and 7 percent.

PHMSA is eliminating the requirement that rail carriers install ECP brake systems on trains transporting Class 3 flammable liquid hazardous materials. The FAST Act required DOT to enter into an agreement with NAS to test ECP brakes and reevaluate the economic analysis supporting the ECP brake system requirements of the HM–251 final rule. Using the 2017 Final RIA, DOT estimated the net cost savings that will be realized by removing the ECP brake system requirements. For the 20-year period analyzed, the estimated net cost savings are between \$280.8 million and \$354.7 million, discounted at 3 percent, and between \$292.7 million and \$372.0 million, discounted at 7 percent.

Cost savings of this final rule will be realized in several categories. First, tank cars would no longer need to be equipped with ECP brakes. The cost savings projections assume that a large portion of the existing tank car fleet would have been retrofitted with ECP brake systems. Second, railroads would not be required to install ECP brake systems on locomotives. The 2017 RIA assumed that any locomotive required to be equipped with ECP brakes would have incurred certain costs to be retrofitted. Third, cost savings will now be realized as rail carriers will no longer be required to train employees on the use of ECP brakes. Current employees would have been trained on ECP brakes within the first three years. Additionally, when new employees started, they would have been trained on ECP brakes.

In the HM–251 final rule and the updated RIA, DOT estimated that rail carriers would realize business benefits in several categories with the implementation of ECP brake systems. First, rail carriers would receive relief from fewer set-outs (*i.e.*, cars taken out of service due to a defect). When a car with defective conventional brakes must be removed from the train, a “set-out”

occurs. ECP brake systems would have removed the need for some set-outs as the train could have traveled to the nearest forward repair location with a car with defective brakes. Second, trains would be allowed to travel farther between required brake tests. Third, due

to the reduced wear on wheels, wheelsets would not be replaced as frequently. The final business benefit was reduced fuel usage. DOT estimated a one percent reduction in fuel usage due to ECP brake systems. Since the 2015 ECP brake system requirements are being removed from

the hazmat regulations, rail carriers will no longer receive the business benefits cited in the 2015 final rule. This offsets some of the cost savings. Table 2, below, shows the costs savings and offsetting business benefits by category, and the total net cost savings.

TABLE 2—COST SAVINGS AND OFFSETTING BUSINESS BENEFITS  
[Millions of dollars]

	7 Percent		3 Percent	
	Low	High	Low	High
Tank Cars .....	\$237.76	\$318.49	\$256.18	\$341.52
Locomotives .....	105.03	140.42	110.79	147.39
Asset Management .....	0.52	0.52	0.52	0.52
Training .....	32.29	32.29	34.62	34.62
Total Cost Savings .....	375.60	491.72	402.11	524.05
Set Out Reliefs .....	5.87	7.46	8.24	10.55
Class IA Brake Test .....	27.54	46.04	45.07	65.12
Wheel Savings .....	26.77	37.40	36.08	52.90
Fuel Savings .....	22.70	28.85	31.90	40.81
Total Offsetting Business Benefits .....	82.87	119.75	121.29	169.37
Total Net Cost Savings .....	292.73	371.97	280.82	354.68
Annualized Net Cost Savings .....	27.63	35.11	18.88	23.84

Using low and high ranges, for the 20-year period of analysis, the cost savings are between \$280.8 million and \$354.7 million, discounted at 3 percent, and between \$292.7 million and \$372.0 million, discounted at 7 percent. The annualized net cost savings are between \$27.6 million and \$35.1 million, discounted at 7 percent.

Our analysis in response to the FAST Act mandate also assessed the safety effects of ECP brake systems. Although the tests of ECP brake system effectiveness mandated by the FAST Act resulted in a lower safety improvement

factor than was used in promulgating the 2015 final rule, they continued to demonstrate that ECP brake systems are more effective than conventional brake systems. As a result, deletion of the ECP brake system requirements from the HMR is forecast to modestly reduce future safety performance, which may result in larger spill sizes and associated damages for future derailments than would be the case if they were maintained.

With the removal of the ECP brake systems requirements from the 2015 rule, the predicted future safety benefits

will be foregone. Estimated discounted values were between \$48.2 million and \$78.2 million over 20 years at 7 percent, and between \$67.2 million and \$109.4 million at 3 percent. Annualized safety benefits were estimated at between \$4.5 million and \$7.4 million at both 3 percent and 7 percent discount rates. Table 3, below, shows the safety benefits estimated for the ECP brake system requirements of the 2015 final rule.

TABLE 3—2015 RULE SAFETY BENEFITS  
[Millions of dollars]

	7 Percent		3 Percent	
	Low	High	Low	High
Safety Benefits .....	\$48.16	\$78.19	\$67.19	\$109.44
Annualized .....	4.55	7.38	4.52	7.36

In the intervening years since the HM-251 final rule, the rail industry attained significant safety improvements transporting flammable liquids, with declines in both incident rates and spill size.

C. Executive Order 13771

This final rule is considered an E.O. 13771 deregulatory analysis. Details on the estimated cost savings of this final rule can be found above.

D. Executive Order 13132

This final rule has been analyzed in accordance with the principles and criteria in Executive Order 13132 (“Federalism”). This final rule does not impose any regulation that has substantial direct effects on States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. While the final rule could act to preempt State, local,

and Indian tribe requirements by operation of law, PHMSA is not aware of any such requirements that are substantively different than what is required by the final rule. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal Hazardous Materials Transportation Law, 49 U.S.C. 5101–5128, contains express preemption provisions (49 U.S.C. 5125) that preempt inconsistent State, local, and

Indian tribe requirements, including requirements on the following subjects:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This rule addresses item (5) described above and, accordingly, State, local, and Indian tribe requirements on this subject that do not meet the “substantively the same” standard will be preempted. Federal preemption also may exist pursuant to Section 20106 of the former Federal Railroad Safety Act of 1970 (FRSA), repealed, revised, reenacted, and recodified at 49 U.S.C. 20106, and the former Safety Appliance Acts (SAA), repealed revised, reenacted, and recodified at 49 U.S.C. 20301–20304, 20306. Section 20106 of 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 section’s “essentially local safety or security hazard.” The former SAA has been interpreted by the Supreme Court as preempting the field “of equipping cars with appliances intended for the protection of employees.” *Southern Ry. Co. v. R.R. Comm’n of Ind.*, 236 U.S. 439, 446 (1915). The train’s power braking system is considered a safety appliance within the terms of the former SAA. 49 U.S.C. 20302(a)(5).

The Federal Hazardous Materials Transportation Law provides at Section 5125(b)(2) that, if DOT issues a regulation concerning any of the covered subjects, DOT must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of

issuance of a final rule and not later than two years after the date of issuance. The effective date of Federal preemption is December 24, 2018. This effective date for preemptive effect should not conflict with the overall effective date for this final rule because the regulation of hazardous materials transport in commerce generally preempts State and local requirements. Historically, the States and localities are aware of this preemptive effect and do not regulate in conflict with Federal requirements in these situations.

#### D. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria in Executive Order 13175 (“Consultation and Coordination with Indian Tribal Governments”). Executive Order 13175 requires agencies to assure meaningful and timely input from Indian tribal government representatives in the development of rules that have tribal implications. Because this final rule does not have tribal implications, the funding and consultation requirements of Executive Order 13175 do not apply.

#### E. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

Section 603 of the Regulatory Flexibility Act (RFA) requires an agency to prepare an initial regulatory flexibility analysis describing effects on small entities whenever an agency is required by 5 U.S.C. 553 to publish a general notice of proposed rulemaking for any proposed rule. Similarly, section 604 of the RFA requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after being required to publish a general notice of proposed rulemaking.

This action is a non-discretionary final rule addressing congressional mandates under the FAST Act of 2015. As prior notice and opportunity for comment under 5 U.S.C. 553 are not required in this situation, a regulatory flexibility analysis—as would otherwise be required per 5 U.S.C. 603–604—was not performed. However, as mandated by the FAST Act, PHMSA reviewed and updated the RIA supporting the HM–251 final rule, which initially adopted the ECP brake system requirements. The original RIA found that, while the ECP brake system requirements from that final rule would have a direct effect on some small railroads, this effect would not have a significant impact. Therefore, the repeal of the ECP brake system requirement will create a limited benefit

for a small number of small entities.

PHMSA’s rationale is as follows.

“Small entity” is defined in 5 U.S.C. 601 as including a small business concern that is independently owned and operated, and is not dominant in its field of operation. The U.S. Small Business Administration (SBA) has authority to regulate issues related to small businesses, and stipulates in its size standards that a “small entity” in the railroad industry is a for-profit “linehaul railroad” that has fewer than 1,500 employees, a “short line railroad” with fewer than 500 employees, or a “commuter rail system” with annual receipts of less than \$15 million. See “Size Eligibility Provisions and Standards,” 13 CFR part 121, subpart A. Additionally, 5 U.S.C. 601(5) defines as “small entities” governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000. Federal agencies may adopt their own size standards for small entities, in consultation with SBA and in conjunction with public comment. Pursuant to that authority, FRA published a final statement of agency policy that formally defines “small entities” or “small businesses” as being railroads, contractors, and hazardous materials shippers that meet the revenue requirements of a Class III railroad as set forth in 49 CFR 1201.1–1 (*i.e.*, \$20 million or less in inflation-adjusted annual revenues) or commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less. See 68 FR 24891 (May 9, 2003), codified at appendix C to 49 CFR part 209. The \$20 million-limit is based on the Surface Transportation Board’s revenue threshold for a Class III railroad. Railroad revenue is adjusted for inflation by applying a revenue deflator formula in accordance with 49 CFR 1201.1–1. DOT is using this definition for this rulemaking.

Under the 2015 final rule, any railroad that operates at speeds 30 mph or less, as is the case for most small railroads, would not have been affected by the ECP brake system requirements. Additionally, as most small railroads do not travel long distances, this requirement for reduced speed did not cause any significant impact. Therefore, of the approximately 690 Class III railroads, most were not affected by the 2015 final rule, and consequently, will not be affected by this final rule.

Those affected would be small rail carriers that have relatively short mileage connecting two or more larger rail carriers and that may operate trains at speeds higher than 30 mph. The impact would not be significant,

however, as these entities do not originate HHFTs, but may serve as a connecting line between larger railroads or allow the larger rail carriers to operate HHFTs over their track. All HHFTs from larger rail carriers would be assembled such that locomotives and cars with ECP brake systems are kept together, precluding speed restrictions under the 2015 final rule. Furthermore, as this final rule is a deregulatory action, this small impact would also be beneficial for small railroads.

#### *F. Unfunded Mandates Reform Act of 1995*

This rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of \$155 million or more, adjusted for inflation, to either State, local, or tribal governments, in the aggregate, or to the private sector in any one year.

#### *G. Paperwork Reduction Act*

PHMSA currently has an approved information collection under OMB Control Number 2137-0628 titled, “Flammable Hazardous Materials by Rail Transportation,” with an expiration date of March 31, 2019. This final rule will result in a minor decrease in the time spent to submit reports pertaining to ECP brake-ready or ECP brake-equipped tank cars, but does not necessitate the revision of this information collection package in either the annual burden or cost for changes under part 110.

#### *H. Regulation Identifier Number (RIN)*

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulatory or Deregulatory Actions (“Unified Agenda”). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document may be used to cross-reference this action with the Unified Agenda.

#### *I. National Environmental Policy Act*

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321-4347), requires Federal agencies to consider the environmental impacts of proposed actions in their decision-making. However, the FAST Act mandates that the results of the updated regulatory impact analysis determine whether the ECP brake requirements remain in place. If the regulatory impact analysis shows that the benefits exceed the costs of the ECP braking requirements, the FAST Act

requires the Secretary to publish a “determination,” in the **Federal Register**. If the Secretary is unable to support such a “determination,” the FAST Act requires the repeal of the ECP brake system requirements. Because the final updated regulatory impact analysis showed that the expected costs of ECP brake system requirements are greater than the expected benefits, the Department is required to promulgate this repeal.

The FAST Act removed the Secretary’s discretion to consider anything other than the costs and benefits outlined in the RIA. Although PHMSA performed a NEPA analysis with respect to the broader rulemaking, the FAST Act precludes consideration of alternatives and their environmental effects under NEPA for this repeal.

#### *J. Privacy Act*

Anyone may search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

#### *K. Executive Order 13609 and International Trade Analysis*

Under Executive Order 13609 (“Promoting International Regulatory Cooperation”), agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, regulatory approaches developed through international cooperation can provide equivalent protection to standards developed independently, while also minimizing unnecessary differences.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96-39), as amended by the Uruguay Round Agreements Act (Pub. L. 103-465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the

standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude 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.

PHMSA participates in the establishment of international standards to protect the safety of the American public, and we have assessed the effects of the proposed rule to ensure that it does not cause unnecessary obstacles to foreign trade. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA’s obligations under the Trade Agreement Act, as amended.

#### *L. Executive Order 13211*

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any “significant energy action” [66 FR 28355; May 22, 2001]. Under the Executive Order, a “significant energy action” is defined as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, advance NPRM, and NPRM) that: (1)(i) Is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

Although this is a non-significant regulatory action under Executive Order 12866, PHMSA has evaluated this action in accordance with Executive Order 13211 and has determined this action will not have a significant adverse effect on the supply, distribution, or use of energy. Consequently, PHMSA has determined this regulatory action is not a “significant energy action” within the meaning of Executive Order 13211.

#### **List of Subjects**

##### *49 CFR Part 174*

Hazardous materials transportation, Rail carriers, Reporting and recordkeeping requirements, Security measures.

##### *49 CFR Part 179*

Hazardous materials transportation, Incorporation by reference, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, we are amending title 49, chapter I, subchapter C, as follows:

**PART 174—CARRIAGE BY RAIL**

■ 1. The authority citation for part 174 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 2. In § 174.310, paragraphs (a)(3) and (5) are revised to read as follows:

**§ 174.310 Requirements for the operation of high-hazard flammable trains.**

(a) \* \* \*

(3) *Braking.* Each rail carrier operating a high-hazard flammable train (as defined in § 171.8 of this subchapter) operating at a speed in excess of 30 mph must ensure the train is equipped and operated with either a two-way end-of-train (EOT) device, as defined in 49 CFR 232.5, or a distributed power (DP) system, as defined in 49 CFR 229.5.

\* \* \* \* \*

(5) *Retrofit reporting.* Owners of non-jacketed DOT–111 tank cars in PG I service in an HHFT, who are unable to meet the January 1, 2017, retrofit deadline specified in § 173.243(a)(1) of this subchapter are required to submit a

report by March 1, 2017, to Department of Transportation. A group representing owners may submit a consolidated report to the Department of Transportation in lieu of individual reports from each tank car owner. The report must include the following information regarding the retrofit progress:

(i) The total number of tank cars retrofitted to meet the DOT–117R specification;

(ii) The total number of tank cars built or retrofitted to meet the DOT–117P specification;

(iii) The total number of DOT–111 tank cars (including those built to CPC–1232 industry standard) that have not been modified;

(iv) The total number of tank cars built to meet the DOT–117 specification; and

(v) Entities required to submit a report under this paragraph shall submit subsequent follow-up reports containing the information identified in this paragraph within 60 days of being notified by PHMSA and FRA.

\* \* \* \* \*

**PART 179—SPECIFICATIONS FOR TANK CARS**

■ 3. The authority citation for part 179 continues to read as follows:

**Authority:** 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

**§ 179.102–10 [Removed]**

■ 4. In subpart D, § 179.102–10 is removed.

**§ 179.202–12 [Amended]**

■ 5. In § 179.202–12, paragraph (g) is removed.

**§ 179.202–13 [Amended]**

■ 6. In § 179.202–13, paragraph (i) is removed.

Issued in Washington, DC, on September 18, 2018, under authority delegated in 49 CFR 1.97.

**Howard McMillan,**  
*Executive Director, Pipeline and Hazardous Materials Safety Administration.*

[FR Doc. 2018–20647 Filed 9–24–18; 8:45 am]

**BILLING CODE 4910–60–P**



# Proposed Rules

Federal Register

Vol. 83, No. 186

Tuesday, September 25, 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.

## FEDERAL RESERVE SYSTEM

### 12 CFR Parts 208 and 211

[Docket No. R-1622 and RIN 7100 AF-16]

#### Registration of Mortgage Loan Originators

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice of proposed rulemaking; request for public comment.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) is proposing to repeal its regulations that incorporated the Secure and Fair Enforcement for Mortgage Licensing Act (the S.A.F.E. Act). Title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) transferred rulemaking authority for a number of consumer financial protection laws, including the S.A.F.E. Act, from the Board to the Bureau of Consumer Financial Protection (Bureau). In December 2011, the Bureau published an interim final rule, incorporating the S.A.F.E. Act into its Regulations G and H. In April 2016, the Bureau finalized the interim final rule. Accordingly, the Board is proposing to repeal its S.A.F.E. Act regulations.

**DATES:** Comments must be received on or before November 26, 2018.

**ADDRESSES:** You may submit comments, identified by Docket No. 1622 and RIN 7100 AF-16, 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](mailto:regs.comments@federalreserve.gov). Include the 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.cfm> as submitted, unless modified for technical reasons or to remove personally identifiable 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 Streets NW), between 9:00 a.m. and 5:00 p.m. on weekdays.

**FOR FURTHER INFORMATION CONTACT:** Clinton Chen, Senior Attorney, (202) 452-3952, Justyna Bolter, Attorney, (202) 452-2686, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263-4869.

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Discussion

The Secure and Fair Enforcement for Mortgage Licensing Act of 2008 (S.A.F.E. Act)<sup>1</sup> mandates a nationwide licensing and registration system for residential mortgage loan originators. The S.A.F.E. Act requires residential mortgage loan originators employed by depository institutions, subsidiaries that are owned and controlled by a depository institution and regulated by a federal banking agency, and institutions regulated by the Farm Credit Administration (FCA) to register with the Nationwide Mortgage Licensing System and Registry, obtain a unique identifier, and maintain such registration. Originally, the federal registration requirements of the S.A.F.E. Act were implemented through a coordinated rulemaking of the federal banking agencies and the FCA, the agencies with authority over the federal registration requirements under the S.A.F.E. Act (the "federal registry agencies").<sup>2</sup> The Board incorporated the S.A.F.E. Act in its Regulation H, 12 CFR

part 208, subpart I, and Regulation K, 12 CFR 211.24(k).

Title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act)<sup>3</sup> amended a number of consumer financial protection laws, including the S.A.F.E. Act. The Dodd-Frank Act transferred rulemaking authority for the S.A.F.E. Act from the federal registry agencies to the Bureau of Consumer Financial Protection (Bureau), effective July 21, 2011.<sup>4</sup> In connection with the transfer of rulemaking authority for the S.A.F.E. Act to the Bureau, the Bureau published an interim final rule to incorporate the S.A.F.E. Act into its own Regulations G and H, 12 CFR parts 1007 and 1008 (Bureau Interim Final Rule).<sup>5</sup> In April 2016, the Bureau finalized the Bureau Interim Final Rule as part of a larger initiative of finalizing interim final rules.<sup>6</sup> The Bureau's regulations that incorporate the S.A.F.E. Act substantially duplicate the federal registry agencies' coordinated rules and cover the entities that were previously subject to the other agencies' rules. Consequently, the Board is publishing this proposal to repeal its regulations that originally incorporated the S.A.F.E. Act.

##### II. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (the "RFA") (5 U.S.C. 601 *et seq.*) requires agencies either to provide an initial regulatory flexibility analysis with a proposed rule or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. In accordance with section 3(a) of the RFA, the Board has reviewed the proposed regulation. This Initial Regulatory Flexibility Analysis has been prepared in accordance with 5 U.S.C. 603 in order

<sup>3</sup> Public Law 111-203, 124 Stat. 1376 (2010).

<sup>4</sup> See Public Law 111-203, sections 1061 & 1100. The Dodd-Frank Act generally excludes from this transfer of authority, subject to certain exceptions, any rulemaking authority over a motor vehicle dealer that is predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both. Public Law 111-203, section 1029. The rulemaking authority retained by the Board under Section 1029 of the Dodd-Frank Act does not extend to residential mortgages. Thus, all rulemaking authority under the S.A.F.E. Act, which pertains only to mortgage loan originator registrations, was transferred to the Bureau.

<sup>5</sup> 76 FR 78483 (Dec. 19, 2011).

<sup>6</sup> 81 FR 25323 (April 28, 2016).

<sup>1</sup> 12 U.S.C. 5101 *et seq.*

<sup>2</sup> 75 FR 44656 (July 28, 2010). The rules were promulgated by the Board; the Office of the Comptroller of the Currency (OCC); the Federal Deposit Insurance Corporation (FDIC); the Office of Thrift Supervision, Treasury (OTS); the FCA; and the National Credit Union Administration (NCUA).

for the Board to solicit comment on the effect of the proposal on small entities. The Board will, if necessary, conduct a final regulatory flexibility analysis after consideration of comments received during the public comment period.

1. *Statement of the need for, and objectives of, the proposed rule.* Title X of the Dodd-Frank Act transferred rulemaking authority for the S.A.F.E. Act and other enumerated consumer financial protection laws from the Board to the Bureau, effective July 21, 2011. In December 2011, the Bureau issued an Interim Final Rule to incorporate the S.A.F.E. Act pursuant to the transfer of rulemaking authority. Although the Board retains authority to issue some consumer financial protection rules, all rulemaking authority under the S.A.F.E. Act concerning mortgage loan originator registration was transferred to the Bureau. Consequently, the Board is proposing to repeal its regulations that incorporated the S.A.F.E. Act.

2. *Small entities affected by the proposed rule.* Any entity that is currently covered by the S.A.F.E. Act is subject to the rules issued by the Bureau, located in 12 CFR part 1007 and 1008. Therefore the Board's repeal of its regulations that incorporated the S.A.F.E. Act would not affect any entity, including small entities.

3. *Recordkeeping, reporting, and compliance requirements.* The proposed rule would repeal parts of the Board's regulations that incorporated the S.A.F.E. Act, and would therefore not impose any recordkeeping, reporting, or compliance requirements on any entities.

4. *Other Federal Rules.* The Board has not identified any federal rules that duplicate, overlap, or conflict with the proposed repeal of the Board's regulations that incorporated the S.A.F.E. Act.

5. *Significant alternatives to the proposed revisions.* The Board is not aware of any significant alternatives that would further minimize the impact on small entities of the proposed repeal, but solicits comment on this approach.

### III. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the rule under the authority delegated to the Federal Reserve by the Office of Management and Budget (OMB). The proposed rule contains no collections of information under the PRA. See 44 U.S.C. 3502(3). Accordingly, there is no paperwork burden associated with the proposed rule.

### List of Subjects

#### 12 CFR Part 208

Accounting, Agriculture, Banks, Banking, Confidential business information, Consumer protection, Crime, Currency, Insurance, Investments, Mortgages, Reporting and recordkeeping requirements, Securities.

#### 12 CFR Part 211

Exports, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

### Authority and Issuance

For the reasons set forth in the preamble, the Board proposes to amend chapter II of title 12 of the Code of Federal Regulations as follows:

#### PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM (REGULATION H)

- 1. The authority citation for part 208 continues to read as follows:

**Authority:** 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1818, 1820(d)(9), 1833(j), 1828(o), 1831, 1831o, 1831p–1, 1831r–1, 1831w, 1831x, 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, 3905–3909, and 5371; 15 U.S.C. 78b, 78l(b), 78l(i), 780–4(c)(5), 78q, 78q–1, and 78w, 1681s, 1681w, 6801, and 6805; 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104a, 4104b, 4106 and 4128.

#### Subpart I—[Removed and Reserved]

- 2. Remove and reserve subpart I, consisting of §§ 208.101 through 208.105 and Appendix A.

#### PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

- 3. The authority citation for part 211 continues to read as follows:

**Authority:** 12 U.S.C. 221 *et seq.*, 1818, 1835a, 1841 *et seq.*, 3101 *et seq.*, 3901 *et seq.*, and 5101 *et seq.*; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

- 4. In § 211.24, remove paragraph (k).

By order of the Board of Governors of the Federal Reserve System, September 20, 2018.

**Ann Misback,**

*Secretary of the Board.*

[FR Doc. 2018–20832 Filed 9–24–18; 8:45 am]

**BILLING CODE 6210–01–P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 886

[Docket No. FDA–2018–N–3074]

#### Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed order.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this proposed order to reclassify the ultrasound cyclodestructive device, a postamendments class III device (regulated under product code LZR), into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. If finalized, this order will reclassify these devices from class III to class II (special controls) and reduce regulatory burdens as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

**DATES:** Submit either electronic or written comments on the proposed order by November 26, 2018. Please see section XI for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 26, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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-N-3074 for "Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

#### FOR FURTHER INFORMATION CONTACT:

Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1652, Silver Spring, MD 20993, 301-796-6351, [hina.pinto@fda.hhs.gov](mailto:hina.pinto@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding

the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in "medical science" (*Upjohn v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the "new information" to support reclassification under section 513(f)(3) of the FD&C Act must be "valid scientific evidence", as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))). Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to

reasonably assure the safety and effectiveness of the device.

## II. Regulatory History of the Devices

On June 30, 1988, FDA approved the first and only ultrasound cyclodestructive device through its PMA process under section 515 of the FD&C Act (21 U.S.C. 360e). On August 10, 1988 (53 FR 30101), FDA announced a PMA order for Sonocare Inc.'s Model CST-100 Therapeutic Ultrasound System (Sonocare CST-100) (Ref. 1). As of the date of issuance of this proposed order, the Sonocare CST-100 is the only PMA approved by FDA for this device type.

## III. Device Description

An ultrasound cyclodestructive device is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. An ultrasound cyclodestructive device is indicated for the treatment of refractory glaucoma; it is intended for patients who are refractory to or are poor candidates for laser or surgical treatment and fail to achieve target intraocular pressures on maximally tolerated drug therapy. The device is designed to reduce intraocular pressure by producing a series of lesions in the ciliary body and trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy. Different technologies, such as laser cyclodestruction to lower intraocular pressure, have been studied since the 1970s (Refs. 2 and 3), which increases FDA's knowledge base for devices used to treat this condition. As stated earlier in section II, FDA has approved only one ultrasound cyclodestructive device through its PMA process under section 515 of the FD&C Act (Ref. 4). More recently, reports in the literature indicate that the HIFU technology has been modified and currently studied in Europe for treatment of refractory glaucoma (Refs. 5 to 8). Based upon our review experience and consistent with the FD&C Act and FDA's regulations, FDA believes that these devices should be reclassified from class III into class II because there is sufficient information to establish special controls that can provide reasonable assurance of the device's safety and effectiveness.

Conventional refractory glaucoma treatment modalities include implantable aqueous shunts and valves, trabeculectomy and other incisional glaucoma surgeries, cyclocryotherapy, as well as laser transcleral cyclophotocoagulation. FDA currently regulates all of the devices indicated for these procedures in a refractory

glaucoma population as class II devices, subject to 510(k) requirements.

## IV. Proposed Reclassification

On April 29, 2015, FDA published a document in the **Federal Register** entitled "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection," in which FDA announced plans to consider reclassifying ultrasound cyclodestructive devices identified with the LZR product code from class III to class II (80 FR 23798) and requested comments. FDA received no adverse comments regarding our proposed intent for LZR.

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify this postamendments class III device into class II. FDA believes that there is sufficient information available to FDA through peer-reviewed literature and knowledge of similar devices to establish special controls that would effectively mitigate the risks to health identified in section V. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA is proposing to create a separate classification regulation for ultrasound cyclodestructive devices that will be reclassified from class III to II. Under this proposed order, if finalized, the ultrasound cyclodestructive devices will be identified as a prescription device. As such, the prescription device must satisfy prescription labeling requirements (see § 801.109 (21 CFR 801.109), *Prescription devices*). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and § 801.5 (21 CFR 801.5), as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). In this proposed order, if finalized, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, will provide a reasonable assurance of the safety and effectiveness for ultrasound cyclodestructive devices.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification

is necessary for ultrasound cyclodestructive devices to provide reasonable assurance of safety and effectiveness. Therefore, the Agency does not intend to exempt these proposed class II devices from 510(k) requirements. Persons who intend to market this type of device must submit to FDA a 510(k) and receive clearance prior to marketing the device.

This proposal, if finalized, will decrease regulatory burden and will reduce private costs and expenditures required to comply with Federal regulations. Specifically, regulated industry will no longer have to submit a PMA but can instead submit a 510(k) to the Agency for review prior to marketing their device. A 510(k) is a less burdensome pathway to market a device, which typically results in a more timely premarket review compared to a PMA and reduces the regulatory burden in addition to providing more timely access of these types of devices to patients.

## V. Risks to Health

After considering the information available to FDA through the review submission, peer-reviewed literature, and knowledge of other technologies indicated to treat the same refractory glaucoma patient population (such as aqueous shunt and cryotherapy), FDA determined that the probable risks to health associated with the use of ultrasound cyclodestructive devices for treatment of refractory glaucoma are as follows:

- *Thermal Injury.* Exposure of the ocular tissue to the HIFU energy causes thermal damage of the tissue. The misdirection or misalignment of the beam may cause temperature elevation in the non-target ocular tissues and overall ocular tissue damage. Unsuitable power and duration of the beam may also result in temperature elevation, which may cause corneal lesions including scleral thinning, corneal ectasia and perforation, eyelid burns, corneal burns, clouding of the cornea (haze) and lens (cataract formation), and retinal and choroidal lesions.

- *Physical Injury.* Exposure of the ocular tissue to the HIFU energy can cause physical damage to the ocular tissue due to cavitation or other mechanical effects. These injuries could be caused by the suboptimal selection of the treatment parameters, misalignment/displacement of the probe during the treatment, device malfunction, or other factors affecting stability of treatment. For example, insonification of the zonular fibers may cause elongation or rupture of ligaments, which can lead to a displacement of the lens.

- *Post-treatment injury.* Post-treatment injury from use of the device may include intraocular inflammation (e.g., iritis, uveitis), increased intraocular pressure in the immediate post-treatment period, ciliary body hemorrhage, persistent or transient low pressure, decreased visual acuity, worsening glaucoma, phthisis, pain/discomfort, corneal edema, hyphema, retinal and choroidal complications, etc.

- *Electrical shock.* While in operation, the device may discharge electricity that could shock the user. Electrical shock can be caused by use error or device malfunction.

- *Electromagnetic interference.* While in operation, electromagnetic interferences from other devices operated in the same environment may cause the device to malfunction, which could result in patient's injury. In addition, the device may interfere with other electrically powered devices, causing them to malfunction.

- *Ocular irritation and corneal infections.* Inadequate biocompatibility of the eye contact components of the device can lead to irritation of the ocular tissue. Inappropriately sterilized or reprocessed eye contact components of the device can lead to inflammation and corneal infections.

## VI. Summary of Reasons for Reclassification

FDA believes that the ultrasound cyclodestructive devices for treatment of refractory glaucoma should be reclassified from class III to class II in light of available information about the effectiveness of these devices. There is sufficient information to establish special controls for ultrasound cyclodestructive devices, in addition to general controls, which can provide reasonable assurance of safety and effectiveness of the device, as general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. FDA believes that the risks to health associated with ultrasound cyclodestructive devices for treatment of refractory glaucoma can be mitigated with special controls and that these mitigations will provide a reasonable assurance of its safety and effectiveness.

Based on a reconsideration of the available information and data, FDA believes that there is valid scientific evidence of effectiveness for ultrasound cyclodestructive devices to reduce intraocular pressure intended for treatment of refractory glaucoma using ultrasound.

## VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Taking into account the probable health benefits of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify this postamendments class III device into class II. FDA has considered and analyzed the following information: An inclusive search of the Agency's Manufacturer and User Facility Device Experience (MAUDE) database, which shows no adverse events for ultrasound cyclodestructive device type; no recalls have been received for this device type; other technologies indicated to treat the same refractory glaucoma patient population, such as aqueous shunt and cryotherapy, and currently regulated as class II devices to compare the probable risks (i.e., between the rate and severity of the adverse events associated with these class II technologies and ultrasound cyclodestructive procedures); and peer-reviewed publications (Refs. 5 to 12) to identify probable device risks (e.g., the types and rates of adverse events) and mitigation strategies.

## VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are necessary and sufficient to mitigate the risks to health described in section V and provide a reasonable assurance of safety and effectiveness for ultrasound cyclodestructive devices.

- Non-clinical performance testing of device features and characteristics will demonstrate:

- The ability of the device to deposit controllable HIFU energy to the target area to evoke the required level of thermal lesion.

- The design and geometry of the HIFU transducer and the output characteristics of the HIFU generator, including operating frequency and power, produce a small focal zone and a steep transition of energy deposition between the focal zone and the untreated areas. In addition, the total acoustic power radiated by the transducer(s), spatial distribution of the ultrasound field (including compressional and rarefactional pressure), and spatial peak, temporal-average intensity will be evaluated. This may be accomplished by demonstrating compliance with the standard International Electrotechnical

Commission (IEC) Technical Specification (TS) 62556: Ultrasonics—Field characterization—Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems. Thermal and physical (due to potential cavitation of gas bubbles) safety analyses will also be evaluated.

- The appropriate alignment and focusing of the ultrasound beam to the target tissue to minimize unintended damage to adjacent ocular tissues.

- The function of all safety features built into the device, including the energy monitoring system.

- Clinical performance data will validate device performance and characterize ocular tissue thermal injuries, physical injury, and postoperative adverse events by establishing the treatment parameters for which the device is safe and effective.

- Electrical safety testing will minimize the risk of electrical shock, thermal or physical injury to the patient and healthcare provider. This may be accomplished by demonstrating compliance with FDA-recognized consensus standard American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) 60601-1: *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.*

- Electromagnetic compatibility testing ensures that electromagnetic interferences do not cause device malfunction. It can also provide assurance that electromagnetic interferences generated by the device do not affect the other devices operated in the same environment. This may be accomplished by demonstrating compliance with FDA-recognized consensus standard IEC 60601-1-2: *Medical electrical equipment, Part 1-2: General requirements for safety.* If the device incorporates radiofrequency (RF) wireless technology to perform medical functions and/or communicates medical data, testing will mitigate the risks associated with interference or degradation when using RF wireless technology. This may be accomplished by demonstrating compliance with FDA-recognized consensus standard AAMI TIR69: *Risk Management of Radio-frequency Wireless Coexistence for Medical Devices and Systems* (risk assessment) and ANSI/Institute of Electrical and Electronics Engineers (IEEE) C63.27: *American National Standard for Evaluation of Wireless Coexistence* (coexistence testing).

- Software verification, validation, and hazard analysis is necessary to

mitigate the risks of thermal and physical injury and ensures that software performs as intended and potential software malfunctions do not impact the safety or effectiveness of the device. If the device incorporates internet network connectivity, testing will demonstrate that cybersecurity concerns are mitigated (e.g., data integrity, unauthorized access, etc.).

- Biocompatibility evaluation can help mitigate the risk of ocular irritation and corneal infection by ensuring that the patient-contacting components of the device are safe for contact with skin and ocular tissue.

- Sterilization validation, for devices provided sterile, and/or cleaning validation, for devices or components that are reusable, help mitigate the risk of inflammation and corneal infections (e.g., keratitis).

- The labeling will also include necessary information to ensure safe and effective use of the ultrasound cyclodestructive device and minimize probability of the ocular treatment-related adverse events. Labeling needs to include sufficient information that will help the patient and healthcare

provider make an informed decision regarding treatment-related adverse effects of the ultrasound cyclodestructive treatment. For example, the labeling needs to include information regarding the most common reported treatment-related injuries, which may include intraocular inflammation (e.g., iritis, uveitis) and increased intraocular pressure in the immediate post-treatment period. Adverse event information related to ciliary body hemorrhage, persistent low pressure, decreased visual acuity, worsening glaucoma, phthisis, pain/discomfort, transient low pressure, corneal edema, hyphema, retinal complications (such as cystoid macula edema), and choroidal effusion or detachment need to be discussed. The labeling will mitigate the risk associated with the intraoperative events, such as pain/discomfort, and postoperative adverse events by providing appropriate clinical information along with mitigation strategies (e.g., retrobulbar or peribulbar anesthesia). Specifically, device labeling must include:

- Appropriate warnings and precautions to ensure safe and effective

use of the device and minimize potential device malfunctions and user errors.

- A summary of the clinical evaluation pertinent to use of the device, including study outcomes and adverse events.

- Information regarding procedure parameters, proper positioning of the HIFU transducer and its coupling with the eye, and typical course of treatment to ensure the user can safely operate the device.

- Validated reprocessing instructions to ensure the safe use of reusable device components.

- Safety information regarding electrical safety and electromagnetic compatibility to minimize risks to the patient and users.

Table 1 shows how FDA believes the risks to health identified and described in section V will be mitigated by the proposed special controls. This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of ultrasound cyclodestructive devices.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR ULTRASOUND CYCLODESTRUCTIVE DEVICES

Identified risk to health	Mitigation measures
Thermal Injury .....	Non-clinical performance testing, Clinical performance data, Electrical Safety, Electromagnetic compatibility, Software verification, validation, and hazard analysis, Labeling.
Physical Injury .....	Non-clinical performance testing, Clinical performance data, Electrical safety, Electromagnetic compatibility, Software verification, validation, and hazard analysis, Labeling.
Post-treatment Injury .....	Non-clinical performance testing, Clinical performance data, Software verification, validation, and hazard analysis, Labeling.
Electrical Shock .....	Electrical safety, Labeling.
Electromagnetic Interference .....	Electromagnetic compatibility, Labeling.
Ocular Irritation and Corneal Infections .....	Biocompatibility evaluation, Sterility/reprocessing validation, Labeling.

In addition, FDA is proposing to limit these devices to prescription use under § 801.109. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and § 801.5, as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) requirements.

This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of ultrasound cyclodestructive devices for the treatment of refractory glaucoma. As discussed below, the reclassification will be codified in 21 CFR 886.5350. FDA believes that adherence to the

proposed special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the devices.

**IX. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**X. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This

proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

**XI. Proposed Effective Date**

FDA proposes that any final order based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

**XII. References**

The following references are on display at the Dockets Management Staff (see **ADDRESSES**), and are available for viewing by interested persons between

9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as they are copyrighted or are available through the website address. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. PMA Database Reference for Sonocare. Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=319101>.
2. Shields, M.B., "Transcleral Diode Cyclophotocoagulation," in Chen, T.C. (ed.), "Surgical Techniques in Ophthalmology: Glaucoma Surgery." Saunders Elsevier, 2008.
3. Chen, T.C., L.R. Pasquale, D.S. Walton, et al., "Diode Laser Transcleral Cyclophotocoagulation." *International Ophthalmology Clinics*, 39(1):169–176, 1999.
4. Muratore, R.A., "History of the Sonocare CST-100: The First FDA-Approved HIFU Device." *Therapeutic Ultrasound*, 809:508–512, 2006.
5. Melamed, S., M. Goldenfeld, D. Cotlear, et al., "High-Intensity Focused Ultrasound Treatment in Refractory Glaucoma Patients: Results at 1 Year of Prospective Clinical Study." *European Journal of Ophthalmology*, 25(6):483–489, 2015.
6. Aptel, F., T. Charrel, C. Labon, et al., "Miniaturized High-Intensity Focused Ultrasound Device in Patients with Glaucoma: A Clinical Pilot Study." *Investigative Ophthalmology and Visual Science*, 52 (12):8747–8753, 2011.
7. Aptel, F. and C. Lafon, "Therapeutic Applications of Ultrasound in Ophthalmology." *International Journal of Hyperthermia*, 28(4):405–418, 2012.
8. Mastropasqua, R., V. Fasanella, A. Mastropasqua, et al., "High-Intensity Focused Ultrasound Circular Cyclocoagulation in Glaucoma: A Step Forward for Cyclodestruction?" *Journal of Ophthalmology*, (2017), 1–14, 2017.
9. Burgess, SE, R.H. Silverman, D.J. Coleman, et al., "Treatment of Glaucoma with High Intensity Focused Ultrasound." *Ophthalmology*, 93:831–838, 1986.
10. Coleman, D.J., F.L. Lizzi, J. Driller, et al., "Therapeutic Ultrasound in the Treatment of Glaucoma. II. Clinical Applications." *Ophthalmology*, 92:347–353, 1985.
11. Valtot, F., J. Kopel, and J. Haut, "Treatment of Glaucoma with High Intensity Focused Ultrasound." *International Ophthalmology*, 13:167–170, 1989.
12. Silverman, R.H., B. Vogelsang, M.J. Rondeau, et al., "Therapeutic Ultrasound for the Treatment of Glaucoma."

*American Journal of Ophthalmology*, 111:327–337, 1991.

#### List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*, as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 886 be amended as follows:

#### PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for part 886 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 886.5350 to subpart F to read as follows:

##### § 886.5350 Ultrasound cyclodestructive device.

(a) *Identification.* An ultrasound cyclodestructive device is a prescription device to reduce intraocular pressure by producing a series of lesions in the ciliary body and trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy and that is intended for treatment of refractory glaucoma.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The clinical performance data must demonstrate an adequate safety profile and an appropriate reduction in intraocular pressure in patients with refractory glaucoma and capture any adverse events observed during clinical use.

(2) Non-clinical performance testing of device features and characteristics must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Ultrasound field characteristics, which must include the total acoustic power radiated by the transducer(s), the spatial distribution of the ultrasound field (including compressional and rarefactional pressure), and spatial-peak, temporal-average intensity;

(ii) Thermal and physical safety characterization of the device; and

(iii) Simulated use testing to validate that the device performs as intended under anticipated conditions of use,

including eye movements and positioning error.

(3) Analysis/testing must demonstrate electrical safety in the appropriate use-environment.

(4) Analysis/testing must demonstrate electromagnetic compatibility (EMC), including wireless coexistence (if applicable) in the appropriate use-environment.

(5) Software verification, validation, and hazard analysis must be performed commensurate with the level of concern of the device.

(6) The patient-contacting components must be demonstrated to be biocompatible.

(7) Performance data must demonstrate sterility of all patient-contacting components labeled as sterile. If the device contains reusable eye-contact components, the validation tests must demonstrate adequate cleaning/reprocessing of these components.

(8) Labeling must include:

(i) A detailed description of the patient population for which the device is indicated for use, as well as warnings, and precautions regarding potential for device malfunction and use-error pertinent to use of the device.

(ii) A detailed summary of the clinical testing, including study outcomes and adverse events.

(iii) Information on how the device operates and the typical course of treatment.

(iv) Description of all main components of the device including HIFU generator, transducer(s), and controls. The labeling must include technical specification of the device including, but not limited to, treatment frequency, total acoustic power delivered by transducer, treatment duration, treatment zone, site targeting, power requirements, weight, and physical dimensions of the device.

(v) Where appropriate, validated methods and instructions for reprocessing of any reusable components.

(vi) Safe-use conditions for electrical safety and electromagnetic compatibility.

Dated: September 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–20763 Filed 9–24–18; 8:45 am]

**BILLING CODE 4164-01-P**

# Notices

Federal Register

Vol. 83, No. 186

Tuesday, September 25, 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 AGRICULTURE

### Submission for OMB Review; Comment Request

September 20, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; 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, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 25, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV) or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs

potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

### Foreign Agricultural Service

*Title:* Agriculture Wood Apparel Manufacturers Trust Fund.

*OMB Control Number:* 0551-0045.

*Summary of Collection:* Section 12315 of the Agricultural Act of 2014 (Pub. L. 113-79) authorizes distribution out of the Agriculture Wood Apparel Manufacturers Trust Fund ("Agriculture Wool Trust Fund") in each of calendar years 2014 through 2019, payable to qualifying claimants. Eligible claimants are directed to submit a notarized affidavit, following the statutory procedures specified Section 12314 (c) or (d) of the Act.

*Need and Use of the Information:* The Foreign Agricultural Service will use the information provided in the affidavits to certify the claimants' eligibility and to authorize payment from the Agriculture Wood Trust Fund.

*Description of Respondents:* Business or other-for-profit.

*Number of Respondents:* 95.

*Frequency of Responses:* Record keeping, Reporting: Annually.

*Total Burden Hours:* 190.

**Ruth Brown,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2018-20822 Filed 9-24-18; 8:45 am]

**BILLING CODE 3410-10-P**

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

September 20, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance

the quality, utility and clarity of the information to be collected; 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, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 25, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV) or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

### Risk Management Agency

*Title:* Acreage/Crop Reporting Streamlining Initiative.

*OMB Control Number:* 0563-0084.

*Summary of Collection:* Section 508(f)(3) of the Federal Crop Insurance Act (7 U.S.C. 1515); 7 U.S.C. 7333(b)(3); 7 CFR 457.8 and 7 CFR 1437.7(d) mandates the collection of acreage and production information from producers who wish to participate in certain USDA programs. The Farm Service Agency (FSA) and the Risk Management Agency (RMA) are implementing the Acreage/Crop Reporting Streamlining Initiative (ACRSI), a web-based single source reporting system to establish a single reporting and data collection.

*Need and Use of the Information:* This initiative is being conducted in phases by geographical area and additional commodities. Counties are selected based on their commonality of historical crop reporting, high percentage of producers participating in



both RMA and FSA programs and the high level of interest of the private agricultural service industry (precision-ag and farm management) in the pilot phases. It will reengineer the procedures, processes, and standards to simplify commodity, acreage and production reporting by producers, eliminate or minimize duplication of information collection by multiple agencies and reduce the burden on producers, insurance agents and AIPs. Information being collected will consist of, but not be limited to: Producer name, location state, commodity name, commodity type or variety, location county, date planted, land location (legal description, FSA farm number, FSA track number, FSA field number), intended use, prevented planting acres, acres planted but failed, planted acres, and production of commodity produced. Failure to collect the applicable information could result in unearned Federal benefits being issued or producers being denied eligibility to program benefits.

*Description of Respondents:* Individuals and households.  
*Number of Respondents:* 501,012.  
*Frequency of Responses:* Reporting: One time.  
*Total Burden Hours:* 187,880.

**Ruth Brown,**  
 Departmental Information Clearance Officer.  
 [FR Doc. 2018-20825 Filed 9-24-18; 8:45 am]  
**BILLING CODE 3410-08-P**

**DEPARTMENT OF AGRICULTURE**

**Commodity Credit Corporation**

**Farm Service Agency**

**Notice of Funds Availability (NOFA);  
 Market Facilitation Program (MFP)  
 Payments to Producers**

**AGENCY:** Commodity Credit Corporation and Farm Service Agency, USDA.  
**ACTION:** Notice.

**SUMMARY:** MFP provides payments to producers with commodities that have been significantly impacted by actions of foreign governments resulting in the loss of traditional exports. This NOFA announces the availability of MFP funds for eligible producers of shelled almonds and fresh sweet cherries and makes a correction to a previously issued NOFA published on August 30, 2018, with respect to MFP funds availability for hogs. On behalf of the Commodity Credit Corporation (CCC), the Farm Service Agency (FSA) administers MFP. MFP participants will receive an MFP payment, calculated

based on the eligible production multiplied by the participant’s share multiplied by the MFP payment rate.

**DATES:** *Application period:* September 24, 2018, through January 15, 2019.

**FOR FURTHER INFORMATION CONTACT:** Bradley Karmen, telephone: (202) 720-3175.

**SUPPLEMENTARY INFORMATION:**

**Background**

CCC published the MFP regulation, 7 CFR part 1409, on August 30, 2018 (83 FR 44173-44178), specifying the eligibility requirements, payment calculations, and application procedures for MFP. CCC also published a NOFA on August 30, 2018 (83 FR 44257-44258) that announced funds available for hogs and other commodities. MFP provides assistance to producers with commodities that have been significantly impacted by actions of foreign governments resulting in the loss of traditional exports. This NOFA announces the availability of initial MFP payments for 2018 for shelled almonds and fresh sweet cherries.

**Correction**

The NOFA announcing funds availability for hogs specifies that the date for which the owner reports the number of head of live hogs is August 1, 2018. It has come to our attention that the inventory on August 1 may not be representative of the operation’s inventory. For example, a producer may have sold a barnful of hogs a few days before August 1, resulting in reduced inventory and then purchased feeder pigs a few days later. To provide an option for those owners to participate in MFP, this NOFA is revising the requirement. Producers may select any day from July 15 through August 15, 2018, as the date for which the ownership is reported.

**Application Process**

Each eligible producer applies for MFP on an application form. A producer applies for MFP once. MFP payments will not be issued until a producer certifies production, as described below.

**Payment Rates**

The MFP payment rates will be as determined by CCC.

The MFP payment rates and units of measure that will be in effect beginning at the start of the application period, are listed in the following table.

Commodity	Unit	Rate (\$/unit)
Shelled Almonds .....	pound ....	\$0.03
Fresh Sweet Cherries	pound ....	0.16

The initial payment rate will apply to the first 50 percent of the producer’s total production of the selected commodity. On or about December 3, 2018, CCC may announce a second payment rate, if applicable, that will apply to the remaining 50 percent of the producer’s production for the selected commodity.

MFP payment at either the initial payment rate or at a second payment rate will be made after a producer harvests 100 percent of the crop and certifies the amount of production.

The actual production used to calculate an MFP payment under this NOFA is 2018 production in which the applicant had an ownership share. Specifically, required production information is as follows:

- Harvested production for the 2018 crop year;
- An ownership share for a crop will be as reported to FSA on the acreage report, form FSA-578, “Report of Acreage.”

**Production Evidence**

On the application, the producer will certify the amount of production and note the source of production evidence. If requested, the producer must provide supporting documentation to CCC to determine the producer’s ownership share and the amount of production.

If supporting documentation is required for the amount of actual production and for ownership share, it needs to be records that substantiate the reported amounts. The participant’s production for the commodity is based on production records. Examples of supporting documentation include evidence provided by the participant that is used to substantiate the amount of production reported, including copies of receipts, ledgers of income, income statements of deposit slips, register tapes, invoices for custom harvesting, and records to verify production costs, contemporaneous measurements, truck scale tickets, or contemporaneous diaries that are determined acceptable by the FSA county committee.

**Payment Limitation**

For MFP payments, there will be a single combined \$125,000 per person or legal entity payment limitation for shelled almonds and fresh sweet cherries.

## Eligible Crops

To be eligible to receive an MFP payment for a crop, the acreage of the crop must have been reported on FSA-578 and amount of production of shelled almonds or fresh sweet cherries must have been harvested and entered on the application. Sweet cherries intended for process market or juice are not eligible for MFP. The quantity of production for sweet cherries is on a "pack-out" basis. The quantity of production for shelled almonds will be based on the total eligible kernels or such similar term as edible meat weight.

## Paperwork Reduction Act Requirements

This NOFA does not require changes to the information collection request currently approved by OMB control number 0560-0292. However, FSA has requested public comments through October 29, 2018, on the information collection requirements as specified in the NOFA published on August 30, 2018 (83 FR 44257-44258).

## Environmental Review

The environmental impacts for MFP have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321-4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500-1508), and the FSA regulation for compliance with NEPA (7 CFR part 799).

As stated in the MFP final rule, the implementation of MFP and the participation in MFP do not constitute major Federal actions that would significantly affect the quality of the human environment, individually or cumulatively. The final rule served as documentation of the programmatic environmental compliance decision for this federal program; therefore, CCC will not prepare additional environmental compliance documentation for this NOFA.

## Federal Assistance Programs

The title and number of the Federal assistance programs, as found in the Catalog of Federal Domestic Assistance, to which this NOFA applies is:

10.123 Market Facilitation Program.

### Steven Peterson,

*Acting Administrator, Farm Service Agency.*

### Robert Stephenson,

*Executive Vice President, Commodity Credit Corporation.*

[FR Doc. 2018-20773 Filed 9-21-18; 8:45 am]

BILLING CODE 3410-05-P

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Indiana Advisory Committee to the U.S. Commission on Civil Rights.

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold a meeting on Thursday September 27, 2018, from 3-4 p.m. EDT for the purpose of discussing a draft op-ed regarding voting rights in the state.

**DATES:** The meeting will be held on Thursday September 27, 2018, from 3-4 p.m. EDT.

**ADDRESSES:** Public call information: Dial: 855-719-5012; Conference ID: 8260781.

#### FOR FURTHER INFORMATION CONTACT:

Melissa Wojnaroski, DFO, at [mwojnaroski@usccr.gov](mailto:mwojnaroski@usccr.gov) or 312-353-8311.

**SUPPLEMENTARY INFORMATION:** This meeting is free and open to the public. Members of the public may join through the above listed toll free call in number. Members of the public will be invited to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago IL 60604. They may also be faxed to the Commission at (312) 353-8324, or emailed to Carolyn Allen at [callen@usccr.gov](mailto:callen@usccr.gov). Persons who desire

additional information may contact the Regional Programs Unit Office at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via [www.facadatabase.gov](http://www.facadatabase.gov) under the Commission on Civil Rights, Indiana Advisory Committee link (<http://www.facadatabase.gov/committee/meetings.aspx?cid=247>). Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit Office at the above email or street address.

#### Agenda:

Welcome and Introductions  
Draft op-ed review: Voting Rights in Indiana

Public Comment  
Adjournment

*Exceptional Circumstance:* Pursuant to 41 CFR 102-3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of this Committee discussing publication of an op-ed regarding voting rights, to be released prior to the voter registration deadline in the state.

Dated: September 20, 2018.

#### David Mussatt,

*Supervisory Chief, Regional Programs Unit.*

[FR Doc. 2018-20900 Filed 9-24-18; 8:45 am]

BILLING CODE P

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

*Agency:* Bureau of Economic Analysis (BEA), Department of Commerce.

*Title:* Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United States.

*OMB Control Number:* 0608-0068.

*Form Number:* BE-9.

*Type of Request:* Regular submission.

*Number of Responses:* 180 annually (45 filed each quarter; 44 reporting mandatory data, and one that would file an exemption claim).

*Average Hours per Response:* 6 hours is the average for those reporting data,

and one hour is the average for those filing an exemption, but hours may vary considerably among respondents because of differences in company size and complexity.

*Estimated Total Annual Burden Hours:* 1,060.

*Needs and Uses:* The Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United States (BE-9) is a survey that collects data from U.S. offices, agents, or other representatives of foreign airline operators that transport freight and express to or from the United States and whose total covered revenues or total covered expenses were \$5 million or more in the previous year or are expected to be \$5 million or more during the current year. The covered revenues are freight revenue on merchandise exported from, or imported into, the United States. The covered expenses are expenses incurred in the United States for: (1) Fuel and oil; (2) wages and salaries paid to employees in the United States; (3) agents' and brokers' fees and commissions for arrangement of freight and passenger transportation; (4) aircraft handling and terminal services, (5) aircraft (with crew) leasing expenses, and (6) all other expenses incurred in the United States except aircraft leasing (without crew) expenses.

Respondents are also asked to report: (1) Shipping weights on which freight revenues were earned; (2) the number of passengers transported to/from the United States; and (3) revenues associated with these passengers.

The data collected on the survey are needed to monitor U.S. trade in transport services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in transport services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the transport component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is not making any modifications to the current BE-9 survey. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

*Affected Public:* Businesses or other for-profit organizations.

*Frequency:* Quarterly.

*Respondent's Obligation:* Mandatory.  
*OMB Desk Officer:* Robert Sivinski, (202) 395-1205.

This information collection request may be viewed at [reginfo.gov](http://www.reginfo.gov/public/) <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20784 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-06-P**

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* Bureau of Economic Analysis (BEA), Department of Commerce.

*Title:* Annual Survey of Foreign Ocean Carriers' Expenses in the United States.

*OMB Control Number:* 0608-0012.

*Form Number:* BE-29.

*Type of Request:* Regular submission.

*Number of Responses:* 80 annually (70 reporting mandatory data, and 10 that would file exemption claims).

*Average Hours per Response:* 3 hours is the average for those reporting data and one hour is the average for those filing an exemption, but hours may vary considerably among respondents because of differences in the volume and complexity of information on the foreign ocean carriers represented by the reporter.

*Estimated Total Annual Burden Hours:* 220.

*Needs and Uses:* The Annual Survey of Foreign Ocean Carriers' Expenses in the United States (BE-29) is a survey that collects data from U.S. agents of foreign ocean carriers who handle 40 or more foreign ocean port calls in the reporting period, or report total covered expenses of \$250,000 or more in the reporting period for all foreign ocean vessels handled by the U.S. agent. The

covered expenses are: (1) Port call services such as pilotage, towing and tugboat services, harbor fees, and berth fees; (2) cargo-related services such as loading, unloading, and storing cargo at U.S. ports; (3) fuels and oils (bunkers) purchased in U.S. ports; (4) other vessel operating expenses such as stores and supplies, vessel repairs, and personnel expenses in the United States; and (5) other expenses such as U.S. agents' and brokers' fees and commissions and expenses related to maintaining U.S. offices, such as rent, advertising, and wages.

The data collected on the survey are needed to monitor U.S. trade in transport services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in transport services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the transport component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is not making any modifications to the current BE-29 survey. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

*Affected Public:* Businesses or other for-profit organizations.

*Frequency:* Annual.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* Robert Sivinski, (202) 395-1205.

This information collection request may be viewed at [reginfo.gov](http://www.reginfo.gov/public/) <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20786 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-06-P**

**DEPARTMENT OF COMMERCE****Submission for OMB Review;  
Comment Request**

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* Bureau of Economic Analysis (BEA), Department of Commerce.

*Title:* Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons.

*OMB Control Number:* 0608–0067.

*Form Number:* BE–125.

*Type of Request:* Regular submission.

*Number of Responses:* 8,800 annually (2,200 filed each quarter; 1,700 reporting mandatory data, and 500 that would file other responses).

*Average Hours per Response:* 21 hours is the average for those reporting data, and one hour is the average for those filing an exemption or providing voluntary responses, but hours may vary considerably among respondents because of differences in company size and complexity.

*Estimated Total Annual Burden Hours:* 144,800.

*Needs and Uses:* The Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons (BE–125) is a survey that collects data from U.S. persons who engage in covered transactions with foreign persons in selected services or intellectual property. A U.S. Person means any individual, branch, partnership, associated group, association, estate, trust, corporation, or other organization (whether or not organized under the laws of any State), resident in the United States or subject to the jurisdiction of the United States. A U.S. person must report if they had sales of covered services or intellectual property to foreign persons that exceeded \$6 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year, or if they had purchases of covered services or intellectual property from foreign persons that exceeded \$4 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year.

The data are needed to monitor U.S. trade in services, to analyze the impact of these cross-border services and intellectual property transactions on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial

policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is implementing one change to the reporting requirements and several modifications to the data collected on the BE–125 survey, beginning with reporting for first quarter 2019. These modifications will allow BEA to align its statistics more closely with international economic accounting guidelines, increasing the quality and usefulness of BEA's published statistics on trade in services.

BEA will adjust the reporting requirements of the survey so they are applied based on “combined” thresholds. Currently, the reporting requirements for the BE–125 survey are applied based on the dollar amount of each covered transaction type collected on the survey. For example, a reporter with transactions in several of the services and intellectual property categories covered by the survey, may only exceed the threshold for mandatorily reporting additional detail by country, and by relationship to the foreign transactor (foreign affiliate, foreign parent group, or unaffiliated) for a single transaction type. Under this approach, the reporter is only required to report this additional detail, on the mandatory schedule(s), for the single transaction type in excess of the \$6 million (sales) or \$4 million (purchases) threshold.

The change will modify the reporting threshold to be applied based on a “combined” threshold for sales or purchases of the covered types of services and intellectual property transactions. U.S. persons with combined sales in excess of \$6 million or with combined purchases in excess of \$4 million, are required to disaggregate all transaction types by country and by relationship to the foreign transactor on the mandatory schedule(s). Because the combined thresholds are applied separately to sales and to purchases, the mandatory reporting requirements may apply only to sales, only to purchases, or to both.

BEA will make the following modifications to the data collection instrument:

(1) *Research and development services will be broken out into two categories:* (1) Provision of customized and non-customized R&D services and

(2) other R&D services, including testing.

(2) *Engineering, architectural, and surveying services will be broken out into three categories:* (1) Architectural services; (2) engineering services; and (3) surveying, cartography, certification, testing, and technical inspection services.

(3) *Management, consulting, and public relation services will be broken out into three categories:* (1) Market research services; (2) public opinion polling services; and (3) other management, consulting, and public relations services. Trade exhibition and sales convention services will be collected separately.

(4) *Database and other information services will be broken out into two components:* (1) News agency services and (2) other information services.

(5) *Computer services will be expanded into three categories:* (1) Computer software, including end-user licenses and customization services; (2) cloud computing and data storage services; and (3) other computer services.

(6) *Several service categories previously collected under “Other selected services” will be collected separately.* These services include contract manufacturing services, disbursements for sales promotion and representation, photographic services (including satellite photography), space transport services, trade exhibition and sales convention services, agricultural services, and waste treatment and depollution services.

(7) *Mandatory Schedule C will be modified to only collect related goods details for construction services.* On the current BE–125 survey, exports (sales) of three service types are collected on a separate schedule, Schedule C, to allow for reporting of information on the gross operating revenues and related goods exports and foreign expenses. The three categories are: (1) Construction services; (2) engineering, architectural, and surveying services; and (3) mining services. Beginning with reporting for first quarter 2019, only construction services will be collected on Schedule C. Mining services, as well as the three new categories that will replace engineering, architectural, and surveying services, will be collected on Schedule A.

BEA estimates the proposed changes, being implemented beginning with reporting for first quarter 2019, will increase the average number of hours per response from 19 hours to 21 hours for those reporting data. The reporting thresholds of the current BE–125 survey will be retained. The effort to keep

current reporting thresholds unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

*Affected Public:* Businesses or other for-profit organizations.

*Frequency:* Quarterly.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* Robert Sivinski, (202) 395-1205.

This information collection request may be viewed at [reginfo.gov](http://reginfo.gov) <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**Sheleen Dumas,**

*Department Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20785 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-06-P**

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* Bureau of Economic Analysis (BEA), Department of Commerce.

*Title:* Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of U.S. Carriers (BE-30) and the Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses (BE-37).

*OMB Control Number:* 0608-0011.

*Form Number:* BE-30 and BE-37.

*Type of Request:* Regular submission.

*Number of Responses:* BE-30 responses: 280 annually (70 filed each quarter; 62 reporting mandatory data, and 8 that would file exemption claims).

BE-37 responses: 120 annually (30 filed each quarter; 29 reporting mandatory data, and one that would file an exemption claim).

*Average Hours per Response:* 4 hours is the average for those reporting data and one hour is the average for those filing an exemption, but hours may vary considerably among respondents because of differences in company size and complexity.

*Estimated Total Annual Burden Hours:* 1,492 (BE-30 burden hours of 1,024 and BE-37 burden hours of 468).

*Needs and Uses:* The Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of U.S. Carriers (BE-30) is a survey that collects data from U.S. ocean freight carriers (owners and operators) whose total covered revenues or total covered expenses incurred outside the United States were \$500,000 or more in the previous year or are expected to be \$500,000 or more during the current year. The covered revenues are: (1) Revenue on cargo outbound from U.S. ports and the associated shipping weight; (2) revenue on cargo inbound into the United States and the associated shipping weight; (3) revenue on cross-trade cargoes; and (4) charter hire (with crew) and space leasing revenues from foreign residents. The covered expenses are: (1) Fuel expenses in foreign countries; (2) expenses in foreign countries (other than fuel expenses); and (3) charter hire (with crew) and space leasing payments to foreign residents.

The Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses (BE-37) is a survey that collects data from U.S. airline operators engaged in the international transportation of goods and/or passengers and whose total covered revenues or total covered expenses incurred outside the United States were \$500,000 or more in the previous year or are expected to be \$500,000 or more during the current year. The covered revenues are: (1) Revenue derived from carriage of export freight and express from the United States to points outside the United States; (2) revenue derived from carriage of freight and express originating from, and destined to, points outside the United States; (3) revenue derived from transporting passengers originating from, and destined to, points outside the United States; (4) revenue from transporting passengers to and from the United States and the associated number of passengers; and (5) interline settlement receipts from foreign airline operators. The covered expenses are: (1) Expenses incurred outside the United States for fuel and oil, station and maintenance bases, wages, and other goods and services purchased abroad (except aircraft leasing expenses); (2) aircraft (with crew) leasing expenses; and (3) interline settlement payments to foreign airline operators.

The data collected on the surveys are needed to monitor U.S. trade in transport services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile

and improve the U.S. economic accounts, to support U.S. commercial policy on trade in transport services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the transport component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is not making any modifications to the current BE-30 and BE-37 surveys. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

*Affected Public:* Businesses or other for-profit organizations.

*Frequency:* Quarterly.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* Robert Sivinski, (202) 395-1205.

This information collection request may be viewed at [reginfo.gov](http://reginfo.gov) <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20788 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-06-P**

## DEPARTMENT OF COMMERCE

### Bureau of Economic Analysis

#### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* Bureau of Economic Analysis (BEA), Department of Commerce.

*Title:* Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons.

*OMB Control Number:* 0608-0066.

*Form Number:* BE-45.

*Type of Request:* Regular submission.

*Number of Responses:* 2,200 annually (550 filed each quarter; 515 reporting mandatory or voluntary data, and 35 that would not report data).

*Average Hours per Response:* 9 hours is the average for those reporting data and one hour is the average for those filing an exemption, but hours may vary considerably among respondents because of differences in company size and complexity.

*Estimated Total Annual Burden Hours:* 18,680.

*Needs and Uses:* The Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons (BE-45) is one of BEA's primary data sources for its estimates of insurance services exports and imports. A U.S. insurance company must report if it had transactions with foreign persons, in any of the data items covered by the survey, that exceeded \$8 million (positive or negative) in the prior calendar year, or are expected to exceed that amount during the current calendar year.

The data are needed to monitor U.S. trade in insurance services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the insurance services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is implementing one change to the data collected on the BE-45 survey, beginning with reporting for first quarter 2019, which will allow BEA to improve the accuracy of our quarterly statistics on insurance services exports and imports.

Schedule B of the BE-45 survey, which currently collects annual data on primary insurance premiums and losses, reinsurance losses, and auxiliary insurance services receipts and payments, on a mandatory basis in the fourth quarter of the year, will now be collected on a mandatory basis every quarter.

BEA estimates the proposed changes, being implemented beginning with reporting for first quarter 2019, will increase the average number of hours per response from 8 hours to 9 hours for those reporting data. The reporting thresholds of the current BE-45 survey will be retained. The effort to keep current reporting thresholds unchanged is intended to minimize respondent

burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

*Affected Public:* Businesses or other for-profit organizations.

*Frequency:* Quarterly.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* Robert Sivinski, (202) 395-1205.

This information collection request may be viewed at <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of Chief Information Officer.*

[FR Doc. 2018-20783 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-06-P**

## DEPARTMENT OF COMMERCE

### Bureau of Economic Analysis

#### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

*Agency:* Bureau of Economic Analysis (BEA), Department of Commerce.

*Title:* Quarterly Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons.

*OMB Control Number:* 0608-0065.

*Form Number:* BE-185.

*Type of Request:* Regular submission.

*Number of Responses:* 2,860 annually (715 filed each quarter; 580 reporting mandatory data, and 135 that would file other responses).

*Average Hours per Response:* 10 hours is the average for those reporting data and one hour is the average for those filing an exemption or providing voluntary responses, but hours may vary considerably among respondents because of differences in company size and complexity.

*Estimated Total Annual Burden Hours:* 23,740.

*Needs and Uses:* The Quarterly Survey of Financial Services

Transactions between U.S. Financial Services Providers and Foreign Persons (BE-185) is one of BEA's primary data sources for its estimates of financial services exports and imports. A U.S. financial services provider must report if they had sales of covered services to foreign persons that exceeded \$20 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year, or if it had purchases of covered services from foreign persons that exceeded \$15 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year.

The data are needed to monitor U.S. trade in financial services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the financial services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is not making any modifications to the current BE-185 survey. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

*Affected Public:* Businesses or other for-profit organizations.

*Frequency:* Quarterly.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* Robert Sivinski, (202) 395-1205.

This information collection request may be viewed at [www.reginfo.gov](http://www.reginfo.gov) <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20787 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-06-P**

**DEPARTMENT OF COMMERCE****International Trade Administration****Calendar of June 2018 Approved International Trade Administration Trade Missions**

**AGENCY:** International Trade Administration, Department of Commerce.

**ACTION:** Notice.

**SUMMARY:** The United States Department of Commerce, International Trade Administration (ITA) is announcing three upcoming trade missions that will be recruited, organized, and implemented by ITA. These missions are:

- Healthcare Technologies Trade Mission to Saudi Arabia, Kuwait, and Qatar—April 6–11, 2019
- Horizontal Trade Mission to Argentina, Uruguay, Paraguay, Bolivia and Chile in Conjunction with Trade Americas—Business Opportunities in the Southern Cone Region Conference—March 24–29, 2019
- Horizontal Trade Mission to Central America in conjunction with the Trade Americas—Business Opportunities in Central America Conference—August 18–23, 2019

A summary of each mission is found below. Application information and more detailed mission information, including the commercial setting and sector information, can be found at the trade mission website: <http://export.gov/trademissions>.

For each mission, recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (<http://export.gov/trademissions>) and other internet websites, press releases to general and trade media, direct mail, broadcast fax, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

**The Following Conditions for Participation Will Be Used for Each Mission**

Applicants must submit a completed and signed mission application and supplemental application materials, including adequate information on their products and/or services, primary market objectives, and goals for participation. If the Department of Commerce receives an incomplete application, the Department may either: Reject the application, request additional information/clarification, or

take the lack of information into account when evaluating the application. If the requisite minimum number of participants is not selected for a particular mission by the recruitment deadline, the mission may be cancelled.

Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the United States, or, if not, are marketed under the name of a U.S. firm and have at least fifty-one percent U.S. content by value. In the case of a trade association or organization, the applicant must certify that, for each firm or service provider to be represented by the association/organization, the products and/or services the represented firm or service provider seeks to export are either produced in the United States or, if not, marketed under the name of a U.S. firm and have at least 51% U.S. content.

A trade association/organization applicant must certify to the above for all of the companies it seeks to represent on the mission.

In addition, each applicant must:

- Certify that the products and services that it wishes to market through the mission would be in compliance with U.S. export controls and regulations;
- Certify that it has identified any matter pending before any bureau or office in the Department of Commerce;
- Certify that it has identified any pending litigation (including any administrative proceedings) to which it is a party that involves the Department of Commerce; and
- Sign and submit an agreement that it and its affiliates (1) have not and will not engage in the bribery of foreign officials in connection with a company's/participant's involvement in this mission, and (2) maintain and enforce a policy that prohibits the bribery of foreign officials.

In the case of a trade association/organization, the applicant must certify that each firm or service provider to be represented by the association/organization can make the above certifications.

**The Following Selection Criteria Will Be Used for Each Mission**

Targeted mission participants are U.S. firms, services providers and trade associations/organizations providing or promoting U.S. products and services that have an interest in entering or expanding their business in the mission's destination country. The following criteria will be evaluated in selecting participants:

- Suitability of the applicant's (or in the case of a trade association/

organization, represented firm or service provider's) products or services to these markets;

- The applicant's (or in the case of a trade association/organization, represented firm or service provider's) past, present, and prospective business activity in relation to the Mission's target market(s) and sector(s);
- The applicant's (or in the case of a trade association/organization, represented firm or service provider's) potential for business in the markets, including likelihood of exports resulting from the mission; and
- Consistency of the applicant's (or in the case of a trade association/organization, represented firm or service provider's) goals and objectives with the stated scope of the mission.

Referrals from a political party or partisan political group or any information, including on the application, containing references to political contributions or other partisan political activities will be excluded from the application and will not be considered during the selection process. The sender will be notified of these exclusions.

**Trade Mission Participation Fees**

If and when an applicant is selected to participate on a particular mission, a payment to the Department of Commerce in the amount of the designated participation fee below is required. Upon notification of acceptance to participate, those selected have 5 business days to submit payment or the acceptance may be revoked.

Participants selected for a trade mission will be expected to pay for the cost of personal expenses, including, but not limited to, international travel, lodging, meals, transportation, communication, and incidentals, unless otherwise noted. Participants will, however, be able to take advantage of U.S. Government rates for hotel rooms. In the event that a mission is cancelled, no personal expenses paid in anticipation of a mission will be reimbursed. However, participation fees for a cancelled mission will be reimbursed to the extent they have not already been expended in anticipation of the mission.

If a visa is required to travel on a particular mission, applying for and obtaining such visas will be the responsibility of the mission participant. Government fees and processing expenses to obtain such visas are not included in the participation fee. However, the Department of Commerce will provide instructions to each participant on the procedures required to obtain business visas.

Trade Mission members participate in trade missions and undertake mission-related travel at their own risk. The nature of the security situation in a given foreign market at a given time cannot be guaranteed. The U.S. Government does not make any representations or guarantees as to the safety or security of participants. The U.S. Department of State issues U.S. Government international travel alerts and warnings for U.S. citizens available at <https://travel.state.gov/content/passports/en/alertswarnings.html>. Any question regarding insurance coverage must be resolved by the participant and its insurer of choice.

**Definition of Small and Medium Sized Enterprise**

For purposes of assessing participation fees, the Department of Commerce defines Small and Medium Sized Enterprises (SME) as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations (see [http://www.sba.gov/services/contracting\\_opportunities/sizestandardsttopics/index.html](http://www.sba.gov/services/contracting_opportunities/sizestandardsttopics/index.html)). Parent companies,

affiliates, and subsidiaries will be considered when determining business size.

*Mission List:* (additional information about each mission can be found at <http://export.gov/trademissions>).

**Healthcare Technologies Trade Mission to Saudi Arabia, Kuwait, and Qatar—April 6–11, 2019**

**Summary**

The United States Department of Commerce, International Trade Administration (ITA), is organizing a Healthcare Technologies Trade Mission to Saudi Arabia, Kuwait, and Qatar from April 6–11, 2019. The purpose of the mission is to introduce U.S. firms to the rapidly expanding healthcare sectors in these three countries and to assist U.S. companies in pursuing opportunities in these sectors.

Target sectors holding high potential for U.S companies include:

- Home healthcare and rehabilitation
- Medical devices
- Trauma care and training
- Emergency services, training, equipment and supplies
- Hospital operation and management

- Healthcare training and staffing services
- Healthcare education
- Health information technology

The mission will help participating U.S. firms and associations/ organizations gain market insights, make industry and government contacts, solidify business strategies and advance specific projects with the goal of increasing U.S. healthcare products and services exports. The trade mission will start in Riyadh, Saudi Arabia, where participants will receive market briefings from U.S. Commercial Service and industry experts, hold one-on-one business meetings, meet with Saudi government officials and organizations, and participate in networking events. The trade mission participants will next travel to Kuwait and subsequently Qatar, where they will have additional opportunities to meet with key contacts and decision makers. Participating in an official U.S. industry delegation, rather than traveling on their own, will enhance the companies' abilities to identify opportunities and meet with local healthcare officials in Saudi Arabia, Kuwait and Qatar.

**SCHEDULE**

Saturday—April 6, Riyadh, Saudi Arabia .....	<ul style="list-style-type: none"> <li>• Arrive Riyadh and hotel check-in.</li> <li>• Welcome reception/ice breaker.</li> </ul>
Sunday—April 7, Riyadh, Saudi Arabia .....	<ul style="list-style-type: none"> <li>• Welcome and overview of Trade Mission (TM).</li> <li>• Market briefings from the U.S. Commercial Service and industry experts.</li> <li>• One-on-one business meetings.</li> <li>• Networking reception in Riyadh.</li> </ul>
Monday—April 8, Riyadh and Kuwait City .....	<ul style="list-style-type: none"> <li>• Government meetings.</li> <li>• Travel to Kuwait.</li> </ul>
Tuesday—April 9, Kuwait City .....	<ul style="list-style-type: none"> <li>• Market briefing.</li> <li>• One-on-one business meetings.</li> <li>• Government meetings.</li> <li>• Networking reception.</li> </ul>
Wednesday—April 10, Kuwait City and Doha .....	<ul style="list-style-type: none"> <li>• Additional meetings.</li> <li>• Depart for Doha.</li> <li>• Networking reception in Doha.</li> </ul>
Thursday—April 11, Doha .....	<ul style="list-style-type: none"> <li>• Market briefing.</li> <li>• Government meetings.</li> <li>• One-on-one business meetings.</li> <li>• Mission ends.</li> </ul>

*Participation Requirements*

All parties interested in participating in the trade mission must complete and submit an application package for consideration by the U.S. Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below and will be notified whether they are chosen to participate in the mission. A minimum of 12 and maximum of 15 companies and/or trade associations/organizations will be selected from the applicant pool to participate in the trade mission.

*Fees and Expenses*

The participation fee for the trade mission to Saudi Arabia, Kuwait, and Qatar is \$3,800 for small or medium-sized enterprises (SME) and \$4,900 for large companies. The fee for each additional representative (large firm or SME or trade association/organization) is \$750.

*Timeline for Recruitment*

Recruitment for the mission will begin immediately and conclude no later than February 15, 2019. The U.S. Department of Commerce will review

applications and make selection decisions on a rolling basis beginning September 10, 2018 until the maximum of 15 participants is selected. Applications received after February 15, 2019, will be considered only if space and scheduling constraints permit.

*Contacts*

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 Kuwait City, Kuwait



Yousif Almahadi, U.S. Commercial Service—Kuwait, Tel: +96522591487, Email: [Yousif.almahadi@trade.gov](mailto:Yousif.almahadi@trade.gov).

*Riyadh, Saudi Arabia*

Nasir Abbasi, U.S. Commercial Service—Riyadh, Tel: +603-2168-4869, Email: [Nasir.Abbasi@trade.gov](mailto:Nasir.Abbasi@trade.gov).

Jeff Hamilton, U.S. Commercial Service—Kuwait, Tel: +965-2259-1354, Email: [Jeff.Hamilton@trade.gov](mailto:Jeff.Hamilton@trade.gov).

Maher Siblini, U.S. Commercial Service—Riyadh, Tel: +966-11-488-3800 x 4302, Email: [maher.siblini@trade.gov](mailto:maher.siblini@trade.gov).

*Doha, Qatar*

Anissa Lahreche, U.S. Commercial Service—Qatar, Tel: 974-488-4101 x6040, Email: [Anissa.Lahreche@trade.gov](mailto:Anissa.Lahreche@trade.gov).

Ilona Shtrom, U.S. Commercial Service—Qatar, Tel: 974- 696-6739, Email: [Ilona.shtrom@trade.gov](mailto:Ilona.shtrom@trade.gov).

**Horizontal Trade Mission to Central America in Conjunction With the Trade Americas—Business Opportunities in Central America Conference—August 18–23, 2019**

*Summary*

The United States Department of Commerce, International Trade Administration is organizing a trade mission to Central America that will include the Trade Americas—Business Opportunities in Central America Conference in Washington, DC on August 18–23, 2019.

U.S. trade mission delegation participants will arrive in Washington, DC on or before August 18 to attend the opening reception for the Trade Americas—Business Opportunities in Central America Conference, which is also open to U.S. companies not participating in the trade mission. Trade mission participants will attend the Conference on August 19. Following the morning session of the conference, trade mission participants will participate in one-on-one consultations with U.S. and Foreign Commercial Service (US&FCS) Commercial Officers and/or Department of State Economic/Commercial Officers from the following U.S. Embassies in the region: Costa Rica, El Salvador, Honduras, Guatemala, Belize, Nicaragua, and Panama. The following day, August 20, trade mission participants will travel to engage in business-to-business appointments, each of which will be with a pre-screened potential buyer, agent, distributor or joint-venture partner, in up to two markets in the Central America Region.

The Department of Commerce's Trade Americas—Business Opportunities in Central America Conference will focus

on regional and industry-specific sessions, market entry strategies, legal, logistics, and trade financing resources as well as pre-arranged one-one-one consultations with US&FCS Commercial Officers and/or Department of State Economic/Commercial Officers with expertise in commercial markets throughout the region.

The mission is open to U.S. companies and trade associations/ organizations from a cross section of industries with growing potential in Central America, but is focused on U.S. companies representing best prospects sectors such as infrastructure and construction, safety & security, auto parts and service equipment, renewable energy, energy & oil & gas, medical equipment, and logistics.

The combination of the Trade Americas—Business Opportunities in Central America Conference and business-to-business matchmaking opportunities in seven Central American countries will provide participants with access to substantive information on strategies for entering or expanding their business across the Central America region.

*Proposed Timetable*

August 18 Travel Day/Arrive in Washington, DC  
Afternoon: Registration, Market Briefings, and U.S. Embassy Officer Consultations, Evening: Networking Reception

August 19 Washington, DC  
Morning: Registration and Trade Americas—Business Opportunities in Central America Conference, Afternoon: U.S. Embassy Officer Consultations, Evening: Networking Reception

*Optional*

August 20–23 Travel and Business-to-Business Meetings in (choice of up to two markets):  
Option (A) Costa Rica. Option (B) Guatemala. Option (C) El Salvador. Option (D) Belize. Option (E) Nicaragua. Option (F) Honduras. Option (G) Panama.

August 24 Travel Day. Return to the U.S.

*Participation Requirements*

All applicants must sign and submit a completed Trade Mission application form and satisfy all of the conditions of participation in order to be eligible for consideration. Applications will be evaluated on the applicant's ability to best satisfy the participation criteria.

A minimum of 20 and a maximum of 40 companies will be selected to participate in the mission. The

Department of Commerce will evaluate applications and inform applicants of selection decisions on a rolling basis until the maximum number of participants has been selected. During the registration process, applicants will indicate their markets of choice and will receive a brief market assessment for each of those markets. Applicants can select up to two markets based on the selection criteria below. Companies that received favorable market opportunities in various markets may be able to participate in business-to-business meetings in a third market, if that post can accommodate those meetings. The number of companies that may be selected for each country are as follows: 20 Companies for Costa Rica, 10 companies for Guatemala, 10 companies for El Salvador; 4 companies for Belize; 10 companies for Honduras; 10 companies for Nicaragua; and 10 companies for Panama. U.S. companies already doing business in, or seeking to enter these markets for the first time may apply.

*Fees and Expenses*

After a company has been selected to participate in the mission, a payment to the Department of Commerce in the form of a participation fee is required.

For business-to-business meetings in one market, the participation fee will be \$2,500 for a small or medium-sized enterprise (SME) \* and \$3,500 for large firms \*.

For business-to-business meetings in two markets, the participation fee will be \$3,500 for a small or medium-sized enterprise (SME) [2] \* and \$4,500 for large firms \*.

The mission participation fee includes the *Trade Americas—Business Opportunities in Central America Conference* registration fee of \$500 per participant from each firm.

There will be a \$300 fee for each additional firm representative (large firm or SME) that wishes to participate in business-to-business meetings in any of the markets selected.

*Timeframe for Recruitment and Application*

Recruitment for the mission will begin immediately and conclude no later than Friday, May 31, 2019. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis until the maximum of 40 participants are selected. After Friday, May 31, 2019, companies will be considered only if space and scheduling constraints permit.

### Contacts

#### U.S. Trade Americas Team Contact Information

Diego Gattesco, Director, U.S. Commercial Service—Wheeling, WV, [Diego.Gattesco@trade.gov](mailto:Diego.Gattesco@trade.gov), Tel: 304-243-5493.

Delia Valdivia, Senior International Trade Specialist, U.S. Commercial Service—Los Angeles (West), CA, [delia.valdivia@trade.gov](mailto:delia.valdivia@trade.gov), Tel: 310-235-7203.

#### Central America Region Contact Information

Eric B. Wolff, Regional Senior Commercial Officer, U.S. Commercial Service—Costa Rica, [Eric.Wolff@trade.gov](mailto:Eric.Wolff@trade.gov), Tel: 506-519-2293.

### Horizontal Trade Mission to the Americas Southern Cone Region in Conjunction With Trade Americas—Business Opportunities in the Southern Cone Region Conference March 24–29, 2019

#### Summary

The United States Department of Commerce, International Trade Administration is organizing a trade mission to Argentina, Uruguay, Paraguay, Bolivia and Chile (Southern Cone Region) that will include the Trade Americas—Business Opportunities in the Southern Cone Region Conference in Buenos Aires, Argentina. Trade mission participants will arrive in Buenos Aires on or before March 24th, and will attend a mission briefing, and will engage in one-on-one consultations with U.S. and Foreign Commercial Service (US&FCS) Commercial Officers and/or Economic/Commercial Officers from the following U.S. Embassies in the Southern Cone region: Argentina, Uruguay, Paraguay, Bolivia and Chile as well as key service providers and resources. On March 25th, following the morning session of the *Trade Americas—Business Opportunities in the Southern Cone Region Conference*, mission participants will meet again one-on-one with Commercial Officers and will network with foreign buyers in the evening. The following day, March 26th, selected trade mission participants will engage in business-to-business appointments in Argentina, or will travel to one or up-to two markets in the Southern Cone Region. All business-to-business appointments in the region will be with a pre-screened potential buyer, agent, distributor or joint-venture partner.

The Department of Commerce's *Trade Americas—Business Opportunities in the Southern Cone Region Conference*

will focus on regional specific sessions, market access, logistics and trade financing resources as well as pre-arranged one-on-one consultations with US&FCS Commercial Officers and/or Department of State Economic/Commercial Officers with expertise in commercial markets throughout the region.

The mission is open to U.S. companies and trade associations/organizations from a cross section of industries with growing potential in the Southern Cone Region, but is focused on U.S. companies representing best prospects sectors such as infrastructure and construction, architecture services, engineering services, construction equipment, building products, airports, ports, transportation, housing, environmental technologies, safety & security, energy & oil & gas, mining equipment, medical equipment, aerospace & defense, ICT & digital services and logistics.

The combination of participation in the *Trade Americas—Business Opportunities in the Southern Cone Region Conference* and business-to-business matchmaking appointments in five countries, will provide participants with access to substantive information about and strategies for entering or expanding their business across the Southern Cone region.

#### Schedule

March 23, 2019 Travel Day/Arrival in Buenos Aires. Optional Local Tour

March 24, 2019 Buenos Aires, Argentina. Afternoon: Registration, Briefing and U.S. Embassy Officer Consultations. Evening: Networking Reception.

March 23, 2019 Travel Day/Arrival in Buenos Aires. Optional Local Tour

March 25, 2019 Buenos Aires, Argentina. Morning: Registration and Trade Americas—Business Opportunities in the Southern Cone Region Conference. Afternoon: U.S. Embassy Officer Consultations. Evening: Networking Reception.

#### Optional

March 26–29, 2019 Travel and Business-to-Business Meetings in (choice of two markets):  
Option (A) Argentina. Option (B) Bolivia. Option (C) Chile. Option (D) Paraguay. Option (E) Uruguay  
March 30, 2019 Travel Day.

#### Participation Requirements

All applicants must sign and submit a completed Trade Mission application form and satisfy all of the conditions of participation in order to be eligible for consideration. Applications will be

evaluated on the applicant's ability to best satisfy the participation criteria.

A minimum of 20 and a maximum of 40 companies will be selected to participate in the mission. The Department of Commerce will evaluate applications and inform applicants of selection decisions on a rolling basis until the maximum number of participants has been selected. During the registration process, applicants will indicate their markets of choice and will receive a brief market assessment for each of those markets. Applicants can select up-to two markets based on the selection criteria below. Companies that received favorable market opportunities in various markets may be able to participate in business-to-business meetings in a third market, if that post can accommodate those meetings. The number of companies that may be selected for each country are as follows: 25 Companies for Argentina, 5 companies for Bolivia; 15 companies for Chile; 8 companies for Paraguay; and 5 companies for Uruguay. U.S. companies already doing business in, or seeking to enter these markets for the first time may apply.

#### Fees and Expenses

After a company has been selected to participate in the mission, a payment to the Department of Commerce in the form of a participation fee is required.

For business-to-business meetings in one market, the participation fee will be \$2,800 for a small or medium-sized enterprise (SME) \* and \$3,800 for large firms \*.

For business-to-business meetings in two markets, the participation fee will be \$3,800 for a small or medium-sized enterprise (SME) <sup>[2]</sup> \* and \$4,800 for large firms \*.

The mission participation fee includes the *Trade Americas—Business Opportunities in the Southern Cone Region Conference* registration fee of \$500 per participant from each firm.

There will be a \$300 fee for each additional firm representative (large firm or SME) that wishes to participate in business-to-business meetings in any of the markets selected.

#### Timeframe for Recruitment and Application

Recruitment for the mission will begin immediately and conclude no later than Friday, January 18, 2019. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis until the maximum of 40 participants are selected. After January 18, 2019, companies will be considered only if

space and scheduling constraints permit.

#### Contacts

##### U.S. Trade Americas Team Contact Information

Diego Gattesco, Director, U.S. Commercial Service—Wheeling, WV, [Diego.Gattesco@trade.gov](mailto:Diego.Gattesco@trade.gov), Tel: 304–243–5493.

Dakshina Voetsch, Argentina Desk Officer, U.S. Commercial Service—Washington, DC, [Dakshina.Voetsch@trade.gov](mailto:Dakshina.Voetsch@trade.gov), Tel: 202–482–470.

##### Southern Cone Region Contact Information

Rick de Lambert, Regional Senior Commercial Officer, U.S. Commercial Service—U.S. Embassy, Buenos Aires, Argentina, [Rick.DeLambert@trade.gov](mailto:Rick.DeLambert@trade.gov).

#### Tiara Hampton-Diggs,

*Trade Promotion Programs.*

[FR Doc. 2018–20805 Filed 9–24–18; 8:45 am]

BILLING CODE 3510-DR-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Environmental Technologies Trade Advisory Committee (ETTAC), Notice of Reestablishment and Solicitation of Nominations for Membership

**AGENCY:** International Trade Administration, DOC.

**ACTION:** Notice of reestablishment of the Environmental Technologies Trade Advisory Committee (ETTAC) and solicitation of nominations for membership.

**SUMMARY:** Pursuant to provisions under Title IV of the Jobs Through Trade Expansion Act, and under the Federal Advisory Committee Act, the Department of Commerce announces the reestablishment of the Environmental Technologies Trade Advisory Committee (ETTAC), as of August 16, 2018. ETTAC was first chartered on May 31, 1994. ETTAC serves as an advisory body to the Environmental Trade Working Group of the Trade Promotion Coordinating Committee (TPCC), reporting directly to the Secretary of Commerce in his/her capacity as Chairman of the TPCC. ETTAC advises on the development and administration of policies and programs to expand U.S. exports of environmental technologies, goods, and services.

**DATES:** Nominations for membership must be received on or before October 19, 2018.

**ADDRESSES:** Please send nominations by post, email, or fax to the attention of

Amy Kreps, Designated Federal Officer/ETTAC, Office of Energy & Environmental Industries, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 28018, Washington, DC 20230; phone 202–482–3835; email [amy.kreps@trade.gov](mailto:amy.kreps@trade.gov); fax 202–482–5665. Electronic responses should be submitted in Microsoft Word format.

#### SUPPLEMENTARY INFORMATION:

**Nominations:** The Secretary of Commerce invites nominations to ETTAC of U.S. citizens who will represent U.S. environmental goods and services companies that trade internationally, or trade associations and non-profit organizations whose members include U.S. companies that trade internationally. Companies must be at least 51 percent owned by U.S. persons. No member may represent a company that is majority-owned or controlled by a foreign government entity or foreign government entities.

Membership in a committee operating under the Federal Advisory Committee Act must be balanced in terms of economic subsector, geographic location, and company size. Committee members serve in a representative capacity and must be able to generally represent the views and interests of a certain subsector of the U.S. environmental industry. Candidates should be senior executive-level representatives from environmental technology companies, trade associations, and non-profit organizations. Members of the ETTAC must have experience in the exportation of environmental goods and/or services, including:

- (1) Air pollution control and monitoring technologies;
- (2) Analytic devices and services;
- (3) Environmental engineering and consulting services;
- (4) Financial services relevant to the environmental sector;
- (5) Process and pollution prevention technologies;
- (6) Solid and hazardous waste management technologies; and/or
- (7) Water and wastewater treatment technologies.

Nominees will be evaluated based upon their ability to carry out the goals of the ETTAC's enabling legislation. A copy of ETTAC's current Charter is available on [www.export.gov/ettac](http://www.export.gov/ettac). Appointments will be made to create a balanced Committee in terms of subsector representation, product lines, firm size, geographic area, and other criteria. Nominees must be U.S. citizens. All appointments are made without regard to political affiliation. Members

shall serve at the pleasure of the Secretary from the date of appointment to the Committee to the date on which the Committee's charter terminates (normally two years).

If you are interested in becoming a member of ETTAC, please provide the following information (2 pages maximum):

- (1) Name
- (2) Title
- (3) Work phone; fax; and email address
- (4) Organization name and address, including website address
- (5) Short biography of nominee, including written certification of U.S. citizenship (this may take form of the statement "I am a citizen of the United States") and a list of citizenships of foreign countries
- (6) Brief description of the organization and its business activities, including
- (7) Company size (number of employees and annual sales)
- (8) Exporting experience.
- (9) An affirmative statement that the nominee will be able to meet the expected time commitments of Committee work. Committee work includes (1) attending in-person committee meetings approximately four times per year, (2) undertaking additional work outside of full committee meetings including subcommittee conference calls or meetings as needed, and (3) drafting or commenting on proposed recommendations to be evaluated at Committee meetings. Please do not send company or trade association brochures or any other information.

**FOR FURTHER INFORMATION CONTACT:** Ms. Amy Kreps, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 28018, 1401 Constitution Avenue NW, Washington, DC 20230. (Phone: 202–482–3835; Fax: 202–482–5665; email: [amy.kreps@trade.gov](mailto:amy.kreps@trade.gov)).

Dated: September 13, 2018.

#### Edward O'Malley,

*Director, Office of Energy and Environmental Industries.*

[FR Doc. 2018–20774 Filed 9–24–18; 8:45 am]

BILLING CODE 3510-DR-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the

following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* International Trade Administration, U.S. Department of Commerce.

*Title:* Proposed Information Collection; Comment Request; Swiss-U.S. Privacy Shield; Invitation for Applications for Inclusion on the Supplemental List of Arbitrators.

*OMB Control Number:* 0625-0278.

*Form Number(s):* None.

*Type of Request:* Regular submission.

*Number of Respondents:* 20.

*Average Hours per Response:* 240 Minutes.

*Burden Hours:* 80.

*Needs and Uses:* Under the Swiss-U.S. Privacy Shield, the U.S. Department of Commerce (DOC) and the Swiss Administration have committed to implement an arbitration mechanism to provide Swiss individuals with the ability to invoke binding arbitration to determine, for residual claims, whether an organization has violated its obligations under the Privacy Shield. The DOC and the Swiss Administration will work together to implement the arbitration mechanism, including developing a list of up to 5 arbitrators. While the DOC is not currently seeking applications for inclusion on the list, it may do so in the future to maintain the list. The arbitrators are chosen on the basis of independence, integrity, and expertise. Parties to a binding arbitration under this Privacy Shield mechanism may only select arbitrators from the list of arbitrators developed under the EU-U.S. Privacy Shield Framework, as supplemented by the list of arbitrators developed under the Swiss-U.S. Privacy Shield Framework. The arbitral mechanism is a critical component of the Swiss-U.S. Privacy Shield Framework. More than 3,700 U.S.-based organizations currently rely on the EU-U.S. and Swiss-U.S. Privacy Shield frameworks to transfer the personal data from EU and Switzerland to the United States necessary to do business across the Atlantic. Such a data transfer mechanism is critically important, because it protects individual privacy while meeting the legitimate needs of companies thereby facilitating over \$1 trillion in transatlantic trade.

*Affected Public:* Private individuals.

*Frequency:* Recurrent, depending on the number of arbitrators required to retain an active list of up to five arbitrators.

*Respondent's Obligation:* Required to obtain or retain benefits.

This information collection request may be viewed at [reginfo.gov](http://reginfo.gov). Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) or fax to (202) 395-5806.

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20782 Filed 9-24-18; 8:45 am]

**BILLING CODE 3510-DR-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Meeting of the United States Travel and Tourism Advisory Board

**AGENCY:** International Trade Administration, U.S. Department of Commerce.

**ACTION:** Notice of an open meeting.

**SUMMARY:** The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Thursday, October 11, 2018. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. This will be the first meeting of the newly appointed 2018-2020 Board. The purpose of the meeting is for Board members to discuss key issues related to the importance of international travel and tourism to the United States and for the Secretary of Commerce to provide an overview of the Administration's priorities in travel and tourism. The final agenda will be posted on the Department of Commerce website for the Board at <http://trade.gov/ttab> at least one week in advance of the meeting.

**DATES:** Thursday, October 11, 2018, 2:00 p.m.-3:30 p.m. EDT. The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on Thursday, October 4, 2018.

**ADDRESSES:** The meeting will be held in Washington, DC. The exact location will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 10003,

Washington, DC 20230 or by email to [TTAB@trade.gov](mailto:TTAB@trade.gov). Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

#### FOR FURTHER INFORMATION CONTACT:

Brian Beall, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 10003, Washington, DC 20230; telephone: 202-482-0140; email: [TTAB@trade.gov](mailto:TTAB@trade.gov).

#### SUPPLEMENTARY INFORMATION:

*Background:* The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

*Public Participation:* The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the DATES caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on Thursday, October 4, 2018, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Brian Beall at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on Thursday, October 4, 2018, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Copies of Board

meeting minutes will be available within 90 days of the meeting.

**Brian Beall,**

*Designated Federal Officer, United States Travel and Tourism Advisory Board.*

[FR Doc. 2018–20837 Filed 9–24–18; 8:45 am]

**BILLING CODE 3510-DR-P**

## COMMODITY FUTURES TRADING COMMISSION

### Sunshine Act Meetings

**TIME AND DATE:** 10:00 a.m., Thursday, September 27, 2018.

**PLACE:** CFTC Headquarters, Lobby-Level Hearing Room, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:** The Commodity Futures Trading Commission (“Commission” or “CFTC”) will hold this meeting to consider the following matters:

- Proposed Rule Amending Registration and Compliance Obligations for Commodity Pool Operators (CPOs) and Commodity Trading Advisors (CTAs);
- Fintech Cooperation Arrangement(s); and
- Paperwork Reduction Act delegation to the Secretary of the Commission.

The agenda for this meeting will be available to the public and posted on the Commission’s website at <https://www.cftc.gov>. In the event that the time, date, or place of this meeting changes, an announcement of the change, along with the new time, date, or place of the meeting, will be posted on the Commission’s website.

**CONTACT PERSON FOR MORE INFORMATION:** Christopher Kirkpatrick, Secretary of the Commission, 202–418–5964.

Dated: September 20, 2018.

**Christopher Kirkpatrick,**

*Secretary of the Commission.*

[FR Doc. 2018–20897 Filed 9–21–18; 11:15 am]

**BILLING CODE 6351-01-P**

## DEPARTMENT OF DEFENSE

### Department of the Air Force

#### Notice is Given of the Names of Members of the Performance Review Board for the Department of the Air Force

**AGENCY:** Department of the Air Force, Department of Defense.

**ACTION:** Notice.

**SUMMARY:** Notice is given of the names of members of the 2018 Performance Review Board for the Department of the Air Force.

*Applicable Dates:* November 5, 2018.

**SUPPLEMENTARY INFORMATION:** Pursuant to 5 U.S.C. 4314(c)(1–5), the Department of the Air Force announces the appointment of members to the Air Force’s Senior Executive Service Performance Review Board.

Appointments are made by the authorizing official. Each board member shall review and evaluate performance scores provided by the Senior Executive’s rater/immediate supervisor. Performance standards must be applied consistently across the Air Force. The board will make final recommendations to the authorizing official relative to the performance of the executive.

The members of the 2018 Performance Review Board for the Air Force are:

1. Board President—Gen John W. Raymond, Commander, Air Force Space Command
2. Board Co-President—Mr. Shon J. Manasco, Assistant Secretary of the Air Force for Manpower and Reserve Affairs
3. Honorable Matthew P. Donovan, Under Secretary of the Air Force
4. General Stephen W. Wilson, Vice Chief of Staff of the Air Force
5. Lt. Gen. Anthony J. Cotton, Commander and President, Air University
6. Lt. Gen. Brian T. Kelly, Deputy Chief of Staff, Manpower, Personnel and Services
7. Mr. Timothy K. Bridges, Assistant Deputy Chief of Staff for Logistics, Engineering and Force Protection
8. Ms. Darlene Costello, Principal Deputy Assistant Secretary of the Air Force Acquisition, Technology & Logistics
9. Ms. Gwendolyn R. DeFilippi, Assistant Deputy Chief of Staff for Manpower, Personnel and Services
10. Mr. Joseph M. McDade, Principal Deputy General Counsel of the Air Force
11. Ms. Marilyn M. Thomas, Principal Deputy Assistant Secretary for Financial Management and Comptroller
12. Ms. Patricia M. Young, Air Force Material Command Executive Director
13. Ms. Patricia J. Zarodkiewicz, Administrative Assistant for the Secretary of the Air Force

Additionally, all career status Air Force Tier 3 SES members not included in the above list are eligible to serve on the 2018 Performance Review Board and are hereby nominated for inclusion on

an ad hoc basis in the event of absence(s).

**FOR FURTHER INFORMATION CONTACT:**

Please direct any written comments or requests for information to Mr. Lawrence Austin, Air Force Executive Talent Management Office, AF/CVXS, 1040 Air Force Pentagon, Washington, DC 20330–1040 (PH: 703–695–6411; or via email at [Lawrence.p.austin.civ@mail.mil](mailto:Lawrence.p.austin.civ@mail.mil)).

**Henry Williams,**

*Acting Air Force Federal Register Liaison Officer.*

[FR Doc. 2018–20798 Filed 9–24–18; 8:45 am]

**BILLING CODE 5001-10-P**

## DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0077]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; High School Longitudinal Study of 2009 (HSL:09) Panel Maintenance 2018 and 2021

**AGENCY:** Institute of Education Sciences (IES), 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 October 25, 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–0077. 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, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Kashka Kubzdela, 202–502–7411.

**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:** High School Longitudinal Study of 2009 (HSL:09) Panel Maintenance 2018 and 2021.

**OMB Control Number:** 1850-0852.

**Type of Review:** A revision of an existing information collection.

**Respondents/Affected Public:** Individuals or Households.

**Total Estimated Number of Annual Responses:** 9,326.

**Total Estimated Number of Annual Burden Hours:** 778.

**Abstract:** The High School Longitudinal Study of 2009 (HSL:09) is a nationally representative, longitudinal study of more than 20,000 9th graders in 944 schools in 2009 who are being followed through their secondary and postsecondary years. The study focuses on understanding students' trajectories from the beginning of high school into postsecondary education or the workforce and beyond. What students decide to pursue when, why, and how are crucial questions for HSL:09, especially, but not solely, in regards to science, technology, engineering, and math (STEM) courses, majors, and careers. HSL:09 measured math achievement gains in the first 3 years of high school and, like past studies, surveyed students, their parents, school administrators, school counselors, and

teachers. After the initial 2009 data collection, the main study students were re-surveyed in 2012 when most were high school 11th-graders, then again in 2013 when most had just graduated from high school, and lastly in 2016. The 2016 second follow-up data collection consisted of a survey, postsecondary transcript collection, financial aid records collection, and file matching to extant data sources. It focused on postsecondary attendance patterns, field of study selection processes with particular emphasis on STEM, the postsecondary academic and social experience, education financing, employment history including instances of unemployment and underemployment, job characteristics including income and benefits, job values, family formation, and civic engagement. The HSL:09 data elements are designed to support research that speaks to the underlying dynamics and education processes that influence student achievement, growth, and personal development over time. This request is to conduct the HSL:09 panel maintenance to keep sample members' contact information up-to-date for future follow-up activities.

Dated: September 20, 2018.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018-20781 Filed 9-24-18; 8:45 am]

**BILLING CODE 4000-01-P**

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## FEDERAL DEPOSIT INSURANCE CORPORATION

### FDIC Advisory Committee on Community Banking; Notice of Meeting

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice of open meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve, with a focus on rural areas.

**DATES:** Wednesday, October 10, 2018, from 9:00 a.m. to 3:00 p.m.

**ADDRESSES:** The meeting will be held in the FDIC Board Room on the sixth floor

of the FDIC Building located at 550 17th Street NW, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898-7043.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

**Type of Meeting:** The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562-6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This meeting of the Advisory Committee on Community Banking will be Webcast live via the internet <http://fdic.windrosemedia.com>. Questions or troubleshooting help can be found at the same link. For optimal viewing, a high-speed internet connection is recommended. Further, a video of the meeting will be available on-demand approximately two weeks after the event.

Federal Deposit Insurance Corporation.

Dated: September 20, 2018.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2018-20780 Filed 9-24-18; 8:45 am]

**BILLING CODE 6714-01-P**

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## FEDERAL ELECTION COMMISSION

[Notice 2018-13]

### Filing Dates for the New York Special Election in the 25th Congressional District

**AGENCY:** Federal Election Commission.

**ACTION:** Notice of filing dates for special election.

**SUMMARY:** New York has scheduled a special general election on November 6, 2018, to fill the U.S. House of Representatives seat in the 25th Congressional District of the late Representative Louise Slaughter.

Committees required to file reports in connection with the Special General Election on November 6, 2018, shall file a 12-day Pre-General Report, and a 30-day Post-General Report.

**FOR FURTHER INFORMATION CONTACT:** Ms. Elizabeth S. Kurland, Information Division, 1050 First Street NE, Washington, DC 20463; Telephone: (202) 694-1100; Toll Free (800) 424-9530.

**SUPPLEMENTARY INFORMATION:**

**Principal Campaign Committees**

All principal campaign committees of candidates who participate in the New York Special General Election shall file a 12-day Pre-General Report on October 25, 2018; and a Post-General Report on December 6, 2018. (See chart below for the closing date for each report).

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See chart below for the closing date for each report.)

**Unauthorized Committees (PACs and Party Committees)**

Political committees filing on a quarterly basis in 2018 are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the New York Special General Election by the close of books for the applicable report(s). (See chart below for the closing date for each report.)

Committees filing monthly that make contributions or expenditures in connection with the New York Special General Election will continue to file according to the monthly reporting schedule.

Additional disclosure information in connection with the New York Special General Election may be found on the FEC website at <https://www.fec.gov/help-candidates-and-committees/dates-and-deadlines/>.

**Disclosure of Lobbyist Bundling Activity**

Principal campaign committees, party committees and Leadership PACs that are otherwise required to file reports in connection with the special elections must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of \$18,200 during the special election reporting periods. (See chart below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b), 110.17(e)(2), (f).

**CALENDAR OF REPORTING DATES FOR NEW YORK SPECIAL GENERAL ELECTION**

Report	Close of books <sup>1</sup>	Reg./cert. and overnight mailing deadline	Filing deadline
<b>Committees Involved in the Special General (11/06/18) Must File</b>			
Pre-General .....	10/17/18	10/22/18	10/25/18
Post-General .....	11/26/18	12/06/18	12/06/18
Year-End .....	12/31/18	01/31/19	01/31/19

<sup>1</sup> The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.

On behalf of the Commission.  
 Dated: August 27, 2018.  
**Caroline C. Hunter,**  
*Chair, Federal Election Commission.*  
 [FR Doc. 2018-20779 Filed 9-24-18; 8:45 am]  
**BILLING CODE 6715-01-P**

**FEDERAL MARITIME COMMISSION**

[Petition No. P4-18]

**Notice of Filing and Request for Comments; Petition of Dole Ocean Cargo Express Inc. for an Exemption**

Notice is hereby given that Dole Ocean Cargo Express Inc. ("Petitioner") has petitioned the Commission pursuant to 46 CFR 502.94 ". . . for relief from provisions of 46 CFR 530.10 relating to the filing of individual service contract amendments." Petitioner states it is an ocean common carrier. "As part of an internal corporate restructuring, on or about November 1, 2018, the assets of [the Petitioner] will be transferred to a new limited liability company, Dole Ocean Cargo Express, LLC." Petitioner states that "among the assets being transferred are . . . service contracts

with its customers, which will be assigned to Dole Ocean Cargo Express, LLC." Petitioner states that the transfer ". . . in accordance with the terms of those contracts and the applicable contract law, would require the filing with the FMC of an amendment to each service contract." Petitioner alleges that "[i]t would be an undue burden on [Petitioner] to prepare and file an individual amendment for each of these service contracts."

In order for the Commission to make a thorough evaluation of the requested exemption and rulemaking presented in the Petition, pursuant to 46 CCFR 502.92, interested parties are requested to submit views or arguments in reply to the Petition no later than October 2, 2018. Replies shall be sent to the Secretary by email to [Secretary@fmc.gov](mailto:Secretary@fmc.gov) or by mail to Federal Maritime Commission, 800 North Capitol Street NW, Washington, DC 20573-0001, and replies shall be served on Petitioner's counsel, Wayne R. Rohde, Cozen O' Connor, 1200 19th St. NW, Suite 300, Washington, DC 20036, [wrohde@cozen.com](mailto:wrohde@cozen.com).

Non-confidential filings may be submitted in hard copy to the Secretary

at the above address or by email as a PDF attachment to [Secretary@fmc.gov](mailto:Secretary@fmc.gov) and include in the subject line: P4-18 (Commenter/Company). Confidential filings should not be filed by email. A confidential filing must be filed with the Secretary in hard copy only, and be accompanied by a transmittal letter that identifies the filing as "Confidential-Restricted" and describes the nature and extent of the confidential treatment requested. The Commission will provide confidential treatment to the extent allowed by law for confidential submissions, or parts of submissions, for which confidentiality has been requested. When a confidential filing is submitted, there must also be submitted a public version of the filing. Such public filing version shall exclude confidential materials, and shall indicate on the cover page and on each affected page "Confidential materials excluded." Public versions of confidential filings may be submitted by email. The Petition will be posted on the Commission's website at <http://www.fmc.gov/P4-18>. Replies filed in response to the Petition will also be posted on the Commission's website at this location.

Served September 17, 2018.

**Rachel E. Dickon,**  
Secretary.

[FR Doc. 2018–20523 Filed 9–24–18; 8:45 am]

BILLING CODE 6731-AA-P

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 10, 2018.

*A. Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *David Phelps, individually and as part of a group acting in concert with The George W. Phelps Bank Stock Trust, George Phelps, Trustee; The Linda K. Phelps Bank Stock Trust, Linda K. Phelps, Trustee; The Robert B Phelps Bank Stock Trust, Robert B Phelps, Trustee; The Carol Phelps Bank Stock Trust, Carol Phelps, Trustee; Alison Hoogveen; and Scott Phelps, all of Kingsley, Iowa; and Robert W. Phelps, Milwaukee, Wisconsin;* to join the Phelps Family Control Group as approved in 1985 and retain control of Kingsley Banc Corp and thereby indirectly control Kingsley State Bank, both in Kingsley, Iowa.

Board of Governors of the Federal Reserve System, September 20, 2018.

**Yao-Chin Chao,**

Assistant Secretary of the Board.

[FR Doc. 2018–20830 Filed 9–24–18; 8:45 am]

BILLING CODE 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 October 19, 2018.

*A. Federal Reserve Bank of Dallas* (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Cadence Bancorporation, Houston, Texas;* to acquire State Bank Financial Corporation, Atlanta, Georgia, and thereby indirectly acquire State Bank and Trust Company, Macon, Georgia.

*B. Federal Reserve Bank of Atlanta* (Kathryn Haney, Director of Applications) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to [Applications.Comments@atl.frb.org](mailto:Applications.Comments@atl.frb.org):

1. *PBD Holdings, LLC, Chattanooga, Tennessee;* to acquire 97.74 percent of the voting shares of First Columbia Bancorp, Inc., and thereby indirectly acquire voting shares of Columbia Bank, both in Lake City, Florida.

Board of Governors of the Federal Reserve System, September 19, 2018.

**Yao-Chin Chao,**

Assistant Secretary of the Board.

[FR Doc. 2018–20747 Filed 9–24–18; 8:45 am]

BILLING CODE P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day–18–18AXG; Docket No. is CDC–2018–0086]

### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “Maritime Illness Database and Reporting System (MIDRS)”. The purpose of this data collection is to provide U.S.-bound passenger vessel operators an electronic reporting system to assist with their legal requirement to notify CDC of the number of passengers and crew members onboard their ship who have reportable acute gastroenteritis (AGE) as defined by federal quarantine regulations.

**DATES:** CDC must receive written comments on or before November 26, 2018.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2018–0086 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [Regulations.gov](https://www.regulations.gov).

*Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.*

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger,



Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

**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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. 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;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

**Proposed Project**

Maritime Illness Database and Reporting System (MIDRS)—NEW—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The purpose of this new information collection request (ICR) is to request a three-year Paperwork Reduction Act (PRA) clearance for CDC's MIDRS surveillance system. MIDRS is currently approved under "Foreign Quarantine Regulations (42 CFR part 71)" (OMB Control No. 0920-0134, Expiration Date: 05/31/2019), sponsored by the National Center for Emerging and Zoonotic Infections Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Operationally, CDC has divided the responsibilities for enforcing foreign quarantine regulations between the Vessel Sanitation Program (VSP) and the Division of Global Migration and Quarantine (DGMQ). VSP takes the lead on overseeing acute gastroenteritis (AGE) illness surveillance and outbreak investigation activities on passenger ships, while DGMQ monitors all non-AGE illnesses and deaths on passenger vessels as well as all diseases of public health concern on all other conveyances with international itineraries bound for the U.S. From 2012 to 2014 all ships submitted their AGE, non-AGE, and death reports to MIDRS using a common web portal; however program and reporting needs changed and dictated a need to move non-AGE illness and death reporting to a separate system. As of June 10, 2014, DGMQ has changed its routing method for receiving reports from ships. It no longer accepts non-AGE illness and death reports via MIDRS.

To complete the separation of shipboard quarantine and inspection functions across the two CDC national centers, the VSP seeks to transition all federally mandated AGE illness

reporting activities to a new ICR housed within its own Center, since MIDRS is housed in and is used exclusively by VSP. DGMQ will continue to surveil non-AGE illnesses on cruise ships and all illnesses on other foreign to U.S. conveyances under Foreign Quarantine Regulations (OMB Control No. 0920-0134, expiration date 05/31/2019).

The MIDRS data collection system consists of a surveillance system that receives information electronically through a web-based reporting portal; data can also be submitted by phone, email or fax and entered into MIDRS by VSP. AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active AGE cases at any given port of call or at disembarkation. The AGE log, 72-hour food/activity history and other required documentation are completed and maintained on the ship.

Data collected will allow VSP to quickly detect AGE outbreaks, provide epidemiologic and sanitation guidance to stop the outbreak, craft public health recommendations to prevent future outbreaks, and monitor AGE illness trends to identify important changes over time.

There are two types of respondents for this data collection: cruise ship medical staff or other designated personnel who report AGE cases, and AGE cases who provide information for the 72-hour food/activity histories. Of note, VSP will not receive any information from or about the AGE cases; this information is collected and owned by the cruise line and maintained on the ship as part of the AGE case's medical record. VSP reviews these records during operational inspections to confirm they are available if needed, and if there is an AGE outbreak or report of unusual AGE illness for a particular voyage.

The total annualized time burden requested is 1,537 burden hours. A summary of the estimated annualized burden hours is shown in the table below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Cruise ship medical staff or other designated personnel.	71.21(c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS).	250	10	3/60	125
	71.21(c) Recordkeeping—Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS).	250	1	1/60	4
	71.21(c) AGE Logs .....	250	10	10/60	417
	71.21(c) Recordkeeping—medical records (AGE Logs) .....	250	1	1/60	4
	71.21(c) Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times.	250	3	5/60	62.5

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
AGE passenger and crew cases.	71.21(c) Recordkeeping—medical records (Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times).	250	1	1/60	4
	71.21(c) Documentation of 3-day pre-embarkation AGE illness assessment for all crew members.	250	5	3/60	62.5
	71.21(c) Recordkeeping—medical records (Documentation of 3-day pre-embarkation AGE illness assessment for all crew members).	250	1	1/60	4
	71.21(c) Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees.	250	1	3/60	12.5
	71.21(c) Recordkeeping—medical records (Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees).	250	1	1/60	4
	71.21(c) Recordkeeping—medical records (72 hour food/activity histories).	250	1	1/60	4
	71.21(c) 72-hour food/activity history .....	5,000	1	10/60	833
<b>Total</b> .....	.....	.....	.....	.....	1,537

**Jeffrey M. Zirger,**  
*Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2018–20808 Filed 9–24–18; 8:45 am]  
 BILLING CODE 4163–18–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-18–0666]

**Agency Forms Undergoing Paperwork Reduction Act Review; Withdraw**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period; withdrawal.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the withdrawal of the notice published under the same title on September 7, 2018 for public comment.

**DATES:** The Centers for Disease Control and Prevention is withdrawing the notice published September 7, 2018 (83 FR 45444) as of September 25, 2018.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

**SUPPLEMENTARY INFORMATION:** On September 7, 2018, CDC published a

notice in the **Federal Register** titled “National Healthcare Safety Network (NHSN)” (Vol. 83, No. 174 Docket No. CDC–2018–0042, Pages 45444–45447). This notice was published inadvertently. The notice is being withdrawn immediately for public comment.

**Jeffrey M. Zirger,**  
*Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2018–20809 Filed 9–24–18; 8:45 am]  
 BILLING CODE 4163–18–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Statement of Organization, Functions, and Delegations of Authority**

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 74 FR 52816, dated October 14, 2009) is amended to reflect the reorganization of the Centers for Disease Control and Prevention (CDC). This reorganization is being undertaken to increase scientific capacity; strengthen infrastructure; create efficiencies across the organization; and improve the links between the national centers.

I. Under Part C, Section C–B, Organization and Functions, the following organizational units are deleted in their entirety:

- Office of the Associate Director for Laboratory Science and Safety (CAC)
- Office of the Associate Director for Science (CAS)
- Office of the Associate Director for Minority Health and Health Equity (CAW)
- Office of State, Tribal, Local and Territorial Support (CP)
- Office of Public Health Preparedness and Response (CQ)

II. Under Part C, Section C–B, Organization and Functions, make the following changes:

- Retitle all references to the Office of the Associate Director for Policy (CAQ) to the Office of the Associate Director for Policy and Strategy (CAQ)
- Retitle all references to the Office of Public Health Scientific Services (CP) to the Deputy Director for Public Health Science and Surveillance (CP)
- Retitle all references to the Office of Noncommunicable Diseases, Injury and Environmental Health (CU) to the Deputy Director for Non-Infectious Diseases (CU)
- Retitle all references to the Office of Infectious Diseases (CV) to the Deputy Director for Infectious Diseases (CV)

III. Under Part C, Section C–B, Organization and Functions, insert the following:

- *Deputy Director for Public Health Service and Implementation Science (CB):* The Deputy Director for Public Health Service and Implementation Science leads, promotes, and facilitates science, programs and policies to identify and respond to public health

threats, both domestically and internationally to its components, which are as follows:

- Center for Global Health (CBB)
- Center for Preparedness and Response (CBC)
- Center for State, Tribal, Local and Territorial Support (CBD)
- Office of Minority Health and Health Equity (CBE)

- Deputy Director for Public Health Science and Surveillance (CP): The Deputy Director for Public Health Science and Surveillance leads, promotes, and facilitates science, surveillance, standards and policies to reduce the burden of diseases in the United States and globally to its components, which are as follows:

- National Center for Health Statistics (CPC)
- Center for Surveillance, Epidemiology, and Laboratory Services (CPN)
- Office of Science (CPP)
- Office of Laboratory Science and Safety (CPQ)

- *Deputy Director for Non-Infectious Diseases (CU)*: The Deputy Director for Non-Infectious Diseases reduces the burden of non-infectious diseases, injuries, birth defects, disabilities and environmental health hazards to its components, which are as follows:

- National Center on Birth Defects and Developmental Disabilities (CUB)
- National Center for Chronic Disease Prevention and Health Promotion (CUC)
- National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (CUG)
- National Center for Injury Prevention and Control (CUH)

- *Deputy Director for Infectious Diseases (CV)*: Deputy Director for Infectious Diseases leads, promotes, and facilitates science, programs, and policies to reduce the burden of infectious disease in the United States and globally and its components, which are as follows:

- National Center for Immunization and Respiratory Diseases (CVG)
- National Center for Emerging and Zoonotic Infectious Diseases (CVL)
- National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

IV. *Delegations of Authority*: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

**Authority:** 44 U.S.C. 3101.

Dated: August 17, 2018.

**Alex M. Azar II,**  
*Secretary.*

[FR Doc. 2018–20835 Filed 9–24–18; 8:45 am]

**BILLING CODE 4160–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day–18–0891]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on May 11, 2018, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and

instruments, call (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement (OMB Control No. 0920–0891, Expires 09/30/2018)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

NIOSH seeks to request OMB approval to revise the currently approved information collection activities that support the World Trade Center (WTC) Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113) created the WTC Health Program to provide medical monitoring and treatment benefits to eligible individuals affected by the terrorist attacks on September 11, 2001. Eligible individuals include firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

This request also seeks to incorporate information collection previously approved under the World Trade Center Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program (OMB No. 0920–0929, expiration date 7/31/2018), which has been discontinued. The revision of OMB No. 0920–0891 will provide a comprehensive summary of information collection needed to administer the World Trade Center Health Program.

Since its inception in 2011, the WTC Health Program has been approved to collect information from applicants and Program members (enrolled WTC responders and survivors) concerning eligibility and enrollment, appointment of a designated representative, medical care, travel reimbursement, and appeal

of adverse Program decisions. The WTC Health Program is also currently approved to collect information from Program medical providers, including health condition certification requests and pharmaceutical claims. The WTC Health Program has determined that some existing forms need to be updated, and new information collections related to a recent rulemaking should be added.

Changes to WTC Health Program regulations in 42 CFR part 88 will require the extension of existing information collections. Specifically, 42 CFR 88.13 establishes procedures for the appeal of Program decisions to disenroll Program members and deny enrollment to applicants. Appeals of enrollment denial decisions, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of disenrollment decisions. Of the over 70,000 Program members, we expect that 0.014 percent (10) will be subsequently disenrolled from the Program. Of those, we expect that 30 percent (3) will appeal the disenrollment decisions. We estimate that the disenrollment appeal requests will take no more than 0.5 hours per respondent. The annual burden estimate is 2 hours (rounded).

Section 42 CFR 88.21 establishes procedures for the appeal of WTC Health Program decisions to decertify a WTC-related health condition, deny certification, and deny treatment authorization. Appeals of health condition certification denials and treatment authorization denials, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of

decertification decisions. The information collection will also be expanded to allow Program members to provide additional information and/or an oral statement. Of the estimated 51,472 Program members who have at least one health condition certification, we estimate that 0.02 percent (10) will be decertified, and 50 percent (5) of those will appeal a decertification. We estimate that the appeal request letter will take no more than 0.5 hours per respondent. Providing additional information and/or an oral statement will take no more than one hour per respondent. The annual burden estimate for decertification appeals is 8 hours.

We further estimate that Program members request certification for 20,000 health conditions each year. Of those 20,000, we estimate that one percent (200) of certification requests are denied by the WTC Health Program. We also expect that 30 percent of denied certifications, or 60 individuals, will be appealed. We estimate that the appeals letter takes no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for certification denial appeals is 90 hours.

In addition, of the projected 51,472 Program members who receive medical care, we estimate that 0.05 percent (26) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for treatment authorization denial appeals is 39 hours.

Finally, 42 CFR 88.23 establishes procedures for the appeal of a WTC

Health Program decision to deny reimbursement to a Program medical provider for treatment determined not to be medically necessary. Accordingly, the Program proposes the addition of information collected in the appeal request. We estimate that of the nearly 52,000 Program providers, we estimate that 1.15 percent (600) annually will be denied reimbursement for treatment found to be not medically necessary or in accordance with treatment protocols, and will appeal the decision. We estimate that the appeal letter will take no more than 0.5 hours to compile. The burden estimate for treatment reimbursement denial appeals is 300 hours.

The revision request also includes the addition of a new form to allow applicants and Program members to grant permission to share information with a third person about an individual's application or case. We estimate that 30 applicants and members will submit a Health Insurance Portability and Accountability Act (HIPAA) Release Form annually. The form will take no longer than 0.25 hours to complete. The burden estimate for the HIPAA Release form is 8 hours.

The total estimated annualized burden hours are 14,063, an increase of 469 hours from the previously approved estimate of 13,594 hours. The revised estimate includes forms that have not been modified; changes due to the appeals processes authorized by 42 CFR 88.21 and 42 CFR 88.23; inclusion of the new HIPAA Release Form; incorporation of a form previously approved under OMB No. 0920-0929; and miscellaneous actions. The revision request provides a detailed summary of each change and its impact on the burden estimate.

BACKGROUND AND BRIEF DESCRIPTION

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
FDNY Responder .....	World Trade Center Health Program FDNY Responder Eligibility Application.	45	1	30/60
General Responder .....	World Trade Center Health Program Responder Eligibility Application (Other than FDNY).	2,475	1	30/60
Pentagon/Shanksville Responder .....	World Trade Center Health Program Pentagon/Shanksville Responder.	630	1	30/60
WTC Survivor .....	World Trade Center Health Program Survivor Eligibility Application (all languages).	1,350	1	30/60
General responder .....	Clinic Selection Postcard for new general responders in NY/NJ to select a clinic.	2,475	1	15/60
Program Medical Provider .....	Physician Request for Certification (WTC-3) .....	20,000	1	30/60
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Enrollment .....	45	1	30/60
Responder (FDNY and General Responder)/Survivor.	Disenrollment Letter and Appeal Notification—Enrollment.	3	1	30/60

BACKGROUND AND BRIEF DESCRIPTION—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Responder (FDNY and General Responder)/Survivor.	Decertification Letter and Appeal Notification—Health Condition.	5	1	1.5
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Health Condition Certification.	60	1	1.5
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Treatment Authorization.	26	1	1.5
Responder (FDNY and General Responder)/Survivor.	WTC Health Program Medical Travel Refund Request.	10	1	10/60
Program Members .....	Designated Representative Form .....	30	1	15/60
Program Member .....	HIPAA Release Form to allow the sharing of member information with a third party.	30	1	15/60
Pharmacy .....	Outpatient prescription pharmaceuticals .....	150	261	1/60
Program Medical Provider .....	Reimbursement Denial Letter and Appeal Notification—Providers.	600	1	30/60
Responder/Survivor/Advocate (physician).	Petition for the addition of health conditions .....	60	1	1

**Jeffrey M. Zirger,**

*Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2018–20807 Filed 9–24–18; 8:45 am]

**BILLING CODE 4163–18–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–N–3404]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Cover Sheet**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collection of information using Form FDA 3794, entitled “Generic Drug User Fee Cover Sheet.”

**DATES:** Submit either electronic or written comments on the collection of information by November 26, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 26, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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–N–3404 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Cover Sheet.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Generic Drug User Fee Coversheet**

*OMB Control Number 0910–0727—Extension*

On July 9, 2012, the President signed the Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title 111) into law. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to the industry. Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f, *et seq.*), as added by GDUFA, authorized FDA to assess and

collect the fees related to generic drugs, beginning fiscal year (FY) 2013 and expiring at the close of FY 2017, on September 30, 2017. GDUFA was reauthorized on August 18, 2017 (GDUFA II) and is effective beginning October 1, 2017, through September 30, 2022. GDUFA II enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

Form FDA 3794, the Generic Drug User Fee Cover Sheet available at <https://www.ipqpubs.com/wp-content/uploads/2012/09/GDUFA-cover-sheet.pdf>, requests the minimum necessary information from applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA’s web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct FY user fee assessment that is due for the submission/program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, and other GDUFA fees, so FDA can verify that the applicant has paid the correct user fee.

Respondents to this proposed collection of information would be potential or actual generic drug application holders or related Active Pharmaceutical Ingredient and Finished Dosage Form manufacturers. Companies with multiple user fee obligations will submit a cover sheet for each user fee obligation.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794 .....	500	7.616	3,808	0.5 (30 minutes) .....	1,904

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden for the information collection reflects an increase since last OMB approval. This adjustment corresponds with an

increase in submissions received by the Agency.

Dated: September 19, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2018–20765 Filed 9–24–18; 8:45 am]  
**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0725]

#### Abbreviated New Drug Application Submissions—Content and Format; 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 final guidance for industry entitled “ANDA Submissions—Content and Format.” This guidance is intended to assist applicants in preparing abbreviated new drug applications (ANDAs) for submission to FDA under the Federal Food, Drug and Cosmetic Act (the FD&C Act).

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 25, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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-2014-D-0725 for “ANDA Submissions—Content and Format.” 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-7930.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “ANDA Submissions—Content and Format of Abbreviated New Drug Applications.” This guidance is intended to assist applicants in preparing ANDAs for submission to FDA under section 505(j) of the FD&C Act (21 U.S.C. 355(j)). This guidance details the information that should be provided in each section of the common technical document format for human pharmaceutical product applications and identifies supporting guidance documents and recommendations issued by FDA to assist applicants in preparing their ANDA submission.

This guidance identifies the information an applicant should include to ensure that a complete, high-quality application is submitted to FDA. FDA has previously published guidance documents on the filing process, including the guidances for industry about refuse-to-accept standards and common, recurring deficiencies, which should be reviewed thoroughly prior to submission of an ANDA.

In the **Federal Register** of June 12, 2014 (79 FR 33758), FDA issued the draft guidance for industry “ANDA Submissions—Content and Format of Abbreviated New Drug Applications.” FDA carefully considered the comments received on the draft guidance, and, where possible, has incorporated into the final guidance additional detailed discussion of our current thinking on the content and format of ANDAs submitted to FDA for review.

This guidance is being issued consistent with FDA’s good guidance

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the content and format of ANDA submissions. 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 found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314 (including subpart C) related to the content and format of ANDAs submitted by applicants and approved by FDA is approved under OMB control number 0910–0001. Applicant submission of controlled correspondence related to generic drug development and FDA approval is approved under OMB control number 0910–0797.

The collection of information for Form FDA 356h (NDA and ANDA cover sheet) has been approved under OMB control number 0910–0338. The collection of information for Form FDA 3674 (application certification) has been approved under OMB control number 0910–0616. The collection of information for Form FDA 3794 (GDUFA cover sheet) has been approved under OMB control number 0910–0727. The collection of information for Form FDA 3454 and Form FDA 3455 (clinical investigator financial interest) has been approved under control number 0910–0396.

The submission of petitions under 21 CFR part 10 (Administrative Practices and Procedures) has been approved under OMB control number 0910–0191. The collection information in 21 CFR part 11 (electronic records) has been approved under OMB control number 0910–0303. Information about the manufacture of the drug product under 21 CFR part 211 has been approved under OMB control number 0910–0139.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–20790 Filed 9–24–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–3344]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with adverse event reporting and recordkeeping for dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA).

**DATES:** Submit either electronic or written comments on the collection of information by November 26, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 26, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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:

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- 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–N–3344 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44

U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act**

*OMB Control Number 0910-0635—Extension*

The DSNDCPA (Pub. L. 109-462) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to serious adverse event reporting and recordkeeping for dietary supplements and non-prescription drugs marketed without an approved application. Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa-1) requires the manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States to submit to us all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (Form FDA 3500A) when submitting a serious adverse event

report to FDA. In addition, section 761(c)(2) of the FD&C Act requires the submitter of the serious adverse event report (referred to in the statute as the "responsible person") to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

Section 761(e)(1) of the FD&C Act requires that responsible persons maintain records related to the dietary supplement adverse event reports they receive, whether or not the adverse event is serious, for a period of 6 years.

As required by the DSNDCPA, we issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. The guidance entitled "Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act" is available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm>. It discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides our recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents.

The guidance recommends that the responsible person document their attempts to obtain the minimum data elements for a serious adverse event report. Along with these records, the guidance recommends that the responsible person keep the following other records: (1) Communications between the responsible person and the initial reporter of the adverse event and between the responsible person and any other person(s) who provided information about the adverse event; (2) the responsible person's serious adverse event report to us with attachments; (3) any new information about the adverse event received by the responsible person; and (4) any reports to us of new information related to the serious adverse event report.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 U.S.C. 379aa-1(b)(1)—serious adverse event reports for dietary supplements .....	230	12	2,760	2	5,520
21 U.S.C. 379aa-1(c)(2)—followup reports of new medical information .....	58	12	696	1	696
Total .....					6,216

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an annual decrease of 219 hours for reporting. We attribute this adjustment to a decrease in the number of reports we received over the last few years.

This estimate is based on our experience with similar adverse event reporting programs and the number of serious adverse event reports and followup reports received in the past 3 years. All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event mandatory reporting.

In the past 3 years, we received an average of 2,760 initial serious adverse event reports. We also estimated an average number of firms filing reports to

be 230. Finally, we estimate that it will take respondents an average of 2 hours per report to collect information about a serious adverse event associated with a dietary supplement and report the information to us on Form FDA 3500A. Thus, the estimated burden associated with submitting initial dietary supplement serious adverse event reports is 5,520 hours (2,760 responses × 2 hours) as shown in row 1 of table 1.

If a respondent that has submitted a serious adverse event report receives new information related to the serious adverse event within 1 year of submitting the initial report, the respondent must provide the new information to us in a followup report.

We estimate that around 25 percent of serious adverse event reports related to dietary supplements will have a followup report submitted, resulting in approximately 696 followup reports submitted annually. Dividing the annual number of reports among the 230 firms reporting results in approximately 12 reports for 58 respondents. We estimate that each followup report will require an hour to assemble and submit, including the time needed to copy and attach the initial serious adverse event report as recommended in the guidance. Thus, the estimated burden for followup reports of new information is 696 hours (696 responses × 1 hour) as shown in row 2 of table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 U.S.C. section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
21 U.S.C. 379aa-1(e)(1)—dietary supplement adverse events records.	1,815	72	130,680	0.5 (30 minutes) .....	65,340

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an annual increase of 2,440 hours for recordkeeping. We attribute this adjustment to an increase in the number of reports we received over the last few years.

All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event recordkeeping. We estimate that there are 1,815 such respondents. Estimating that each recordkeeper will keep approximately 72 records per year results in an annual burden of 130,680 records. Estimating that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hour, per record, results in an annual burden of 65,340 hours (130,680 records × 0.5 hour).

Once the documents pertaining to an adverse event report have been

assembled and filed in accordance with the safety reporting portal, we expect the records retention burden to be minimal, as we believe most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice.

Dated: September 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-20766 Filed 9-24-18; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-3103]

**Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications; Draft Guidance for Industry and Review Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and review staff entitled “Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications.” This draft guidance describes the fundamental values and

operational principles that serve as the foundation for the review process. It also clarifies the roles and responsibilities of review staff and identifies ways in which applicants may support a robust and efficient review process. This draft guidance revises the guidance for review staff and industry entitled “Good Review Management Principles and Practices for PDUFA Products” issued April 2005.

**DATES:** Submit either electronic or written comments on the draft guidance by December 24, 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-3103 for “Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications.” 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, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Pinakini Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6367, Silver Spring, MD 20993-0002, 301-796-7475; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry and review staff entitled “Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications.” This draft guidance describes good review management principles and practices (GRMPs) for the review of a new drug application (NDA), biologics license application (BLA), or an efficacy supplement/supplement with clinical data. This guidance applies to *human drug applications* (as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g(1))) and *biosimilar biological product applications* (section 744G(4) of the FD&C Act (21 U.S.C. 379j-51(4))). This guidance also discusses the roles and responsibilities of review staff in managing the review process and identifies ways in which applicants may support an efficient and robust review process.

This draft guidance revises the guidance for review staff and industry entitled “Good Review Management Principles and Practices for PDUFA Products” issued in April 2005. FDA committed to updating the 2005 guidance as part of the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Act (BsUFA) II. This draft guidance meets that commitment by reflecting advances in the PDUFA program and implementation of BsUFA. This draft guidance also reflects the evolution of GRMPs to support new regulatory programs such as breakthrough therapy, the Program for Enhanced Review

Transparency and Communication for NME (New Molecular Entity) NDAs and Original BLAs, and risk evaluation and mitigation strategies.

In addition, the draft guidance has been consolidated to focus on the fundamental values and operational principles that serve as the foundation for the GRMPs. Details of the review process are covered in other documents referenced by this guidance. Fundamental values and operational principles should remain relatively constant over time, while processes must be able to adapt and respond to scientific advances in product development and evolving public health needs.

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 GRMPs for NDAs and BLAs. 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. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: September 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-20789 Filed 9-24-18; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0007]

### Fee for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2019

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rates for using a tropical disease priority review voucher for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C

Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for review of drug or biological products when those applications use a tropical disease priority review voucher. These vouchers are awarded to the applicants of certain tropical disease product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee submitted to FDA with applications using a tropical disease priority review voucher is determined each fiscal year based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous fiscal year and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the tropical disease priority review fee rate for FY 2019.

#### FOR FURTHER INFORMATION CONTACT:

Lola Olajide, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14541B, Silver Spring, MD 20993-0002, 240-402-4244.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 1102 of FDAAA (Pub. L. 110-85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the applicant of an eligible human drug application submitted after September 27, 2007, for a tropical disease (as defined in section 524(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the tropical disease product application (assuming other criteria are met). The recipient of a tropical disease priority review voucher may either use the voucher with a future submission to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262), or transfer (including by sale) the voucher to another party. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of

6 months after the receipt or filing date, depending upon the type of application. Information regarding the PDUFA goals is available at: <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf>.

The applicant that uses a priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published guidance on its website about how this tropical disease priority review voucher program operates (available at: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf>).

This notice establishes the tropical disease priority review fee rate for FY 2019 as \$2,457,140 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2018, and will remain in effect through September 30, 2019, for applications submitted with a tropical disease priority review voucher. The payment of this priority review user fee is required in addition to the payment of any other fee that would normally apply to such an application under PDUFA before FDA will consider the application complete and acceptable for filing.

##### II. Tropical Disease Priority Review User Fee for FY 2019

FDA interprets section 524(c)(2) of the FD&C Act as requiring that FDA determine the amount of the tropical disease priority review user fee each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted priority review status within this expedited timeframe. Normally, an application for a human drug or biological product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. An application that does not receive a priority designation receives a standard review. Under the

PDUFA goals letter, FDA committed to reviewing and acting on 90 percent of standard applications within 10 months of the receipt or filing date, depending on the type of application. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

FDA is setting fees for FY 2019, and the previous fiscal year is FY 2018. However, the FY 2018 submission cohort has not been closed out yet, and the cost data for FY 2018 are not complete. The latest year for which FDA has complete cost data is FY 2017. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. FDA uses data that the Agency estimates and publishes on its website each year—standard costs for review. FDA does not publish a standard cost for “the review of a human drug application subject to priority review in the previous fiscal year.” However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA does publish each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The worksheets for standard costs for FY 2017 show a standard cost of \$5,340,560 for an NME NDA and \$4,596,936 for a BLA. Based on these standard costs, the total cost to review the 57 applications in these two categories in FY 2017 (31 NME NDAs with clinical data and 26 BLAs) was \$285,077,688. (Note: These numbers exclude the President’s Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Of these applications 33 (20 NDAs and 13 BLAs) received priority review, which would mean that the remaining 24 received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject, which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2017 figures, the costs of a priority and standard review are estimated using the following formula:  

$$(33 \alpha \times 1.67) + (24 \alpha) = \$285,077,688$$
 where “ $\alpha$ ” is the cost of a standard review and “ $\alpha$  times 1.67” is the cost of a priority review. Using this formula, the cost of a standard review for NME

NDAs and BLAs is calculated to be \$3,603,561 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$6,017,946 (rounded to the nearest dollar). The difference between these two cost estimates, or \$2,414,386, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2019 fee, FDA will need to adjust the FY 2017 incremental cost by the average amount by which FDA’s average costs increased in the 3 years prior to FY 2018, to adjust the FY 2017 amount for cost increases in FY 2018. That adjustment, published in the **Federal Register** on August 1, 2018 (83 FR 37504), setting FY 2019 PDUFA fees, is 1.7708 percent for the most recent year, not compounded. Increasing the FY 2017 incremental priority review cost of \$2,414,386 by 1.7708 percent (or 0.017708) results in an estimated cost of \$2,457,140 (rounded to the nearest dollar). This is the tropical disease priority review user fee amount for FY 2019 that must be submitted with a priority review voucher for a human drug application in FY 2019, in addition to any PDUFA fee that is required for such an application.

**III. Fee Schedule for FY 2019**

The fee rate for FY 2019 is set out in table 1:

TABLE 1—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2019

Fee category	Fee rate for FY 2019
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee .....	\$2,457,140

**IV. Implementation of Tropical Disease Priority Review User Fee**

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of a human drug application for which the priority review voucher is used. Section 524(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under section 524 of the FD&C Act (see section 524(c)(4)(C)), and FDA may not collect priority review voucher fees “except to the extent provided in advance in appropriation Acts.” (Section 524(c)(5)(B) of the FD&C Act.)

The tropical disease priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2018, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment should be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select “Pay Now” to be

redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments should be made using U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after the user fee identification (ID) number is generated.

If paying with a paper check, the user fee ID number should be included on the check, followed by the words “Tropical Disease Priority Review.” All paper checks should be in U.S. currency from a U.S. bank made payable and

mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only.) If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. (This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA's tax identification number is 53–0196965.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. The account information is as follows: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33.

## V. Reference

The following reference is on display with the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at <https://www.regulations.gov> as this reference is copyright protected. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

- Ridley, D.B., H.G. Grabowski, and J.L. Moe, "Developing Drugs for Developing Countries," *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006, available at: [https://faculty.fuqua.duke.edu/~willm/HSM\\_RA/Documents/HA2006\\_Ridley\\_Vouchers.pdf](https://faculty.fuqua.duke.edu/~willm/HSM_RA/Documents/HA2006_Ridley_Vouchers.pdf).

Dated: September 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–20772 Filed 9–24–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–D–0900]

#### Benefit-Risk Factors To Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) With Different Technological Characteristics; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the final guidance entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics." This guidance document describes factors FDA considers when evaluating the benefit-risk profile of a device in comparison to a predicate device in a 510(k) when the device has the same intended use as the predicate device, and different technological characteristics that do not raise different questions of safety and effectiveness. This guidance can be helpful in situations when there is an increase in risk and increase or equivalent benefit, or a decrease in benefit and a decrease or equivalent risk when comparing a new device to a predicate device. FDA developed this guidance to improve the predictability, consistency, and transparency of the 510(k) premarket review process.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 25, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2014–D–0900 for "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics." 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Ifeanyi Uwemedimo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1609, Silver Spring, MD 20993–0002, 240–402–5243.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Submitters seeking 510(k) submission must demonstrate to FDA that the new device is substantially equivalent (SE) to a legally marketed predicate device

using the criteria identified in section 513(i) of the FD&C Act (21 U.S.C. 360c(i)). To find a new device SE to a predicate device, FDA must first find that the devices have the same intended use. FDA must then determine that the devices have the same technological characteristics, or that any differences in technological characteristics do not raise different questions of safety and effectiveness, and that the new device is as safe and effective as the predicate device.

FDA evaluates differences in technological characteristics between the new device and the predicate device to determine their effect on substantial equivalence (*i.e.*, whether the new device is as safe and effective as the predicate device). Under section 513(a)(2) of the FD&C Act, FDA determines the safety and effectiveness of a device by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use, among other relevant factors.

This guidance document is consistent with FDA guidance entitled “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443>), issued on July 28, 2014, and provides additional clarification on factors that FDA takes into consideration when evaluating the benefit-risk profile of a new device in comparison to a predicate device when FDA must evaluate whether the new device is substantially equivalent to the predicate device. More specifically, in situations where (1) an increase in risk and increase or equivalent benefit or (2) a decrease in benefit and a decrease or equivalent risk when comparing a new device to a predicate device, FDA recommends that a benefit-risk assessment be conducted to provide further perspective regarding whether the new device is substantially equivalent to the predicate. FDA does not recommend a benefit-risk assessment in situations where there is (1) an increase in risk and decrease in benefit or (2) decrease or equivalent risk and increase or equivalent benefit because benefit-risk factors are not warranted to determine whether a device is substantially equivalent. This guidance does not add new regulatory requirements for submitters, it does not change the 510(k) premarket review standard, nor does it create extra or new burdens on what has traditionally been submitted in 510(k)s.

In the **Federal Register** on July 15, 2014 (79 FR 41289), FDA announced the availability of the draft guidance and interested parties were invited to comment by October 14, 2014. FDA has considered all the public comments received prior to finalizing this guidance.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on benefit-risk factors to consider when determining substantial equivalence in premarket notifications (510(k)) with different technological characteristics. 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.

##### **III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.fda.gov/Biologics/BloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of “Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1818 to identify the guidance you are requesting.

##### **IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E ..... "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff".	Premarket notification ..... Q-submissions .....	0910-0120 0910-0756
803 .....	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910-0437

Dated: September 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-20771 Filed 9-24-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0559]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to this notice. This notice solicits comments on the collection of information contained in the Public Health Service (PHS) guideline entitled "PHS Guideline on Infectious Disease Issues in Xenotransplantation" dated January 19, 2001.

**DATES:** Submit either electronic or written comments on the collection of information by November 26, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 26, 2018. Comments received by mail/hand delivery/courier (for written/paper

submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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-2012-N-0559 for "PHS Guideline on Infectious Disease Issues in Xenotransplantation." Received

comments, those filed in a timely manner (see **ADDRESSES**), 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.



**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### **PHS Guideline on Infectious Disease Issues in Xenotransplantation**

*OMB Control Number 0910–0456—Extension*

The statutory authority to collect this information is provided under sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264) and the provisions of the Federal Food, Drug, and Cosmetic Act that apply to drugs (21 U.S.C. 321 *et seq.*). The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and to the general public. The PHS guideline is intended to address public

health issues raised by xenotransplantation, through identification of general principles of prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to the public health. The collection of information described in this guideline is intended to provide general guidance on the following topics: (1) The development of xenotransplantation clinical protocols; (2) the preparation of submissions to FDA; and (3) the conduct of xenotransplantation clinical trials. Also, the collection of information will help ensure that the sponsor maintains important information in a cross-referenced system that links the relevant records of the xenotransplantation product recipient, xenotransplantation product, source animal(s), animal procurement center, and significant nosocomial exposures. The PHS guideline describes an occupational health service program for the protection of health care workers involved in xenotransplantation procedures, caring for xenotransplantation product recipients, and performing associated laboratory testing. The PHS guideline is intended to protect the public health and to help ensure the safety of using xenotransplantation products in humans by preventing the introduction, transmission, and spread of infectious diseases associated with xenotransplantation.

The PHS guideline also recommends that certain specimens and records be maintained for 50 years beyond the date of the xenotransplantation. These include: (1) Records linking each xenotransplantation product recipient with relevant health records of the source animal, herd or colony, and the specific organ, tissue, or cell type included in or used in the manufacture of the product (3.2.7.1); (2) aliquots of serum samples from randomly selected animal and specific disease investigations (3.4.3.1); (3) source animal biological specimens designated for PHS use (3.7.1); animal health records (3.7.2), including necropsy results (3.6.4); and (4) recipients’ biological specimens (4.1.2). The retention period is intended to assist health care practitioners and officials in surveillance and in tracking the source of an infection, disease, or illness that might emerge in the recipient, the source animal, or the animal herd or colony after a xenotransplantation.

The recommendation for maintaining records for 50 years is based on clinical experience with several human viruses that have presented problems in human

to human transplantation and are therefore thought to share certain characteristics with viruses that may pose potential risks in xenotransplantation. These characteristics include long latency periods and the ability to establish persistent infections. Several also share the possibility of transmission among individuals through intimate contact with human body fluids. Human immunodeficiency virus (HIV) and Human T-lymphotropic virus are human retroviruses. Retroviruses contain ribonucleic acid that is reverse-transcribed into deoxyribonucleic acid (DNA) using an enzyme provided by the virus and the human cell machinery. That viral DNA can then be integrated into the human cellular DNA. Both viruses establish persistent infections and have long latency periods before the onset of disease, 10 years and 40 to 60 years, respectively. The human hepatitis viruses are not retroviruses, but several share with HIV the characteristic that they can be transmitted through body fluids, can establish persistent infections, and have long latency periods, *e.g.*, approximately 30 years for Hepatitis C.

In addition, the PHS guideline recommends that a record system be developed that allows easy, accurate, and rapid linkage of information among the specimen archive, the recipient’s medical records, and the records of the source animal for 50 years. The development of such a record system is a one-time burden. Such a system is intended to cross-reference and locate relevant records of recipients, products, source animals, animal procurement centers, and significant nosocomial exposures.

Respondents to this collection of information are the sponsors of clinical studies of investigational xenotransplantation products under investigational new drug applications (INDs) and xenotransplantation product procurement centers, referred to as source animal facilities. There are an estimated three respondents who are sponsors of INDs that include protocols for xenotransplantation in humans and five clinical centers doing xenotransplantation procedures. Other respondents for this collection of information are an estimated four source animal facilities which provide source xenotransplantation product material to sponsors for use in human xenotransplantation procedures. These four source animal facilities keep medical records of the herds/colonies as well as the medical records of the individual source animal(s). The burden estimates are based on FDA’s records of

xenotransplantation-related INDs and estimates of time required to complete the various reporting, recordkeeping,

and third-party disclosure tasks described in the PHS guideline. FDA is requesting an extension of OMB approval for the following

reporting, recordkeeping, and third-party disclosure recommendations in the PHS guideline:

TABLE 1—REPORTING RECOMMENDATIONS

PHS guideline section	Description
3.2.7.2 .....	Notify sponsor or FDA of new archive site when the source animal facility or sponsor ceases operations.

TABLE 2—RECORDKEEPING RECOMMENDATIONS

PHS guideline section	Description
3.2.7 .....	Establish records linking each xenotransplantation product recipient with relevant records.
4.3 .....	Sponsor to maintain cross-referenced system that links all relevant records (recipient, product, source animal, animal procurement center, and nosocomial exposures).
3.4.2 .....	Document results of monitoring program used to detect introduction of infectious agents which may not be apparent clinically.
3.4.3.2 .....	Document full necropsy investigations including evaluation for infectious etiologies.
3.5.1 .....	Justify shortening a source animal's quarantine period of 3 weeks prior to xenotransplantation product procurement.
3.5.2 .....	Document absence of infectious agent in xenotransplantation product if its presence elsewhere in source animal does not preclude using it.
3.5.4 .....	Add summary of individual source animal record to permanent medical record of the xenotransplantation product recipient.
3.6.4 .....	Document complete necropsy results on source animals (50-year record retention).
3.7 .....	Link xenotransplantation product recipients to individual source animal records and archived biologic specimens.
4.2.3.2 .....	Record baseline sera of xenotransplantation health care workers and specific nosocomial exposure.
4.2.3.3 and 4.3.2	Keep a log of health care workers' significant nosocomial exposure(s).
4.3.1 .....	Document each xenotransplant procedure.
5.2 .....	Document location and nature of archived specimens in health care records of xenotransplantation product recipient and source animal.

TABLE 3—DISCLOSURE RECOMMENDATIONS

PHS guideline section	Description
3.2.7.2 .....	Notify sponsor or FDA of new archive site when the source animal facility or sponsor ceases operations.
3.4 .....	Standard operating procedures (SOPs) of source animal facility should be available to review bodies.
3.5.1 .....	Include increased infectious risk in informed consent if source animal quarantine period of 3 weeks is shortened.
3.5.4 .....	Sponsor to make linked records described in section 3.2.7 available for review.
3.5.5 .....	Source animal facility to notify clinical center when infectious agent is identified in source animal or herd after xenotransplantation product procurement.

FDA estimates the burden for this collection of information as follows:

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

PHS guideline section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3.2.7.2 <sup>2</sup> .....	1	1	1	0.50 (30 minutes)	0.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> FDA is using 1 animal facility or sponsor for estimation purposes.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

PHS guideline section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
3.2.7 <sup>2</sup> .....	1	1	1	16	16
4.3 <sup>3</sup> .....	3	1	3	0.75 (45 minutes)	2.25
3.4.2 <sup>4</sup> .....	3	10.67	32	0.25 (15 minutes)	8

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

PHS guideline section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
3.4.3.2 <sup>5</sup>	3	2.67	8	0.25 (15 minutes)	2
3.5.1 <sup>6</sup>	3	0.33	1	0.50 (30 minutes)	0.5
3.5.2 <sup>6</sup>	3	0.33	1	0.25 (15 minutes)	0.25
3.5.4	3	1	3	0.17 (10 minutes)	0.51
3.6.4 <sup>7</sup>	3	2.67	8	0.25 (15 minutes)	2
3.7 <sup>7</sup>	4	2	8	0.08 (5 minutes)	0.64
4.2.3.2 <sup>8</sup>	5	25	125	0.17 (10 minutes)	21.25
4.2.3.2 <sup>6</sup>	5	0.20	1	0.17 (10 minutes)	0.17
4.2.3.3 and 4.3.2 <sup>6</sup>	5	0.20	1	0.17 (10 minutes)	0.17
4.3.1	3	1	3	0.25 (15 minutes)	0.75
5.2 <sup>9</sup>	3	4	12	0.08 (5 minutes)	0.96
Total					55.45

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> A one-time burden for new respondents to set up a recordkeeping system linking all relevant records. FDA is using 1 new sponsor for estimation purposes.

<sup>3</sup> FDA estimates there is minimal recordkeeping burden associated with maintaining the record system.

<sup>4</sup> Monitoring for sentinel animals (subset representative of herd) plus all source animals. There are approximately 6 sentinel animals per herd × 1 herd per facility × 4 facilities = 24 sentinel animals. There are approximately 8 source animals per year (see footnote 7 of this table); 24 + 8 = 32 monitoring records to document.

<sup>5</sup> Necropsy for animal deaths of unknown cause estimated to be approximately 2 per herd per year × 1 herd per facility × 4 facilities = 8.

<sup>6</sup> Has not occurred in the past 3 years and is expected to continue to be a rare occurrence.

<sup>7</sup> On average 2 source animals are used for preparing xenotransplantation product material for one recipient. The average number of source animals is 2 source animals per recipient × 4 recipients annually = 8 source animals per year. (See footnote 5 of table 6 of this document.)

<sup>8</sup> FDA estimates there are 5 clinical centers doing xenotransplantation procedures × approximately 25 health care workers involved per center = 125 health care workers.

<sup>9</sup> Eight source animal records + 4 recipient records = 12 total records.

TABLE 6—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

PHS guideline section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
3.2.7.2 <sup>2</sup>	1	1	1	0.50 (30 minutes)	0.5
3.4 <sup>3</sup>	4	0.25	1	0.08 (5 minutes)	0.08
3.5.1 <sup>4</sup>	4	0.25	1	0.25 (15 minutes)	0.25
3.5.4 <sup>5</sup>	4	1	4	0.50 (30 minutes)	2
3.5.5 <sup>4</sup>	4	0.25	1	0.25 (15 minutes)	0.25
Total					3.08

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> FDA is using 1 animal facility or sponsor for estimation purposes.

<sup>3</sup> FDA's records indicate that an average of 1 INDs are expected to be submitted per year.

<sup>4</sup> To our knowledge, has not occurred in the past 3 years and is expected to continue to be a rare occurrence.

<sup>5</sup> Based on an estimate of 12 patients treated over a 3 year period, the average number of xenotransplantation product recipients per year is estimated to be 4.

Because of the potential risk for cross-species transmission of pathogenic persistent virus, the guideline recommends that health records be

retained for 50 years. Since these records are medical records, the retention of such records for up to 50 years is not information subject to the

PRA (5 CFR 1320.3(h)(5)). Also, because of the limited number of clinical studies with small patient populations, the

number of records is expected to be insignificant at this time.

Information collections in this guideline not included in tables 1 through 6 can be found under existing regulations and approved under the OMB control numbers as follows: (1) “Current Good Manufacturing Practice for Finished Pharmaceuticals,” 21 CFR 211.1 through 211.208, approved under OMB control number 0910–0139; (2) “Investigational New Drug Application,” 21 CFR 312.1 through 312.160, approved under OMB control

number 0910–0014; and (3) information included in a biologics license application, 21 CFR 601.2, approved under OMB control number 0910–0338. (Although it is possible that a xenotransplantation product may not be regulated as a biological product (e.g., it may be regulated as a medical device), FDA believes, based on its knowledge and experience with xenotransplantation, that any xenotransplantation product subject to FDA regulation within the next 3 years will most likely be regulated as a

biological product.). However, FDA recognized that some of the information collections go beyond approved collections; assessments for these burdens are included in tables 1 through 6.

In table 7, FDA identifies those collection of information activities that are already encompassed by existing regulations or are consistent with voluntary standards which reflect industry’s usual and customary business practice.

TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS

PHS guideline section	Description of collection of information activity	21 CFR section (unless otherwise stated)
2.2.1 .....	Document off-site collaborations .....	312.52.
2.5 .....	Sponsor ensures counseling patient + family + contacts .....	312.62(c).
3.1.1 and 3.1.6 ..	Document well-characterized health history and lineage of source animals .....	312.23(a)(7)(a) and 211.84.
3.1.8 .....	Registration with and import permit from the Centers for Disease Control and Prevention.	42 CFR 71.53.
3.2.2 .....	Document collaboration with accredited microbiology labs .....	312.52.
3.2.3 .....	Procedures to ensure the humane care of animals .....	9 CFR parts 1, 2, and 3 and PHS Policy <sup>1</sup> .
3.2.4 .....	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council’s (NRC) Guide.	AAALAC International Rules of Accreditation <sup>2</sup> and NRC Guide <sup>3</sup> .
3.2.5, 3.4, and 3.4.1.	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122.
3.2.6 .....	Animal facility SOPs .....	PHS Policy <sup>1</sup> .
3.3.3 .....	Validate assay methods .....	211.160(a).
3.6.1 .....	Procurement and processing of xenografts using documented aseptic conditions	211.100 and 211.122.
3.6.2 .....	Develop, implement, and enforce SOP’s for procurement and screening processes.	211.84(d) and 211.122(c).
3.6.4 .....	Communicate to FDA animal necropsy findings pertinent to health of recipient .....	312.32(c).
3.7.1 .....	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6).
4.1.1 .....	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 yrs.); investigator case histories (2 yrs. after investigation is discontinued).	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c).
4.1.2 .....	Sponsor to justify amount and type of reserve samples .....	211.122.
4.1.2.2 .....	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a).
4.1.2.3 .....	Notify FDA of a clinical episode potentially representing a xenogeneic infection .....	312.32.
4.2.2.1 .....	Document collaborations (transfer of obligation) .....	312.52.
4.2.3.1 .....	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly).	312.50.
4.3 .....	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b).

<sup>1</sup> The “Public Health Service Policy on Humane Care and Use of Laboratory Animals” (<https://www.grants.nih.gov/grants/olaw/references/phspol.htm>).

<sup>2</sup> AAALAC International Rules of Accreditation (<https://www.aaalac.org/accreditation/rules.cfm>).

<sup>3</sup> The NRC’s “Guide for the Care and Use of Laboratory Animals.”

Based on a review of the information collection since our last request for

OMB approval, we have made no adjustments to our burden estimate.

Dated: September 19, 2018.

**Leslie Kux,**  
Associate Commissioner for Policy.

[FR Doc. 2018–20764 Filed 9–24–18; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-3197]

**Further Testing of Donations That Are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; 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 document entitled “Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry.” The draft guidance document provides blood establishments that collect Whole Blood and blood components, including Source Plasma, with recommendations for further testing of donations that are reactive on a licensed donor screening test for antibodies to hepatitis C virus (anti-HCV). The draft guidance also provides guidance to blood establishments on how to report the implementation of these recommendations. The draft guidance, when finalized, will update the recommendations related to the use of an appropriate multiantigen supplemental test contained in “Guidance for Industry: ‘Lookback’ for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV” dated December 2010.

**DATES:** Submit either electronic or written comments on the draft guidance by December 24, 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-3197 for “Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the 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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled “Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry.” The draft guidance provides blood establishments that collect Whole Blood and blood components, including Source Plasma, with recommendations for further testing of donations that are reactive on a licensed donor screening test for anti-

HCV, as required under § 610.40(e) (21 CFR 610.40(e)). The draft guidance also provides guidance to blood establishments on how to report the implementation of these recommendations.

In accordance with § 610.40(e), each donation, including autologous donations, found to be reactive by a donor screening test must be further tested using a licensed, approved, or cleared supplemental test, when available. If no such supplemental test is available, blood establishments must perform one or more licensed, approved, or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status (§ 610.40(e)). The draft guidance provides recommendations for adequate and appropriate testing under § 610.40(e), with the licensed HCV NAT (nucleic acid test) and anti-HCV donor screening tests that are currently available, to provide additional information concerning the anti-HCV reactive donor's infection status. The draft guidance, when finalized, will update the recommendations related to the use of an appropriate multiantigen supplemental test contained in "Guidance for Industry: 'Lookback' for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV" dated December 2010.

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 further testing of donations that are reactive on a licensed donor screening test for antibodies to HCV. 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 draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 610 and

21 CFR 630.40 have been approved under OMB control number 0910–0116.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–20776 Filed 9–24–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–0404]

#### Pediatric Medical Device Development; Public Meeting; Request for Comments; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is reopening the comment period provided in the notice entitled "Pediatric Medical Device Development; Public Meeting; Request for Comments" that appeared in the **Federal Register** on February 16, 2018. That notice announced the public meeting to be held on August 13 and 14, 2018, and requested comments by September 14, 2018. FDA is reopening the public meeting's comment period until November 26, 2018. The Agency is taking this action to allow interested parties additional time to submit comments.

**DATES:** FDA is reopening the comment period for the public meeting "Pediatric Medical Device Development; Public Meeting; Request for Comments" published on February 16, 2018 (83 FR 7052). Submit either electronic or written comments on this meeting by November 26, 2018.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* 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–N–0404 for "Pediatric Medical Device Development; Public Meeting; Request for Comments; Reopening of Comment Period." 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.

**FOR FURTHER INFORMATION CONTACT:** Victoria Wagman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5562, Silver Spring, MD 20993, 301-796-6581, [Victoria.Wagman@fda.hhs.gov](mailto:Victoria.Wagman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of February 16, 2018 (83 FR 7052), FDA published a notice announcing the public meeting entitled “Pediatric Medical Device Development” with a 30-day comment period post the meeting to request comments. The public meeting was held on August 13 and 14, 2018. FDA is reopening the comment period for the public meeting until November 26, 2018. The Agency believes that this will allow adequate time for interested persons to submit comments without significantly delaying action by the Agency.

Dated: September 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-20795 Filed 9-24-18; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-3324]

**Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II; 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 document entitled “Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II); Draft Guidance for Industry.” The draft guidance document provides blood establishments that collect Whole Blood and blood components with recommendations for a requalification method for deferred donors, based on a determination that their previous reactive test results for anti-HTLV-I/II were falsely positive.

**DATES:** Submit either electronic or written comments on the draft guidance by December 24, 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-3324 for “Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II); Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be 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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Gretchen Oppen, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled "Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II); Draft Guidance for Industry." The draft guidance provides blood establishments that collect Whole Blood and blood components with recommendations for a requalification method under 21 CFR 610.41(b) for deferred donors, based on a determination that their previous reactive test results for anti-HTLV-I/II were falsely positive. Blood establishments are not required to test Source Plasma for HTLV I/II (21 CFR 610.40 (a)(2)(ii)). Therefore, this guidance does not apply to the collection of Source Plasma.

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 recommendations for requalification of blood donors deferred because of reactive test results for antibodies to human T-lymphotropic virus types I and II (anti-HTLV-I/II). 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 found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910-0338, and the collections of information in 21 CFR parts 610 and 606 have been approved under OMB control number 0910-0116.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-20775 Filed 9-24-18; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-4040-0016]

**Agency Information Collection Request. 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the

following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before October 25, 2018.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 4040-0016-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collections:*  
INSTRUCTIONS FOR THE SF-429 Real Property Status Report, SF-429 Real Property Status Report (Cover Page), SF-429-A Real Property Status Report ATTACHMENT A (General Reporting), SF-429-B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), and SF-429-C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request) forms.

*Type of Collection:* Extension.

*OMB No.:* 4040-0016.

*Abstract:* INSTRUCTIONS FOR THE SF-429 Real Property Status Report, SF-429 Real Property Status Report (Cover Page), SF-429-A Real Property Status Report ATTACHMENT A (General Reporting), SF-429-B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), and SF-429-C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request) forms are OMB-approved collections (4040-0016). These information collections are used by grant awardees to report on their grant award. The ICs expire on January 31, 2019. We are requesting a three-year clearance of these collections.



ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
INSTRUCTIONS FOR THE:				
SF-429 Real Property Status Report .....	100,000	1	0.5	50,000
SF-429 Real Property Status Report (Cover Page) .....	100,000	1	1	100,000
SF-429-A Real Property Status Report—ATTACHMENT A .....	100,000	1	1	100,000
SF-429-B Real Property Status Report—ATTACHMENT B (Request to Acquire, Improve or Furnish) .....	100,000	1	1	100,000
SF-429-C Real Property Status Report—ATTACHMENT C (Disposition or Encumbrance Request) .....	100,000	1	1	100,000
Total .....	500,000	.....	.....	450,000

Terry Clark,

Asst. Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018-20815 Filed 9-24-18; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service Purchased/ Referred Care Proof of Residency

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) is submitting to the Office of Management and Budget (OMB) a request for approval of a new collection of information titled, "Purchased/Referred Care Proof of Residency" (OMB Control Number 0917-XXXX). This proposed information collection project was recently published in the **Federal Register** (83 FR 13764) on March 30, 2018, and allowed 60 days for public comment. The IHS received one comment regarding this collection. The question summary and response is listed in the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

A copy of the draft supporting statement is available at [www.regulations.gov](http://www.regulations.gov) (see Docket ID IHS\_FRDOC\_0001).

**DATES:** October 25, 2018. Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

*Direct Your Comments to OMB:* Send your comments and suggestions regarding the proposed information

collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

*Public Comments:* The Agency received one comment.

*Comment:* The commenter asked for clarification of the Proof of Residency form, to whom it would apply and requested a copy of the data collection instrument and instruction.

*Response:* The Proof of Residency form, IHS-976, is a Federal form applicable to only Federal Purchased/ Referred Care (PRC) programs. For Tribes operating under Title I contracts or Title V compacts in accordance with Indian Self-Determination Education Assistance Act (ISDEAA) the IHS-976 is an optional use. Tribes may adopt usage of the form but all OMB text and the OMB Burden Statement should be removed. The form is developed to document residency within a PRC delivery area. The PRC eligibility requires residency documentation and the form will be used during the process of a PRC eligibility determination. The form is included in the IHS Indian Health Manual Part 2, Chapter 3, Purchased/Referred Care Manual. On May 23, IHS initiated Tribal Consultation per the ISDEAA for the manual.

**SUPPLEMENTARY INFORMATION:** The IHS Office of Resource Access and Partnerships/Division of Contract Care is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995.

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the

agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, e.g., permitting electronic submission of responses.

*Proposed Collection: Title:* 0917-XXXX, "Indian Health Service Purchased/Referred Care Proof of Residency."

*Type of Information Collection Request:* This is a new information request for a three year approval of this new information collection, 0917-XXXX.

*Forms:* Purchase/Referred Care Proof of Residency Form.

*OMB Control Number:* To be assigned.

*Need and Use of Information Collection:* The IHS PRC Program needs this information to certify that the health care services requested and authorized by the IHS have been provided to individuals who are documented to meet the eligibility requirements to receive medical services from PRC provider(s); and to serve as a legal document for health and medical care authorized by IHS and rendered by health care providers under contract with the IHS.

*Agency Form Number:* "None".

*Members of Affected Public:* Patients.

*Status of the Proposed Information Collection:* New request.

*Type of Respondents:* Individuals.

The table below provides: Types of data collection instruments; estimation to number of respondents, number of responses per respondent, annual number of responses, average burden hour per response, and total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Annual number of responses	Average burden hour per response*	Total annual burden hours
Individual Patient Count .....	77,185	1	77,185	3	3,859.25
Total .....	77,185	1	77,185	3	3,859.25

\*For ease of understanding, average burden hours are provided in actual minutes.

There are no direct costs to respondents to report.

Dated: September 18, 2018.

**Michael D. Weahkee,**

*Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.*

[FR Doc. 2018–20818 Filed 9–24–18; 8:45 am]

**BILLING CODE 4165–16–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Nursing Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Nursing Research Special Emphasis Panel; Institutional Training Grants.

*Date:* September 28, 2018.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Tamizchelvi Thyagarajan, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, Bethesda, MD 20892, (301) 594–0343, [tamizchelvi.thyagarajan@nih.gov](mailto:tamizchelvi.thyagarajan@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Nursing Research Initial Review Group.

*Date:* October 22–23, 2018.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Cheryl Nordstrom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, Bethesda, MD 20892, 301–435–1160.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: September 19, 2018.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–20755 Filed 9–24–18; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Review of NIGMS Support of Competitive Research (SCORE) Award Applications.

*Date:* September 27, 2018.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Room 3An12N, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Ruth Grossman, DDS, Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, 6701 Rockledge Drive, Room 5215, Bethesda, MD 20892, (301) 435–2409, [grossmanrs@mail.nih.gov](mailto:grossmanrs@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 19, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–20754 Filed 9–24–18; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG–2018–0853]

#### Cooperative Research and Development Agreement: Automatic Identification System/Data Marker Buoy (AIS/DMB) Using/Adapting COTS Technology

**AGENCY:** U.S. Coast Guard, DHS.

**ACTION:** Notice of intent; request for comments.

**SUMMARY:** The Coast Guard is announcing its intent to enter into a Cooperative Research and Development Agreement (CRADA) with Astronics DME to investigate adding/substituting an AIS component into the RB–100 series DMB. While the Coast Guard is currently considering collaborating with Astronics DME, we are soliciting public comment on the possible nature of and participation of other parties in the proposed CRADA. In addition, the Coast Guard also invites other potential non-Federal participants, who have the interest and capability to bring similar contributions to this type of research, to consider submitting proposals for consideration in similar CRADAs.

**DATES:** Comments must be submitted to the online docket via <http://www.regulations.gov>, or reach the

Docket Management Facility, on or before October 25, 2018.

Synopses of proposals regarding future CRADAs must reach the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) on or before October 25, 2018.

**ADDRESSES:** Submit comments online at <http://www.regulations.gov> following website instructions.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice or wish to submit proposals for future CRADAs, contact LT Carlon Brietzke, Project Official, Science & Technology Innovation Center, U.S. Coast Guard Research and Development Center, 1 Chelsea Street, New London, CT 06320, telephone 860-271-2891, email [Carlon.F.Brietzke@uscg.mil](mailto:Carlon.F.Brietzke@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

We request public comments on this notice. Although we do not plan to respond to comments in the **Federal Register**, we will respond directly to commenters and may modify our proposal in light of comments.

Comments should be marked with docket number USCG-2018-0853 and should provide a reason for each suggestion or recommendation. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the **Federal Register** Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008). We also accept anonymous comments.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**). Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

Do not submit detailed proposals for future CRADAs to the Docket Management Facility. Instead, submit them directly to the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**).

**Discussion**

CRADAs are authorized under 15 U.S.C. 3710(a).<sup>1</sup> A CRADA promotes the transfer of technology to the private sector for commercial use, as well as specified research or development efforts that are consistent with the mission of the Federal parties to the CRADA. The Federal party or parties agree with one or more non-Federal parties to share research resources, but the Federal party does not contribute funding.

CRADAs are not procurement contracts. Care is taken to ensure that CRADAs are not used to circumvent the contracting process. CRADAs have a specific purpose and should not be confused with procurement contracts, grants, and other type of agreements.

Under the proposed CRADA, the R&D Center will collaborate with one non-Federal participant. Together, the R&D Center and the non-Federal participant using the RB-100 series DMB (this product has been in use by the aviation community for several years and is a proven design that utilizes AM/FM Radio Frequency location) will investigate adding/substituting an AIS component into the RB-100 series DMB.

We anticipate that the Coast Guard's contributions under the proposed CRADA will include the following:

(1) Provide a USCG AIS transmitter system technical data package for evaluation, modification, fabrication, and testing of an AIS transmitter system for incorporation into an RB-100 series DMB.

(2) Provide technical input related to the AIS transmitter system and its technical data package, as required, along with specific data on known or suspected design weaknesses in the AIS transmitter based on operational assessments.

(3) Provide all support resources, including travel, for Coast Guard staff that supports this CRADA.

(4) Shall accomplish a deployment trial and operational assessment of the demo prototypes AIS-DMBs and share assessment results.

We anticipate that the non-Federal participants' contributions under the proposed CRADA will include the following:

(1) Provide appropriate staff with pertinent expertise to support the above mentioned tasks.

(2) Provide all necessary facility resources needed to integrate the

existing or modified USCG AIS transmitter into the existing AM/FM DMB in such a way as to preserve the air deployment stability, water stability and mission reliability characteristics of the existing AM/FM DMB in the resulting AIS-DMB product.

(3) Support testing and analysis efforts as the AIS-DMB evolves during development and completes advanced development tasks, in order to verify achievement of CRADA objectives.

(4) Support an AIS-DMB deployment trial and operational assessment.

The Coast Guard reserves the right to select for CRADA participants all, some, or no proposals submitted for this CRADA. The Coast Guard will provide no funding for reimbursement of proposal development costs. Proposals and any other material submitted in response to this notice will not be returned. Proposals submitted are expected to be unclassified and have not more than five single-sided pages (excluding cover page, DD 1494, JF-12, etc.). The Coast Guard will select proposals at its sole discretion on the basis of:

(1) How well they communicate an understanding, of and ability to meet, the proposed CRADA's goal; and

(2) How well they address the following criteria:

(a) Technical capability to support the non-Federal party contributions described, and

(b) Resources available for supporting the non-Federal party contributions described.

Currently, the Coast Guard is considering Astronics DME for participation in this CRADA. This consideration is based on the fact that Astronics DME manufactures the RB-100 series Datum Marker Buoy. However, we do not wish to exclude other viable participants who manufacture Datum Marker Buoys and/or AIS technologies from this or future similar CRADAs.

This is a technology merging effort. The goal of the Coast Guard for this CRADA is to merge AIS capabilities into Datum Marker Buoys to reduce the amount of manpower, time, and asset availability needed to track and recover jettisoned cargo, derelict vessels, and aid in search-and-rescue cases. Special consideration will be given to small business firms/consortia, and preference will be given to business units located in the U.S. This notice is issued under the authority of 5 U.S.C. 552(a).

<sup>1</sup> The statute confers this authority on the head of each Federal agency. The Secretary of DHS's authority is delegated to the Coast Guard and other DHS organizational elements by DHS Delegation No. 0160.1, para. II.B.34.

Dated: September 11, 2018.

**G.C. Rothrock,**

*Captain, Commanding Officer, U.S. Coast Guard Research and Development Center.*

[FR Doc. 2018-20834 Filed 9-24-18; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-HQ-FAC-2018-N099;  
FXFR13360900000-FF09F14000-189]

#### Aquatic Nuisance Species Task Force Meeting

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

**ACTION:** Notice of teleconference/web meeting.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce a teleconference/web meeting of the Aquatic Nuisance Species (ANS) Task Force, in accordance with the Federal Advisory Committee Act. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

**DATES:** *Teleconference/web meeting:* Monday, October 15, 2018, from 1 p.m. to 4 p.m. (Eastern Time). For security purposes, registration is required. For deadlines to listen to the meeting by telephone, listen and view through the internet, or provide oral public comment by phone, please see Public Input under **SUPPLEMENTARY INFORMATION**. For more information, contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**).

**ADDRESSES:**

*Meeting location:* We are holding the meeting via teleconference and over the web so that participants can attend remotely. To receive the web address and telephone number for participation, contact the Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) or visit the ANS Task Force website at: website at <http://anstaskforce.gov>.

*Comment submission:* You may submit written comments in advance of the meeting by emailing them to the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Susan Pasko, Executive Secretary, ANS Task Force, by telephone at (703) 358-2466, or by email at [Susan\\_Pasko@fws.gov](mailto:Susan_Pasko@fws.gov). If you use a telecommunications device for the deaf

(TDD), please call the Federal Relay Service at (800) 877-8339.

**SUPPLEMENTARY INFORMATION:** We, the U.S. Fish and Wildlife Service (Service), announce a public teleconference/web meeting of the ANS Task Force, in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 2). The ANS Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as amended (NANPCA; 16 U.S.C. 4701 *et seq.*), is composed of 13 Federal and 15 ex-officio members, and is co-chaired by the Service and the National Oceanic and Atmospheric Administration. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

#### Meeting Agenda

- Review and discuss the draft ANS Task Force goals, priorities, and strategies that will form the foundation of the next ANS Task Force Strategic Plan.
- Public comment period.

The final agenda and other related meeting information will be posted on the ANS Task Force website at <http://anstaskforce.gov>. Summary minutes of the meeting will be maintained by the Executive Secretary and will be available for public inspection within 90 days after the meeting at <http://anstaskforce.gov>.

#### Public Input

If you wish to listen to the webinar by telephone, listen and view through the internet, provide oral public comment by phone, or provide a written comment for the ANS Task Force to consider, contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than Monday, October 8, 2018.

The U.S. Fish and Wildlife Service is committed to providing access to this teleconference/webinar for all participants. Please direct all requests for sign language interpretation services, closed captioning, or other accommodation to the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) by close of business Monday, October 8, 2018.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Authority** 5 U.S.C. Appendix 2.

Dated: September 19, 2018.

**David W. Hoskins,**

*Co-Chair, Aquatic Nuisance Species Task Force, Assistant Director for Fish and Aquatic Conservation.*

[FR Doc. 2018-20799 Filed 9-24-18; 8:45 am]

**BILLING CODE 4333-15-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[LLWO31000.L13100000.PB0000.18X; OMB Control Number 1004-0185]

#### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Onshore Oil and Gas Leasing and Drainage Protection

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Land Management (BLM), are proposing to renew an information collection with revisions.

**DATES:** Interested persons are invited to submit comments on or before October 30, 2018.

**ADDRESSES:** Send written comments on this information collection request (ICR) to the Office of Management and Budget's (OMB) Desk Officer for the Department of the Interior by email at [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov); or via facsimile to (202) 395-5806. Please provide a copy of your comments to the BLM at U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 2134LM, Washington, DC 20240, Attention: Jean Sonneman; or by email to [jesonnem@blm.gov](mailto:jesonnem@blm.gov). Please reference OMB Control Number 1004-0185 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Jennifer Spencer by email at [j35spenc@blm.gov](mailto:j35spenc@blm.gov), or by telephone at 202-912-7146. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal

agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 24, 2018 (83 FR 17840). No comments were received.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BLM; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BLM enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BLM minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Abstract:** The BLM collects information to monitor and enforce compliance with drainage protection and other requirements pertaining to Federal and Indian oil and gas leasing and operations (except on the Osage Reservation).

**Title of Collection:** Onshore Oil and Gas Leasing and Drainage Protection.

**OMB Control Number:** 1004-0185.

**Form Number:** None.

**Type of Review:** Revision of a currently approved collection.

**Respondents/Affected Public:** Holders of onshore oil and gas lease and public lands and Indian lands (except on the Osage Reservation), operators of such leases, and holders of operating rights on such leases.

**Total Estimated Number of Annual Respondents:** 19,712.

**Total Estimated Number of Annual Responses:** 19,712.

**Estimated Completion Time per Response:** Varies from 1 hour to 24 hours per response, depending on activity.

**Total Estimated Number of Annual Burden Hours:** 42,936.

**Respondent's Obligation:** Required to Obtain or Retain a Benefit.

**Frequency of Collection:** "On occasion," except for the activity titled "Option statement," which is required twice a year.

**Total Estimated Annual Nonhour Burden Cost:** \$3,278,348.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Jean Sonneman,**

*Information Collection Clearance Officer,  
Bureau of Land Management.*

[FR Doc. 2018-20831 Filed 9-24-18; 8:45 am]

**BILLING CODE 4310-84-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Safety and Environmental Enforcement

**[Docket ID BSEE-2018-0003; 189E1700D2 ET1SF0000.PSB000.EEEE500000; OMB Control Number 1014-0007]**

#### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Oil-Spill Response Requirements for Facilities Located Seaward of the Coast Line

**AGENCY:** Bureau of Safety and Environmental Enforcement, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

**DATES:** Interested persons are invited to submit comments on or before October 25, 2018.

**ADDRESSES:** Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov); or via facsimile to (202) 395-5806. Please provide a copy of your comments to the Bureau of Safety and Environmental

Enforcement; Regulations and Standards Branch; ATTN: Nicole Mason; 45600 Woodland Road, Sterling, VA 20166; or by email to [kye.mason@bsee.gov](mailto:kye.mason@bsee.gov). Please reference OMB Control Number 1014-0007 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Nicole Mason by email at [kye.mason@bsee.gov](mailto:kye.mason@bsee.gov), or by telephone at (703) 787-1607. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on March 6, 2018 (83 FR 9542). We received one comment in response to the **Federal Register** Notice. BSEE has reviewed the comment and considers it to be outside the scope of this current information collection comment request. However, BSEE does feel the comment has merit and could be examined in a future revision to the 30 CFR 254 regulations.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comments addressing the following issues: (1) Is the collection necessary to the proper functions of BSEE; (2) Will this information be processed and used in a timely manner; (3) Is the estimate of burden accurate; (4) How might BSEE enhance the quality, utility, and clarity of the information to be collected; and (5) How might BSEE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to

withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Abstract:** The regulations at 30 CFR 254 establish requirements for spill-response plans for oil-handling facilities seaward of the coast line, including associated pipelines, and are the subject of this collection. This request also covers any related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

BSEE uses the information collected under 30 CFR 254 to determine compliance with the Oil Pollution Act of 1990 (OPA) by lessees/operators. Specifically, BSEE needs the information to:

- Determine that lessees/operators have an adequate plan and are sufficiently prepared to implement a quick and effective response to a discharge of oil from their facilities or operations.
- Review plans prepared under the regulations of a State and submitted to BSEE to satisfy the requirements in 30 CFR 254 to ensure that they meet minimum requirements of OPA.
- Verify that personnel involved in oil-spill response are properly trained and familiar with the requirements of the spill-response plans and to lead and witness spill-response exercises.
- Assess the sufficiency and availability of contractor equipment and materials.
- Verify that sufficient quantities of equipment are available and in working order.
- Oversee spill-response efforts and maintain official records of pollution events.

• Assess the efforts of lessees/operators to prevent oil spills or prevent substantial threats of such discharges.

**Title of Collection:** 30 CFR part 254, Oil-Spill Response Requirements for Facilities Located Seaward of the Coast Line.

**OMB Control Number:** 1014-0007.

**Form Number:** None.

**Type of Review:** Extension of a currently approved collection.

**Respondents/Affected Public:**

Potential respondents comprise Federal oil, gas, or sulphur lessees or operators of facilities located in both State and Federal waters seaward of the coast line and oil-spill response companies.

**Total Estimated Number of Annual Respondents:** Varies, not all of the potential respondents will submit information in any given year and some may submit multiple times.

**Total Estimated Number of Annual Responses:** 1,675.

**Estimated Completion Time per Response:** Varies from 10 minutes to 338 hours, depending on activity.

**Total Estimated Number of Annual Burden Hours:** 60,989.

**Respondent's Obligation:** Most responses are mandatory, while others are required to obtain or retain benefits.

**Frequency of Collection:** On occasion, monthly, annually, biennially, and varies by section.

**Total Estimated Annual Nonhour Burden Cost:** We have not identified any non-hour cost burdens associated with this collection of information.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 3, 2018.

**Doug Morris,**

*Chief, Office of Offshore Regulatory Programs.*

[FR Doc. 2018-20800 Filed 9-24-18; 8:45 am]

**BILLING CODE 4310-VH-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1047]

### Certain Semiconductor Devices and Consumer Audiovisual Products Containing the Same; Commission's Final Determination of No Violation of Section 337; Termination of the Investigation

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has found no violation of section 337 of the Tariff Act of 1930, as amended, by respondents Sigma Designs, Inc. and Vizio, Inc. The investigation is terminated.

#### FOR FURTHER INFORMATION CONTACT:

Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its

internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on April 12, 2017, based on a complaint filed by Broadcom Corporation ("Broadcom") of Irvine, California. 82 FR 17688. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain semiconductor devices and consumer audiovisual products containing the same that infringe U.S. Patent Nos. 7,310,104 ("the '104 patent"); 7,342,967 ("the '967 patent"); 7,590,059 ("the '059 patent"); 8,068,171 ("the '171 patent"); and 8,284,844 ("the '844 patent"). *Id.* The Commission's notice of investigation named as respondents MediaTek Inc. of Hsinchu City, Taiwan, MediaTek USA Inc. of San Jose, California, and MStar Semiconductor Inc. of ChuPei Hsinchu Hsien, Taiwan (together, "MediaTek"); Sigma Designs, Inc. of Fremont, California ("Sigma"); LG Electronics Inc. of Seoul, Republic of Korea and LG Electronics U.S.A., Inc. of Englewood Cliffs, New Jersey (together, "LG"); Funai Electric Company, Ltd., of Osaka, Japan, Funai Corporation, Inc. of Rutherford, New Jersey, and P&F USA, Inc. of Alpharetta, Georgia (together, "Funai"); and Vizio, Inc., of Irvine, California ("Vizio"). *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

Several parties were terminated from the investigation based on settlement. Specifically, the Commission terminated the investigation with respect to Funai, Order No. 31 (Nov. 7, 2017), *not reviewed* Notice (Dec. 12, 2017); MediaTek, Order No. 35 (Nov. 29, 2017), *not reviewed* Notice (Dec. 19, 2017); and LG, Order No. 42 (Apr. 9, 2018), *not reviewed* Notice (May 4, 2018). Accordingly, only respondents Sigma and Vizio (together, "Respondents") remained in the investigation at the time of the final ID.

The Commission also terminated two patents and several claims of the remaining patents based on Broadcom's partial withdrawal of the complaint. Specifically, the Commission terminated the investigation with

respect to the '967 patent, the '171 patent, claims 21–30 of the '059 patent, and claim 14 of the '844 patent. Order No. 24 (Oct. 10, 2017), *not reviewed* Notice (Oct. 24, 2017). Broadcom also elected to withdraw claims 5 and 11–13 of the '844 patent in its post-hearing brief. ID at 7. Accordingly, at the time of the final ID, the only remaining claims were claims 1, 10, 11, 16, 17, and 22 of the '104 patent; claims 1–4, 6–10, of the '844 patent; and claims 11–20 of the '059 patent.

On May 11, 2018, the ALJ issued a final ID finding no violation of section 337. Specifically, he found that Respondents did not infringe any claim, that the asserted claims of the '844 patent are invalid, and that Broadcom did not satisfy the technical prong of the domestic industry requirement for the '104 patent. On May 29, 2018, Broadcom and Respondents each petitioned for review of the ID. On June 6, 2018, the parties opposed each other's petitions.

On July 17, 2018, the Commission determined to review the following issues: (1) The construction of “a processor adapted to control a decoding process” in claim 1 of the '844 patent, as well as related issues of infringement, invalidity, and the technical prong of the domestic industry requirement with respect to the limitation; (2) the finding that the prior art reference Fandrianto anticipates the limitation “adapted to perform a decoding function on a digital media stream” of claim 1 of the '844 patent; (3) the construction of “the blended graphics image” in claim 1 of the '104 patent, as well as related issues of infringement, invalidity, and the technical prong of the domestic industry requirement with respect to the limitation; (4) the construction of “blend the blended graphics image with the video image using the alpha values and/or at least one value derived from the alpha values” limitation in claim 1 of the '104 patent, as well as related issues of infringement, invalidity, and the technical prong of the domestic industry requirement with respect to the limitation; and (5) the finding that claims 1 and 10 of the '104 patent are invalid as obvious if certain claim constructions are modified. The Commission determined not to review the ID's finding of no violation with respect to the '059 patent.

Having examined the record of this investigation, including the ALJ's final ID, the petitions, responses, and other submissions from the parties and the public, the Commission has determined that Broadcom has not proven a violation of section 337 by Sigma and Vizio. Specifically, the Commission has

determined to modify the ID's construction of “a processor adapted to control a decoding process,” and, under the modified construction, finds that the limitation is satisfied for the technical prong of the domestic industry requirement and invalidity, but is not satisfied for infringement. The Commission also has determined to affirm under modified reasoning that Fandrianto satisfies the limitation “adapted to perform a decoding function on a digital media stream.” The Commission has additionally determined to modify the ID's construction of “the blended graphics image,” and, under the modified construction, finds that the limitation is satisfied for infringement and the technical prong. The Commission has further determined to affirm under modified reasoning the ID's construction of “blend the blended graphic image with the video image using the alpha values and/or at least one value derived from the alpha values,” and affirms the ID's findings on infringement, invalidity, and the technical prong with respect to the limitation. Finally, the Commission has determined to take no position on the ID's finding that claims 1 and 10 of the '104 patent are obvious.

Accordingly, the Commission has determined that Broadcom has failed to show a violation of section 337 with respect to both the '844 and '104 patents. For the '844 patent, the Commission finds that Broadcom failed to establish infringement, but did satisfy the technical prong of the domestic industry requirement. The Commission further finds that the Respondents showed by clear and convincing evidence that claims 1–10 are invalid as anticipated. For the '104 patent, the Commission finds that Broadcom failed to show both infringement and the satisfaction of the technical prong of the domestic industry requirement. The Commission's determinations are explained more fully in the accompanying Opinion. All other findings in the ID under review that are consistent with the Commission's determinations are affirmed.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: September 19, 2018.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2018–20778 Filed 9–24–18; 8:45 am]

**BILLING CODE 7020–02–P**

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## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

#### Petitions for Modification of Application of Existing Mandatory Safety Standard

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

**DATES:** All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before October 25, 2018.

**ADDRESSES:** You may submit your comments, identified by “docket number” on the subject line, by any of the following methods:

1. *Email:* [zzMSHA-comments@dol.gov](mailto:zzMSHA-comments@dol.gov). Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect a copy of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

**FOR FURTHER INFORMATION CONTACT:** Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (voice), [barron.barbara@dol.gov](mailto:barron.barbara@dol.gov) (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

**SUPPLEMENTARY INFORMATION:** Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification.

## I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor (Secretary) determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

## II. Petition for Modification

*Docket Number:* M-2018-017-C.

*Petitioner:* Raw Coal Mining Company, Inc., 356 South College Avenue, Bluefield, Virginia 24605.

*Mine:* EDM No. 1 Mine, MSHA I.D. No. 46-09507, located in McDowell County, West Virginia.

*Regulation Affected:* 30 CFR 75.1101-1(b) (Deluge-type water spray systems).

*Modification Request:* The petitioner requests a modification of the existing standard to permit the removal of blow-off dust covers from nozzles on deluge-type water spray systems.

The petitioner states that:

(1) Sections 75.1101-1 through 75.1101-4 set forth various requirements regarding deluge-type water spray systems; among the requirements there is no mandate to inspect and functionally test those systems. The petitioner conducts a weekly inspection and functional test of the complete deluge-type water spray system at its EDM No. 1 Mine.

(2) Currently, the petitioner complies with the requirements of section 75.1101-1(b) by providing each nozzle with a blow-off cover. The petitioner states that because of the frequent inspections and functional testing of the system, the blow-off dust covers are not necessary because the nozzles can be maintained in an unclogged condition through weekly use. Further, it is burdensome to recap the large number of blow-off dust covers after each weekly inspection and functional test.

(3) Petitioner proposes the following alternative method of achieving the result of the standard in section 75.1101-1(b), insofar as it requires that nozzles be provided with blow-off dust covers:

(a) Continue weekly inspection and functional testing of the complete deluge-type water spray system; and

(b) Remove blow-off dust covers from the nozzles.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the standard.

**Patricia W. Silvey,**

*Deputy Assistant Secretary for Operations, Mine Safety and Health Administration.*

[FR Doc. 2018-20756 Filed 9-24-18; 8:45 am]

**BILLING CODE 4520-43-P**

## OFFICE OF MANAGEMENT AND BUDGET

### Request for Comments on 2018 Federal Cloud Computing Strategy

**AGENCY:** Office of Management and Budget.

**ACTION:** Notice of public comment period.

**SUMMARY:** The Office of Management and Budget (OMB) is seeking public comment on a draft document titled “2018 Federal Cloud Computing Strategy.”

**DATES:** The public comment period on the draft memorandum begins on September 24, 2018, and will last for 30 days. The public comment period will end on October 24, 2018.

**ADDRESSES:** Interested parties should provide comments at the following link: <https://cloud.cio.gov/>. The Office of Management and Budget is located at 725 17th Street NW, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Bill Hunt at [ofcio@omb.eop.gov](mailto:ofcio@omb.eop.gov) or the Office of the Federal Chief Information Officer at (202) 395-3080.

**SUPPLEMENTARY INFORMATION:** The Office of Management and Budget (OMB) is proposing a new Federal Cloud Computing Strategy (“Cloud Smart”) to increase cloud adoption across the Federal portfolio. As part of the President’s Management Agenda, the U.S. Government has committed to modernize legacy technology and leverage leading practices from industry to improve citizen services, reduce operational costs, and enhance the security of the Federal enterprise. The 2018 Federal Cloud Computing Strategy, “Cloud Smart,” an update of the original Cloud approach, addresses gaps in previous guidance, embraces new capabilities, and provides an end-to-end strategy to accelerate transformation.

This new, transformative strategy focuses on three key inter-related areas—security, procurement, and workforce—necessary to drive cloud adoption through building knowledge in government and removing burdensome policy barriers. This strategy will be available for review and public comment at <https://cloud.cio.gov/>.

**Suzette Kent,**

*U.S. Federal Chief Information Officer.*

[FR Doc. 2018-20819 Filed 9-24-18; 8:45 am]

**BILLING CODE 3110-05-P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Office of Government Information Services

[NARA-2018-061]

#### Chief FOIA Officers Council Meeting

**AGENCY:** Office of Government Information Services (OGIS), National Archives and Records Administration (NARA).

**ACTION:** Notice of Chief FOIA Officers Council meeting.

**SUMMARY:** OGIS and the Office of Information Policy (OIP), U.S. Department of Justice, announce a second 2018 meeting of the Chief FOIA Officers Council.

**DATES:** The meeting will be Thursday, October 4, 2018, from 10:00 a.m. to 12 p.m. EDT. Please register for the meeting no later than October 2, at 5:00 p.m. EDT (registration information below).

*Location:* National Archives and Records Administration (NARA); 700 Pennsylvania Avenue NW; William G. McGowan Theater; Washington, DC 20408.

**FOR FURTHER INFORMATION CONTACT:** Martha Murphy, by mail at National Archives and Records Administration; Office of Government Information Services; 8601 Adelphi Road—OGIS; College Park, MD 20740-6001, by telephone at 202-741-5772, or by email at [martha.murphy@nara.gov](mailto:martha.murphy@nara.gov), with the subject line “Chief FOIA Officers Council.” To request additional accommodations (e.g., a transcript), email [ogis@nara.gov](mailto:ogis@nara.gov) or call 202-741-5770.

**SUPPLEMENTARY INFORMATION:** This meeting is open to the public in accordance with the Freedom of Information Act (5 U.S.C. 552(k)). The Chief FOIA Officers Council is co-chaired by the Directors of OIP and OGIS. Among the purposes of the Chief FOIA Officers Council is developing



recommendations to increase compliance and efficiency and sharing best practices and innovative approaches. Additional details about the meeting are available on OGIS's website at <https://archives.gov/ogis/about-ogis/Chief-FOIA-Officers-Council> and OIP's website at <https://www.justice.gov/oip/chief-foia-officers-council>.

**Procedures:** Due to security requirements, you must register in advance if you wish to attend the meeting. You will also go through security screening when you enter the building. To register for the meeting, please do so at the following Eventbrite link: <https://www.eventbrite.com/e/chief-foia-officers-council-meeting-100418-tickets-49346272028>.

We will also live-stream this program on the U.S. National Archives' YouTube channel, at <https://www.youtube.com/user/usnationalarchives/>. The webcast will include a captioning option.

Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Martha Murphy at the phone number, mailing address, or email address listed above.

**Alina M. Semo,**

*Director, Office of Government Information Services.*

[FR Doc. 2018-20746 Filed 9-24-18; 8:45 am]

**BILLING CODE 7515-01-P**

## NATIONAL SCIENCE FOUNDATION

### Notice of Intent To Seek Approval To Establish an Information Collection

**AGENCY:** National Science Foundation.

**ACTION:** Notice and request for comments.

**SUMMARY:** The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment. NSF is forwarding the proposed new information collection submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

The National Science Foundation (NSF) is announcing plans to request approval for a new information collection. The primary purpose of this data collection is for institutional authorized organizational representatives to inform NSF of any finding/determination regarding the PI or any co-PI that demonstrates a

violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; and/or if the PI or any co-PI is placed on administrative leave or if any administrative action has been imposed on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault.

**SUPPLEMENTARY INFORMATION:** This is the second notice for public comment; the first was published in the **Federal Register** at 83 FR 9342, and 192 comments were received. The full submission may be found at: <http://www.reginfo.gov/public/do/PRAMain>.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**Comments:** On March 5, 2018, NSF published a request for public comment regarding the agency's proposed implementation of new notification requirements specified in Important Notice No. 144. (83 FR 9342-9343, March 5, 2018). All comments were carefully considered in developing the final version of the term and condition. A table listing the comments and NSF responses is posted on the NSF website at: [www.nsf.gov/harassment](http://www.nsf.gov/harassment).

Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on 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 should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street NW, Room 10235, Washington, DC 20503, and to

Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to [splimpto@nsf.gov](mailto:splimpto@nsf.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703-292-7556.

**Title of Collection:** Notification Requirements Regarding Sexual Harassment, Other Forms of Harassment, or Sexual Assault.

**OMB Number:** 3145-NEW.

**Type of Request:** Intent to seek approval for a new information collection.

**Proposed Information Collection:** The awardee is required to notify NSF of: (1) Any finding/determination regarding the PI or any co-PI that demonstrates a violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; and/or (2) if the PI or any co-PI is placed on administrative leave or if any administrative action has been imposed on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault. Such notification must be submitted by the Authorized Organizational Representative (AOR) or designee to NSF's Office of Diversity and Inclusion at [www.nsf.gov/harassment](http://www.nsf.gov/harassment) within ten business days from the date of the finding/determination, or the date of the placement of a PI or co-PI by the awardee on administrative leave or the imposition of an administrative action, whichever is sooner. Each notification must include the following information:

- NSF Award Number;
- Name of PI or co-PI being reported;
- Type of Notification: Select one of the following:
  - Finding/Determination that the reported individual has been found to have violated awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; or
  - Placement by the awardee of the reported individual on administrative

leave or the imposition of any administrative action on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault.

- Description of the finding/determination and action(s) taken, if any; and
- Reason(s) for, and conditions of, placement of the PI or any co-PI on administrative leave or imposition of administrative action.

*Use of the Information:* NSF will use the information in consultation with the awardee to determine whether the NSF award activities can be carried out as proposed and in a manner that protects the safety and security of award personnel.

*Burden on the Public:* It has been estimated that respondents will expend an average of one hour to complete the form.

Dated: September 20, 2018.

**Suzanne H. Plimpton,**

*Reports Clearance Officer, National Science Foundation.*

[FR Doc. 2018-20836 Filed 9-24-18; 8:45 am]

**BILLING CODE 7555-01-P**

## NATIONAL TRANSPORTATION SAFETY BOARD

[Docket No. NTSB-CIO-2017-0005]

### Privacy Act of 1974; System of Records

**AGENCY:** National Transportation Safety Board (NTSB).

**ACTION:** Notice of a new System of Records.

**SUMMARY:** The NTSB is notifying the public about a new Privacy Act System of Records for its Medical Investigation Catalog System (MEDICS). MEDICS includes electronically held personally identifiable health information about individuals involved in transportation accidents and incidents that the NTSB investigates.

**DATES:** Comments are due by October 25, 2018. Unless the NTSB determines that comments warrant a revision to the routine uses, new routine uses will be applicable October 25, 2018.

**ADDRESSES:** You may send written comments, identified by docket number NTSB-CIO-2017-0005, using any of the following methods:

1. *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow

the instructions for sending your comments electronically.

2. *Mail:* Mail comments concerning this notice to Melba D. Moye, CIO-40, National Transportation Safety Board, 490 L'Enfant Plaza SW, Washington, DC 20594-2000.

3. *Fax:* (202) 558-4290, Attention: Melba D. Moye.

4. *Hand Delivery:* 6th Floor, National Transportation Safety Board, CIO-40, 490 L'Enfant Plaza SW, Washington, DC, between 9 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

*Instructions:* All comments received must contain the agency name and docket number for this System of Records. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

#### FOR FURTHER INFORMATION CONTACT:

Melba D. Moye, Office of Chief Information Officer, Records Management Division, (202) 314-6551.

**SUPPLEMENTARY INFORMATION:** The NTSB first published a System of Records Notice for MEDICS on May 19, 2017. 82 FR 23075. The NTSB received and incorporated input from the Office of Management and Budget (OMB), and it is now re-publishing the SORN.

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the NTSB notes that the descriptions below reference the Chief of the NTSB's Records Management Division. Individuals may request access to or amendment of records pertaining to themselves by contacting the Chief of the NTSB's Records Management Division, or the Chief's designee.

#### SYSTEM NAME AND NUMBER:

Medical Investigation Catalog System (MEDICS) NTSB-33.

#### SECURITY CLASSIFICATION:

Unclassified.

#### SYSTEM LOCATION:

National Transportation Safety Board, Office of Chief Information Officer, 490 L'Enfant Plaza SW, Washington, DC 20594.

#### SYSTEM MANAGER(S):

Chief Medical Officer(s), Office of Research and Engineering, National Transportation Safety Board, 490 L'Enfant Plaza SW, Washington, DC 20594, (202) 314-6031.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

49 U.S.C. chapter 11 and 49 CFR parts 802 and 831.

#### PURPOSE(S) OF THE SYSTEM:

The purpose of MEDICS is to securely receive and store investigative health information records. The NTSB is an independent federal agency responsible for determining the probable cause of transportation accidents or incidents, conducting transportation safety research, promoting transportation safety, and assisting victims of transportation accidents and their families. In support of the agency's statutory mandate, NTSB investigators, medical officers, and staff review health information records to (1) determine the facts or circumstances of an accident or incident; (2) determine the probable cause of an accident or incident; (3) evaluate human performance or survival factors issues arising during an accident or incident investigation; (4) provide victim and family assistance following an accident or incident; (5) carry out special studies and investigations about transportation safety (including avoiding personal injury); and/or (6) examine techniques and methods of accident or incident investigation, and publish recommended procedures for accident or incident investigations.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

MEDICS records contain personally identifiable information (PII), which may include health information as defined below, of individuals such as operators, crewmembers, occupants, and bystanders involved in transportation accidents or incidents investigated or studied by the NTSB, as well as related PII of individuals responsible for providing their medical care.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

MEDICS contains electronically recorded PII, including health information, which means any information that—

(A) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, health care clearinghouse, or federal, state, or local agency; and

(B) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; and/or the past, present, or future payment for the provision of health care to an individual.

MEDICS may also contain electronically recorded health information, as described by paragraph B above, from individuals, families, or other entities, whether created or received by or from one of the entities described in paragraph A above, and

from accident sites and wreckage. For the NTSB's purposes, health information includes any record of medical conditions or care, for example, notes from a health care provider; medical certification documentation such as Federal Aviation Administration blue ribbon files and commercial driver's license long forms; results of any drug or toxicology tests; radiology images; autopsy reports; laboratory reports; prehospital patient care reports; ambulance run sheets or patient care reports; pharmacy records; billing and insurance information; results from a search of a prescription monitoring program; and any other official record related to an individual's health or health care.

**RECORD SOURCE CATEGORIES:**

Health information is obtained from health care providers, insurers, employers, individuals, family members of accident victims, and the accident site and wreckage. The NTSB may also obtain health information from other federal, state, or local agencies.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND THE PURPOSES OF SUCH USES:**

In addition to the disclosures permitted under the Privacy Act, 5 U.S.C. 552a(b), the NTSB is establishing twelve routine uses under which the NTSB may disclose records contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected.

1. Records may be disclosed to a participant in an NTSB investigation, appointed pursuant to 49 CFR 831.11 to provide suitable technical expertise and assist in establishing the facts and circumstances of an accident. Participants may include representatives from operators or manufacturers involved in accidents or incidents, as well as representatives from federal, state, and local agencies. Participation is governed by 49 CFR part 831, and section 831.13 prohibits participants from further disseminating the information.

2. Records may be disclosed to other medical consultants or contractors not named under routine use number 1, as appropriate to enable consultation related to an NTSB investigation.

3. Records may be disclosed to a foreign government agency acting as an accredited representative to an NTSB investigation pursuant to Annex 13 of the International Convention on Civil Aviation, and any technical advisor assisting the accredited representative.

4. Records may be disclosed to a foreign government agency when the NTSB is acting as an accredited representative to the foreign government agency's investigation pursuant to Annex 13 of the International Convention on Civil Aviation.

5. Records may be disclosed to the public in a docket or report for an accident investigation, or in a safety study report. The NTSB is required to inform the public of the facts, circumstances, and probable cause of accidents, and to publish findings in safety studies and reports. 49 U.S.C. 1116, 1131(e). The NTSB will disclose a record or part of a record in a public docket or report only if (1) the subject of the record's actions or decision making may have contributed to an accident or may be related to a safety hazard; (2) disclosure is reasonably necessary to support a finding, conclusion, and/or probable cause determination, or safety recommendation; and (3) the NTSB determines that the public's and the NTSB's interest in disclosure outweighs the individual's privacy interest.

6. When information indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, records may be disclosed to the appropriate agency, whether federal, foreign, state, local, or tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative or prosecutory responsibility of the receiving entity. This routine use allows for disclosures other than those provided by the Privacy Act exemption for law enforcement activities, 5 U.S.C. 552a(b)(7). The law enforcement exemption requires the head of the agency requesting disclosure to make a written request specifying the records requested and the relevant law enforcement activity. The NTSB must be able to disclose a record relevant to a potential violation of law without a request from the agency to whom records are disclosed because the NTSB may be the first to discover the potential violation of law, and the NTSB must be able to confer with other agencies about whether it will relinquish investigative priority pursuant to 49 U.S.C. 1131(a)(2).

7. Records may be disclosed to a federal, foreign, state, local, or tribal

agency that (1) performs safety related functions; (2) is not a participant to an NTSB investigation as described in routine use number 1; and (3) is not conducting an investigation, enforcement action, or prosecution as described in routine use number 6, if the NTSB determines that disclosure would enable the receiving agency to take corrective action or address a safety risk.

8. Records may be disclosed to an agency or organization that regulates, oversees, licenses, or accredits healthcare providers or organizations if the NTSB determines that a provider's conduct or decision-making may warrant corrective action or creates a safety risk.

9. Records may be disclosed to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which the NTSB is authorized to appear, when (1) the NTSB, or any component thereof; (2) any employee of the NTSB in his or her official capacity; (3) any employee of the NTSB in his or her individual capacity whom the Department of Justice or the NTSB has agreed to represent; or (4) the United States is a party to litigation, and the NTSB determines that the records are both relevant and necessary to the litigation and the use of such records is deemed by the NTSB to be for a purpose that is compatible with the purpose for which the records were collected.

10. Records may be disclosed to the National Archives and Records Administration or General Services Administration for records management inspections conducted under 44 U.S.C. 2904, 2906.

11. Records may be disclosed to appropriate agencies, entities, and persons when (1) the NTSB suspects or has confirmed that there has been a breach of the system of records; (2) the NTSB has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the NTSB (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the NTSB's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

12. Records may be disclosed to another Federal agency or Federal entity, when the NTSB determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1)

responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

MEDICS records are primarily maintained electronically in a database. Some paper records may also be kept, and their location will be identified in the database. Paper records whose location is identified in MEDICS will be secured in a locked file cabinet, a secure office, or both, and will be searchable only by NTSB accident investigation number, not by PII. Paper records that are uploaded to MEDICS are destroyed. The database may be accessed from NTSB approved computers. In the future, the database may become accessible from any computer that provides for an authorized user's authentication.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Once an authorized user accesses MEDICS with his or her user ID and password, the MEDICS system is searchable by NTSB accident or incident number, accident city, accident state, accident country, and an individual's name, age, and date of birth.

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

MEDICS records that are disclosed in the NTSB's public docket pursuant to routine use number 5 will be retained permanently. All other MEDICS records will be destroyed one year after the conclusion of the investigation or safety study to which the record relates, unless required to be retained under another record retention statute, regulation or court order.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

NTSB headquarters is guarded and monitored by security personnel, cameras, a Physical Access Control System (PACS), and other physical security measures. The computerized records contained within MEDICS are maintained in a secure, password-protected, encrypted computer system. Access to and use of these records are limited to NTSB employees and contractors whose official duties require such access. NTSB personnel may access the records only when access is relevant to (1) determining the facts or

circumstances of an accident or incident; (2) determining the probable cause of an accident or incident; (3) evaluating human performance or survival factors issues arising during an accident or incident investigation; (4) providing victim and family assistance following an accident or incident; (5) carrying out special studies and investigations about transportation safety (including avoiding personal injury); and/or (6) examining techniques and methods of accident or incident investigation, and periodically publishing recommended procedures for accident or incident investigations. Electronic records are protected from unauthorized access through password identification procedures, limited access, firewalls and other system-based protection methods. This system conforms to all applicable Federal laws and regulations, as well as NTSB policies and standards, as they relate to information security and data privacy. Access is limited by user roles. Participants to an investigation may access only the records relevant to that accident, while NTSB Medical Officers will have access to all records. MEDICS will identify the location of paper records, which will be stored in a locked cabinet, a secured office, or both.

**RECORD ACCESS PROCEDURE:**

Individuals wishing to access information about themselves in this system of records may contact the Chief, Records Management Division, National Transportation Safety Board, 490 L'Enfant Plaza SW, Washington, DC 20594. Individuals must comply with NTSB regulations regarding the Privacy Act, 49 CFR part 802, and must furnish the following information for their records to be located and identified:

1. Full name(s).
2. Date of birth.
3. If known, the date and location of the accident, incident, or occurrence, or the NTSB investigation identifier(s) for the investigation(s) in which the NTSB created or obtained the record.
4. Signature.

**CONTESTING RECORD PROCEDURE:**

Individuals wishing to amend their records should contact the agency office identified in the Record Access Procedure section and furnish such identifying information described in that section to identify the records to be amended. Individuals seeking amendment of their records must also follow the agency's Privacy Act regulations, 49 CFR part 802. Where the requested amendment implicates information provided by a third-party source, the agency will refer the

individual to the source from which the agency obtained the information. The NTSB is not authorized to amend records from non-agency sources. Additionally, the NTSB is not authorized to direct a non-agency source to change or alter records. Because medical practitioners may provide differing but equally valid medical judgments and opinions when making medical evaluations of an individual's health status, review of requests from individuals seeking amendment of their medical records, beyond administrative correction such as association of a medical record with an incorrect individual, may be limited to consideration of including the differing opinion in the record rather than attempting to determine whether the original opinion is accurate.

**NOTIFICATION PROCEDURE:**

Individuals wishing to inquire about whether this system of records contains information about them may contact the agency office listed in the Record Access Procedure section, and provide the identifying information described in that section.

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

82 FR 23075.

Dated: September 20, 2018.

**Robert L. Sumwalt, III,**  
*Chairman.*

[FR Doc. 2018-20821 Filed 9-24-18; 8:45 am]

**BILLING CODE 7533-01-P**

**NUCLEAR REGULATORY COMMISSION**

**[Docket No. 40-8964; NRC-2012-0214]**

**Cameco Resources; Smith Ranch-Highland Uranium Project**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Environmental assessment and finding of no significant impact; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is considering the renewal of NRC source materials license SUA-1548, to authorize continued uranium in-situ recovery (ISR) operations at the sites under the Smith Ranch-Highland Uranium Project (Smith Ranch Project) (Docket No. 40-8964). The NRC has prepared an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this licensing action.

**DATES:** The EA referenced in this document is available on September 25, 2018.

**ADDRESSES:** Please refer to Docket ID NRC-2012-0214 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-2012-0214. Address questions about NRC dockets to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto: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 "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in 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:** James Park, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-6954; email: [James.Park@nrc.gov](mailto:James.Park@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

The NRC is considering the renewal of NRC source materials license No. SUA-1548 issued to Power Resources Inc. (doing business as Cameco Resources [Cameco]). License SUA-1548 authorizes Cameco to conduct ISR operations at the following four sites under the Smith Ranch Project located in Wyoming: The Smith Ranch site in Converse County (which encompasses the contiguous Smith Ranch, Highland, and Reynolds Ranch properties); the North Butte remote satellite site in Campbell County; the Ruth remote satellite site in Johnson County; and the Gas Hills remote satellite site in Fremont and Natrona Counties.

Therefore, as required by part 51 of title 10 of the *Code of Federal Regulations* (10 CFR part 51), "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the NRC performed an EA. Based on the results of the EA, the NRC has determined not to prepare an environmental impact statement (EIS) for the amendment, and is issuing a FONSI.

**II. Environmental Assessment**

*Description of the Proposed Action*

The proposed action would allow Cameco to continue ISR operations at the four sites under the Smith Ranch Project. As proposed, Cameco would continue to recover uranium from subsurface uranium deposits using the ISR process, open new wellfield areas for additional uranium recovery, perform aquifer restoration in wellfields where uranium recovery has ended, and conduct decommissioning activities as site-wide activities wind down. Additionally, Cameco requested NRC approval of increased ground water flowrates at certain project sites and the commencement of previously approved uranium recovery at the Reynolds Ranch satellite and at the Gas Hills remote satellite site. The proposed action is in accordance with the licensee's application dated February 1, 2012 (ADAMS Accession Nos. ML12234A537 and ML12234A539).

*Need for the Proposed Action*

The proposed action would allow Cameco to continue recovering uranium at the Smith Ranch Project sites. The licensee would process the recovered uranium into yellowcake at the existing central processing plant currently located on the Smith Ranch property and at the central processing facility located on the Highland property. Yellowcake is the uranium oxide product of the ISR milling process that is used to produce various products, including fuel for commercially-operated nuclear power reactors.

*Environmental Impacts of the Proposed Action*

The NRC staff has assessed the potential environmental impacts from Cameco's continued ISR-related construction, operation, aquifer restoration, and decommissioning activities at the Smith Ranch Project sites. The NRC staff assessed the impacts of the proposed action on land use; historical and cultural resources; visual and scenic resources; climatology, meteorology and air quality; geology, minerals, and soils;

water resources; ecological resources; socioeconomics; noise; traffic and transportation; public and occupational health and safety; and waste management. Impacts to all resources except ground water and noise were determined to be SMALL (*i.e.*, not detectable or minor); ground water impacts were determined to be SMALL to MODERATE and noise impacts MODERATE (*i.e.*, sufficient to alter noticeably, but not to destabilize, important attributes of the resource) to onsite workers and wildlife. The NRC staff concluded that renewal of source materials license SUA-1548 for the Smith Ranch Project would not significantly affect the quality of the human environment. Approval of the proposed action would not result in an increased radiological risk to public health or the environment.

*Environmental Impacts of the Alternatives to the Proposed Action*

As an alternative to the proposed action, the staff considered denial of the proposed license renewal (*i.e.*, the "No-Action" alternative). Under the No-Action Alternative, Cameco would transition ongoing ISR operations at the Smith Ranch and Highland properties and at the North Butte remote satellite site from active uranium recovery to aquifer restoration and decommissioning. A much smaller amount of yellowcake would be produced, resulting from aquifer restoration activities.

Decommissioning activities also would occur at the Reynolds Ranch satellite and the Ruth and Gas Hills remote satellite sites to remove existing infrastructure. Cameco would be required by 10 CFR part 40.42(d) to submit a detailed decommissioning plan to the NRC staff for review and approval at least 12 months before the planned commencement of final decommissioning. The NRC concluded that environmental impacts from the No-Action Alternative would be not significant.

*Agencies and Persons Consulted*

In accordance with its stated policy, on August 8, 2018, the staff provided the Wyoming Department of Environmental Quality (WDEQ) and the Wyoming State Historic Preservation Office (WY SHPO), with the draft EA for review and comment (ADAMS Accession Nos. ML18211A382 and ML18215A054). On August 29, 2018, the WDEQ stated that it had no comment on the draft EA, but noted one typographical error in the NRC's transmittal letter (ADAMS Accession No. ML18247A356). The WY SHPO also

responded on August 29, 2018, stating that the WY SHPO would not be commenting, considering its understanding that Section 106 consultation was completed during the original licensing for the project (ADAMS Accession No. ML18242A349).

On August 9, 2018, the NRC staff made sections of the draft EA concerning historic and cultural resources available on the NRC public web page for the Smith Ranch Project for public comment at <https://www.nrc.gov/materials/uranium-recovery/license-apps/smith-ranch/section106-smith-ranch.html>. On the same date, the NRC staff also made these same sections of the draft EA available to the Tribal Historic Preservation Officers (THPOs) from 27 Native American Tribes for their review and comment.

No comments were received from members of the public. In response to comments received from the THPO for the Northern Arapaho Tribe (ADAMS Accession No. ML18247A228), the NRC staff hosted two conference calls, on August 28 and 30, 2018, to discuss the staff's approach concerning protection of historic and cultural resources (ADAMS Accession No. ML18243A262); no THPOs attended these calls. The NRC staff also held a conference call with the Northern Cheyenne THPO on August 31, 2018 (ADAMS Accession No. ML18260A046). No written comments were received from the Northern Cheyenne THPO. However, the NRC staff addressed the Northern Arapaho THPO's comments provided on August 31, 2018, conference call in the final EA.

#### *Additional Information*

The NRC staff conducted its environmental review in accordance with 10 CFR part 51, which implements the requirements of the National Environmental Policy Act of 1969, as amended (NEPA) and following the NRC staff guidance in NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs" (ADAMS Accession No. ML032450279).

In May 2009, the NRC staff issued NUREG-1910, "Generic Environmental Impact Statement for In-Situ Leach Uranium Milling Facilities" (herein referred to as the GEIS) (ADAMS Accession No. ML15093A368 and ML15093A486). In the GEIS, the NRC staff assessed the potential environmental impacts from construction, operation, aquifer restoration, and decommissioning of an in-situ leach uranium milling facility (also known as an ISR facility) located

in four specific geographic regions of the western United States. Smith Ranch Project properties are located in two of these four regions.

Where applicable, this EA incorporates by reference relevant portions from the GEIS, and uses site-specific information from Cameco's license renewal application and responses to NRC staff requests for additional information, and from independent sources to fulfill the requirements in 10 CFR 51.20(b)(8).

License SUA-1548 authorizes Cameco to conduct ISR operations at four properties under the Smith Ranch Project located in Wyoming: The contiguous Smith Ranch, Highland, and Reynolds Ranch properties in Converse County; the North Butte remote satellite site in Campbell County; the Ruth remote satellite site in Johnson County; and the Gas Hills remote satellite site in Fremont and Natrona Counties.

In the EA, the NRC staff assessed the potential environmental impacts from the continued construction, operation, aquifer restoration, and decommissioning of the sites under the Smith Ranch Project. The NRC staff assessed the impacts of the proposed action on land use; historical and cultural resources; visual and scenic resources; climatology, meteorology and air quality; geology, minerals, and soils; water resources; ecological resources; socioeconomic; noise; traffic and transportation; public and occupational health and safety; and waste management.

In addition to the action proposed by the licensee, the NRC staff addressed the No-Action Alternative that serves as a baseline for comparison of the potential environmental impacts of the proposed action. Under the No-Action Alternative, the NRC staff would deny renewal of License SUA-1548.

After weighing the impacts of the proposed license renewal and comparing to the No-Action Alternative, the NRC staff, in accordance with 10 CFR 51.91(d), sets forth its NEPA recommendation regarding the proposed action (granting the NRC license renewal request for the Smith Ranch Project). Unless safety issues mandate otherwise, the NRC staff recommendation related to the environmental aspects of the proposed action is that a renewed NRC license be issued. The EA for the proposed renewal of License SUA-1548 may be accessed at ADAMS Accession No. ML18257A071.

### **III. Finding of No Significant Impact**

Based on its review of the proposed action, and in accordance with the

requirements in 10 CFR part 51, the NRC staff has determined that renewal of source materials license SUA-1548 for the Smith Ranch Project would not significantly affect the quality of the human environment. In its license renewal request, Cameco proposed increased ground water flowrates at certain of the project properties with previously approved uranium recovery to commence at the Reynolds Ranch satellite and at the Gas Hills remote satellite site. No other significant changes in Cameco's authorized operations for the Smith Ranch Project were requested. Approval of the proposed action would not result in an increased radiological risk to public health or the environment. The NRC staff has determined that pursuant to 10 CFR 51.31, preparation of an EIS is not required for the proposed action and that, pursuant to 10 CFR 51.32, a FONSI is appropriate.

Dated at Rockville, Maryland, this 20th day of September 2018.

For the Nuclear Regulatory Commission.

**Craig G. Erlanger,**

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

[FR Doc. 2018-20793 Filed 9-24-18; 8:45 am]

**BILLING CODE 7590-01-P**

## **NUCLEAR REGULATORY COMMISSION**

**[NRC-2018-0208]**

### **Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Biweekly notice.

**SUMMARY:** Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from August 28, 2018 to September 10, 2018. The last biweekly notice was published on September 11, 2018.

**DATES:** Comments must be filed by October 25, 2018. A request for a hearing must be filed by November 26, 2018.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0208. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov). For technical questions, contact the individual(s) 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:** Kay Goldstein, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-1506, email: [Kay.Goldstein@nrc.gov](mailto:Kay.Goldstein@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Obtaining Information and Submitting Comments**

*A. Obtaining Information*

Please refer to Docket ID NRC-2018-0208 facility name, unit number(s), plant docket number, application date, and subject 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-2018-0208.
- *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 "Begin Web-based ADAMS Search." For problems with ADAMS, please contact

the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in 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-2018-0208, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC 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. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination.**

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, 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. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period 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.

*A. 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.

### *B. 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](mailto: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](mailto: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 these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

*Southern Nuclear Operating Company, Inc., Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama*

*Date of amendment request:* July 27, 2018. A publicly-available version is in ADAMS under Accession No. ML18208A619.

*Description of amendment request:* The proposed amendment would modify Technical Specification requirements to permit use of Risk Informed Completion Times in accordance with NEI 06-09, Revision 0-A, "Risk-Informed Technical Specifications Initiative 4b, Risk-Managed Technical Specifications (RMTS) Guidelines."

*Basis for proposed no significant hazards consideration determination:*

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment [change] involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change permits the extension of completion times provided risk is assessed and managed within the Risk Informed Completion Time Program. The proposed change does not involve a significant increase in the probability of an accident previously evaluated because the changes involve no change to the plant or its mode of operation. The proposed change does not increase the consequences of an accident because the design-basis mitigation function of the affected systems is not changed and the consequences of an accident during the extended completion time are no different from those during the existing COMPLETION TIME.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed TS revision does not change the design, configuration, or method of plant operation. The proposed change does not involve a physical alteration of the plant in that no new or different kind of equipment will be installed.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change permits the extension of completion times provided risk is assessed and managed within the Risk Informed Completion Time Program. The proposed change implements a risk-informed configuration management program to assure that adequate safety margins are maintained. Application of these new specifications and the configuration management program considers cumulative effects of multiple systems or components being out of service and does so more effectively than the current TS.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Millicent Ronnlund, Vice President and General

Counsel, Southern Nuclear Operating Company, Inc., P.O. Box 1295, Birmingham, AL 35201-1295.

*Southern Nuclear Operating Company, Docket Nos. 52-025 and 52-026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia*

*Date of amendment request:* July 19, 2018. A publicly-available version is in ADAMS under Accession No. ML18200A415.

*Description of amendment request:* The amendment request proposes changes to combined license Appendix C (and plant-specific design control document Tier 1) to revise Inspections, Tests, Analysis, and Acceptance Criteria (ITAAC) related to flow testing of low pressure makeup from the cask loading pit to the reactor coolant system via the normal residual heat removal system (RNS) and RNS pump testing at reduced inventory.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed changes to the RNS ITAAC revise the acceptance criteria for flow testing of low pressure makeup from the CLP [cask loading pit] to the RCS [reactor coolant system] (via RNS) and clarify the acceptance criteria for RNS pump flow testing at reduced inventory. The proposed changes do not have any adverse effects on the design functions of the RNS. The probabilities of accidents evaluated in the UFSAR [Updated Safety Analysis Report] are not affected.

The changes do not adversely impact the support, design, or operation of mechanical and fluid systems. The changes do not impact the support, design, or operation of any safety-related structures. There is no change to the plant systems or response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to normal operation or postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor do the proposed changes create any new accident precursors.

Therefore, the requested amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed changes to the RNS ITAAC revise the acceptance criteria for flow testing

of low pressure makeup from the CLP to the RCS (via RNS) and clarify the acceptance criteria for RNS pump flow testing at reduced inventory. The proposed changes do not have any adverse effects on the design function of the RNS, the structures and systems in which the RNS is used, or any other SSC [structure system or component] design functions or methods of operation that result in a new failure mode, malfunction, or sequence of events that affect safety-related or non-safety related equipment. This activity does not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that result in significant fuel cladding failures.

Therefore, the requested amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The proposed changes to the RNS ITAAC revise the acceptance criteria for flow testing of low pressure makeup from the CLP to the RCS (via RNS) and clarify the acceptance criteria for RNS pump flow testing at reduced inventory.

Because no safety analysis or design basis acceptance limit/criterion is challenged or exceeded by these changes, no significant margin of safety is reduced. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203-2015.

*NRC Branch Chief:* Jennifer Dixon-Herrity.

*Southern Nuclear Operating Company, Docket Nos. 52-025 and 52-026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia*

*Date of amendment request:* August 10, 2018. A publicly-available version is in ADAMS under Accession No. ML18222A254.

*Description of amendment request:* The requested amendment proposes changes to Combined License Appendix A, Technical Specifications, to change Technical Specifications Limiting Condition for Operation (LCO) 3.1.8, "Physics Tests Exception—Mode 2," related to Functions of LCO 3.3.1, "Reactor Trip System (RTS) Instrumentation," for which the required number of channels may be reduced from 4 channels to 3 channels, to include Function 4. Additionally, for LCO 3.8.3, "Inverters—Operating," the

request proposes to make an editorial nomenclature change from "constant voltage source transformer" to "voltage regulating transformer."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed changes do not involve changes to current plant design or safety analysis assumptions. These changes provide Technical Specifications consistency with the approved plant design and safety analysis assumptions. The changes do not affect the operation of any systems or equipment that initiate an analyzed accident or alter any structures, systems, and components (SSCs) accident initiator or initiating sequence of events. The proposed changes do not adversely impact the ability of any SSCs provided for, or credited in, mitigating any analyzed accident. Therefore, the requested amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed changes do not involve changes to current plant design or safety analysis assumptions. These changes provide Technical Specifications consistency with the approved plant design and safety analysis assumptions. The proposed changes do not adversely affect plant protection instrumentation systems, and do not affect the design function, support, design, or operation of mechanical and fluid systems. The proposed changes do not result in a new failure mechanism or introduce any new accident precursors. No design function described in the Updated Final Safety Analysis Report (UFSAR) is affected by the proposed changes. Therefore, the requested amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The proposed changes do not involve changes to current plant design or safety analysis assumptions. These changes provide Technical Specifications consistency with the approved plant design and safety analysis assumptions. No safety analysis or design basis acceptance limit/criterion is involved. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are

satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

*NRC Branch Chief:* Jennifer Dixon-Herrity.

*Southern Nuclear Operating Company, Inc., Docket Nos.: 52–025 and 52–026, Vogtle Electric Generating Plant (VEGP) Units 3 and 4, Burke County, Georgia*

*Date of amendment request:* August 3, 2018. A publicly-available version is in ADAMS under Accession No. ML18215A382.

*Description of amendment request:* The requested amendment requires changes to the Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document (DCD) Tier 2\* and Tier 2 information and related changes to the VEGP Units 3 and 4 Combined License (COL) and COL Appendix C (and corresponding plant-specific DCD Tier 1) information. Specifically, the requested amendment includes changes to credit previously completed first plant only and first three plant only testing as described in the licensing basis documents, including COL Condition 2.D.(2)(a) and plant-specific Tier 1 Section 2.1.3. In particular, the proposed changes would revise the COL to delete conditions requiring the following tests: In-Containment Refueling Water Storage Tank (IRWST) Heatup Test, Reactor Vessel Internals Vibration Testing, and Core Makeup Tank (CMT) Heated Recirculation Tests. The documentation to establish a valid prototype reactor internals in accordance with Regulatory Guide 1.20 is also included.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change does not affect the operation of any systems or equipment that initiates an analyzed accident or alter any structures, systems, or components (SSC) accident initiator or initiating sequence of events. The proposed changes remove first plant and first three plant only tests including the IRWST heatup test, reactor vessel internals vibration testing, and CMT recirculation tests based on the successful

completion of the tests at the lead AP1000 units. The change does not adversely affect any methodology which would increase the probability or consequences of a previously evaluated accident.

The change does not impact the support, design, or operation of mechanical or fluid systems. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to predicted radioactive releases due to normal operation or postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor does the proposed change create any new accident precursors.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of a previously evaluated accident.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change does not affect the operation of any systems or equipment that may initiate a new or different kind of accident, or alter any SSC such that a new accident initiator or initiating sequence of events is created.

The proposed change credits previously completed first plant and first three plant only tests including the IRWST heatup test, reactor vessel internals vibration testing, and CMT recirculation tests based on the successful completion of the tests at the lead AP1000 units. The proposed changes do not adversely affect any design function of any SSC design functions or methods of operation in a manner that results in a new failure mode, malfunction, or sequence of events that affect safety-related or non-safety-related equipment. This activity does not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that result in significant fuel cladding failures.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change maintains existing safety margin and provides adequate protection through continued application of the existing requirement in the UFSAR. The proposed change satisfies the same design functions in accordance with the same codes and standards as stated in the UFSAR. This change does not adversely affect any design code, function, design analysis, safety analysis input or result, or design/safety margin. No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the proposed change.

Since no safety analysis or design basis acceptance limit/criterion is challenged or exceeded by this change, no significant margin of safety is reduced.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North Birmingham, AL 35203–2015.

*NRC Branch Chief:* Jennifer Dixon-Herrity.

### III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

*Energy Northwest, Docket No. 50-397, Columbia Generating Station, Benton County, Washington*

*Date of amendment request:* December 12, 2017.

*Brief description of amendment:* The amendment revised Technical Specification (TS) 3.6.4.1, "Secondary Containment." The changes are based on Technical Specifications Task Force (TSTF) Traveler TSTF-551, Revision 3, "Revise Secondary Containment Surveillance Requirements."

*Date of issuance:* September 6, 2018.

*Effective date:* As of its date of issuance and shall be implemented within 60 days from the date of issuance.

*Amendment No.:* 250. A publicly-available version is in ADAMS under Accession No. ML18221A107; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. NPF-21:* The amendment revised the Renewed Facility Operating License and Technical Specifications.

*Date of initial notice in Federal Register:* March 13, 2018 (83 FR 10915).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 6, 2018.

*No significant hazards consideration comments received:* No.

*Exelon Generation Company, LLC, Docket No. 50-244, R. E. Ginna Nuclear Power Plant, Wayne County, New York*

*Date of amendment request:* October 31, 2017.

*Brief description of amendment:* The amendment revised Technical Specification (TS) Surveillance Requirement 3.8.4.3, "DC [Direct Current] Sources—MODES 1, 2, 3, and 4," to allow for a modified performance discharge test.

*Date of issuance:* August 31, 2018.

*Effective date:* As of the date of issuance and shall be implemented within 60 days of issuance.

*Amendment No.:* 130. A publicly-available version is in ADAMS under Accession No. ML18214A176; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. DPR-18:* Amendment revised the Renewed Facility Operating License and TS.

*Date of initial notice in Federal Register:* January 2, 2018 (83 FR 168).

The Commission's related evaluation of the amendment is contained in a

Safety Evaluation dated August 31, 2018.

*No significant hazards consideration comments received:* No.

*Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station (CNS), Nemaha County, Nebraska*

*Date of amendment request:* May 10, 2018.

*Brief description of amendment:* The amendment modified CNS Technical Specification 2.1.1.2 by revising the values of the safety limit minimum critical power ratio for two recirculation loop operation and for single recirculation loop operation to reflect the results of a cycle-specific calculation.

*Date of issuance:* September 6, 2018.

*Effective date:* As of the date of issuance and shall be implemented prior to startup from Refuel Outage 30.

*Amendment No.:* 261. A publicly-available version is in ADAMS under Accession No. ML18218A483; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. DPR-46:* The amendment revised the Renewed Facility Operating License and Technical Specifications.

*Date of initial notice in Federal Register:* July 2, 2018 (83 FR 30984).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 6, 2018.

*No significant hazards consideration comments received:* No.

*Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366, Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2, Appling County, Georgia*

*Date of amendment request:* July 10, 2017. A publicly-available version is in ADAMS under Accession No. ML17191B163.

*Brief description of amendments:* The amendments revise the Technical Specifications (TSs) by: (1) Adding a Note to the Surveillance Requirements (SRs) of TS 3.7.7 to clarify that the SRs are not required to be met when the Limiting Condition for Operation (LCO) does not require the Main Turbine Bypass System to be operable; (2) clarifying that LCO 3.2.3, "LINEAR HEAT GENERATION RATE," also has limits for an inoperable Main Turbine Bypass System that are made applicable as specified in the Core Operating

Limits Report; and (3) deleting an outdated footnote for LCO 3.2.3.

*Date of issuance:* August 29, 2018.

*Effective date:* As of the date of issuance and shall be implemented within 90 days from the date of issuance.

*Amendment Nos.:* Unit 1—292, Unit 2—237. A publicly-available version is in ADAMS under Accession No. ML18222A296; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Renewed Facility Operating License Nos. DPR-57 and NPF-5:* Amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

*Date of initial notice in Federal Register:* November 21, 2017 (82 FR 55412).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 29, 2018.

*No significant hazards consideration comments received:* No.

*Southern Nuclear Operating Company, Docket Nos. 52-025 and 52-026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia*

*Date of amendment request:* January 31, 2018, as supplemented by letters dated April 25, and June 21, 2018.

*Description of amendment:* The amendments make changes to the VEGP Units 3 and 4 Combined Operating License (COL) in the form of departure from the approved COL Appendix A, Technical Specifications. The amendments make changes to COL Appendix A, Surveillance Requirement 3.8.7.6 to align the test frequency with the expected life of the AP1000 Class 1E batteries.

*Date of issuance:* The amendments were issued on July 26, 2018.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 135 (Unit 3) and 134 (Unit 4). A publicly-available version is in ADAMS under Accession No. ML18173A301; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Facility Combined Licenses Nos. NPF-91 and NPF-92:* Amendment revised the Facility Combined License.

*Date of initial notice in Federal Register:* April 24, 2018 (83 FR 17858). The supplements dated April 25, 2018 and June 21, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's

original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in the Safety Evaluation dated July 26, 2018.

*No significant hazards consideration comments received:* No.

*Southern Nuclear Operating Company, Docket Nos. 52-025 and 52-026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia*

*Date of amendment request:* June 15, 2018 and supplemented on June 25, 2018 and July 10, 2018.

*Description of amendment:* The amendment revises commitments related to the construction fitness-for-duty (FFD) program described in the VEGP Units 3 and 4 Updated Final Safety Analysis Report. Specifically, the change involves the creation of a new type of FFD Authorization that allows construction workers temporary access to the construction site pending completion of all pre-access FFD requirements. The individuals will not be given assignments to work on safety or security-related structures, systems, and components prior to the completion of the FFD requirements.

*Date of issuance:* August 29, 2018.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 141 (Unit 3) and 140 (Unit 4). A publicly-available version is in ADAMS under Accession No. ML18214A659; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Facility Combined Licenses No. NPF-91 and NPF-92:* Amendment revised the Facility Combined Licenses.

*Date of initial notice in Federal Register:* June 27, 2018 (83 FR 30199). The supplements dated June 25, 2018, and July 10, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in the Safety Evaluation dated August 29, 2018.

*No significant hazards consideration comments received:* No.

*Tennessee Valley Authority (TVA) Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant (SQN), Units 1 and 2, Hamilton County, Tennessee*  
*TVA Docket Nos. 50-390 and 50-391, Watts Bar Nuclear Plant (WBN), Units 1 and 2, Rhea County, Tennessee*

*Date of amendment request:* August 7, 2017.

*Brief description of amendments:* The amendments revised technical specifications (TSs) limiting conditions for operation and surveillance requirements related to the reactor trip system instrumentation for all four units.

*Date of issuance:* August 30, 2018.

*Effective date:* As of the date of issuance and shall be implemented in 30 days.

*Amendment Nos.:* SQN, 343 (Unit 1) and 336 (Unit 2); and WBN, 122 (Unit 1) and 21 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18197A307; documents related to these amendments are listed in the Safety Evaluation (SE) enclosed with the amendments.

*Renewed Facility Operating License Nos. DPR-77, DPR-79 and Facility Operating License Nos. NPF-90 and NPF-96:* Amendments revised the Facility Operating Licenses and TSs.

*Date of initial notice in Federal Register:* November 21, 2017 (82 FR 55416).

The Commission's related evaluation of the amendments is contained in SE dated August 30, 2018.

*No significant hazards consideration comments received:* No.

Dated at Rockville, Maryland, on September 14, 2018.

For the Nuclear Regulatory Commission.

**Kathryn M. Brock**,  
*Acting Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2018-20333 Filed 9-24-18; 8:45 am]

**BILLING CODE 7590-01-P**

## **NUCLEAR REGULATORY COMMISSION**

**[NRC-2018-0001]**

### **Sunshine Act Meetings**

**TIME AND DATE:** Weeks of September 24, October 1, 8, 15, 22, 29, 2018.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and closed.

**MATTERS TO BE CONSIDERED:**

### **Week of September 24, 2018**

*Thursday, September 27, 2018*

10:00 a.m. Strategic Programmatic Overview of the Operating Reactors Business Line (Public) (Contact: Trent Wertz: 301-415-1568).

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

### **Week of October 1, 2018—Tentative**

There are no meetings scheduled for the week of October 1, 2018.

### **Week of October 8, 2018—Tentative**

*Thursday, October 11, 2018*

9:00 a.m. Strategic Programmatic Overview of the Decommissioning and Low-Level Waste and Spent Fuel Storage and Transportation Business Lines (Public) (Contact: Matthew Meyer: 301-415-6198).

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

### **Week of October 15, 2018—Tentative**

There are no meetings scheduled for the week of October 15, 2018.

### **Week of October 22, 2018—Tentative**

*Thursday, October 25, 2018*

9:00 a.m. Briefing on Digital Instrumentation and Control (Public) (Contact: Jason Paige: 301-415-1474).

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

### **Week of October 29, 2018—Tentative**

There are no meetings scheduled for the week of October 29, 2018.

### **CONTACT PERSON FOR MORE INFORMATION:**

For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at [Denise.McGovern@nrc.gov](mailto:Denise.McGovern@nrc.gov). The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: <http://www.nrc.gov/public-involve/public-meetings/schedule.html>.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301-287-0739, by videophone at 240-428-3217, or by email at [Kimberly.Meyer-Chambers@nrc.gov](mailto:Kimberly.Meyer-Chambers@nrc.gov). Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or you may email [Patricia.Jimenez@nrc.gov](mailto:Patricia.Jimenez@nrc.gov) or [Wendy.Moore@nrc.gov](mailto:Wendy.Moore@nrc.gov).

Dated at Rockville, Maryland, this 20th day of September, 2018.

For the Nuclear Regulatory Commission.

**Denise L. McGovern,**

*Policy Coordinator, Office of the Secretary.*

[FR Doc. 2018-20888 Filed 9-21-18; 11:15 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

RIN 3150-A101

[NRC-2014-0137]

### Regulatory Guidance and Technical Basis on the Alternate Pressurized Thermal Shock Rule

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Regulatory guide; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 0 to Regulatory Guide (RG) 1.230, “Regulatory Guidance on the Alternate Pressurized Thermal Shock Rule” and the associated technical basis, NUREG-2163, “Technical Basis for Regulatory Guidance on the Alternate Pressurized Thermal Shock Rule.” This guidance describes a method that the NRC staff considers acceptable to permit use of the alternate fracture toughness requirements for protection against pressurized thermal shock events for pressurized water reactor pressure vessels.

**DATES:** Revision 0 to RG 1.230 is available on September 25, 2018.

**ADDRESSES:** Please refer to Docket ID NRC-2014-0137 when contacting the NRC about the availability of information regarding this document. You may obtain publically-available information related to this document, using the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2014-0137. Address questions about docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov). For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System*

(ADAMS): You may obtain publicly-available documents online in the ADAMS Public Document collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. Revision 0 to Regulatory Guide 1.230, and the regulatory analysis may be found in ADAMS under Accession No. ML15344A402 and ML14056A013 respectively. Revision 0 to NUREG-2163 may be found in ADAMS under Accession No. ML18255A118.

- *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.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

#### FOR FURTHER INFORMATION CONTACT:

Mark Kirk, Office of Nuclear Regulatory Research, telephone: 301-415-2456, email: [Mark.Kirk@nrc.gov](mailto:Mark.Kirk@nrc.gov), and Stephen Burton, Office of Nuclear Regulatory Research, telephone: 301-415-7000, email: [Stephen.Burton@nrc.gov](mailto:Stephen.Burton@nrc.gov). Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

The NRC is issuing a new guide in the NRC’s “Regulatory Guide” series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency’s regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 0 of RG 1.230 was issued with a temporary identification of Draft Regulatory Guide, DG-1299. This RG is being issued to describe a method that the staff of the NRC considers acceptable to meet the alternate fracture toughness requirements for protection against pressurized thermal shock (PTS) events for pressurized water reactor (PWR) reactor pressure vessels (RPVs) in section 50.61a of title 10 of the *Code of Federal Regulations* (10 CFR), “Alternate Fracture Toughness

Requirements for Protection against Pressurized Thermal Shock Events.” The alternate PTS requirements are based on updated analysis methods, whereas the requirements in 10 CFR 50.61, “Fracture Toughness Requirements for Protection against Pressurized Thermal Shock Events,” are based on overly conservative probabilistic fracture mechanics analyses.

NUREG-2163 explains the basis for the requirements that establish the threshold conditions to permit use of 10 CFR 50.61a in lieu of 10 CFR 50.61 and describes methods by which the following four requirements can be met: (1) Criteria relating to the date of construction and design requirements, (2) criteria relating to evaluation of plant specific surveillance data, (3) criteria relating to inservice inspection data and non-destructive examination requirements, and (4) criteria relating to alternate limits on embrittlement. Revision 0 of RG 1.230 also describes these methods in a manner consistent with NUREG-2163.

##### II. Additional Information

The DG-1299 and draft NUREG-2163 were published in the **Federal Register** on March 13, 2015 (80 FR 13449) for a 60-day public comment period. The public comment period closed on May 12, 2015. Public comments on DG-1299 and draft NUREG-2163 and the NRC staff responses to the public comments are available in ADAMS under Accession No. ML15344A398.

##### III. Congressional Review Act

RG 1.230 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.

##### IV. Backfitting and Issue Finality

The RG 1.230 provides guidance on the methods acceptable to the NRC for complying with the NRC’s regulations associated with alternate fracture toughness requirements for protection against PTS events for PWR RPVs. NUREG-2163 provides technical bases that support the RG. The RG, like the alternate PTS requirements of 10 CFR 50.61a, applies to holders of operating licenses for a PWR whose construction permit was issued before February 3, 2010.

Issuance of this RG and NUREG does not constitute backfitting under 10 CFR part 50. As discussed in the “Implementation” section of RG 1.230, the NRC has no current intention to impose the RG on current holders of 10

CFR part 50 operating licenses. Also, this RG is the first guidance issued for the 10 CFR 50.61a final rule, which itself was an alternative to 10 CFR 50.61 and therefore not a backfit on current licensees (75 FR 1322; January 4, 2010). The first issuance of guidance on a newly-added rule does not constitute backfitting when, as here, the guidance is consistent with the regulatory requirements in the newly-added rule, and the backfitting considerations applicable to the newly-added rule apply to this guidance. Therefore, issuance of RG 1.230 does not constitute backfitting within the definition provided in 10 CFR 50.109(a)(1).

Dated at Rockville, Maryland, this 20th day of September 2018.

For the Nuclear Regulatory Commission.

**Thomas H. Boyce,**

*Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2018-20827 Filed 9-24-18; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[NRC-2017-0060]

### Information Collection: NRC Form 361, Reactor Plant Event Notification Worksheet; NRC Form 361A, Fuel Cycle and Materials Event Notification Worksheet; NRC Form 361N, Non-Power Reactor Event Notification Worksheet

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed information collection; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) invites public comment on this proposed collection of information. The information collection is entitled, “NRC Form 361, Reactor Plant Event Notification Worksheet; NRC Form 361A, Fuel Cycle and Materials Event Notification Worksheet; NRC Form 361N, Non-Power Reactor Event Notification Worksheet.”

**DATES:** Submit comments by November 26, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

**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-2017-0060. Address questions about docket IDs in *Regulations.gov* to Jennifer Borges;

telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: O-1 F13, 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:

David Cullison, Office of the Chief Information Officer, Mail Stop: O-1 F13, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Obtaining Information and Submitting Comments

#### A. Obtaining Information

Please refer to Docket ID NRC-2017-0060 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 Docket ID NRC-2017-0060. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2017-0060 on this website.

- *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 “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML18038A512. The supporting statement is available in ADAMS under Accession No. ML18038A511.

- *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 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](mailto:Infocollects.Resource@nrc.gov).

#### B. Submitting Comments

Please include Docket ID NRC-2017-0060 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS, and 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. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB’s approval for the information collection summarized below.

1. *The title of the information collection:* “NRC Form 361, Reactor Plant Event Notification Worksheet; NRC Form 361A, Fuel Cycle and Materials Event Notification Worksheet; NRC Form 361N, Non-Power Reactor Event Notification Worksheet.”

2. *OMB approval number:* 3150-XXXX.

3. *Type of submission:* New.

4. *The form number, if applicable:* NRC Form 361, NRC Form 361A, NRC Form 361N.

5. *How often the collection is required or requested:* On occasion, as defined NRC licensee events are reportable when they occur.

6. *Who will be required or asked to respond:* Holders of NRC licenses for commercial nuclear power plants, fuel

cycle facilities, NRC material licensees, and non-power reactors.

7. *The estimated number of annual responses:* 537.

8. *The estimated number of annual respondents:* 200.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 268.5 hours.

10. *Abstract:* The NRC requires its licensees to report by telephone certain reactor events and emergencies that have potential impact to public health and safety. In order to efficiently process the information received through such reports for reactors, the NRC created Forms 361 to provide a templated worksheet for recording the information. NRC licensees are not required to fill out or submit the worksheet, but the form provides the usual order of questions and discussion to enable a licensee to prepare answers for a more clear and complete telephonic notification. Without the templated format of the NRC Forms 361, the information exchange between licensees and NRC Headquarters Operations Officers via telephone could result in delays as well as unnecessary transposition errors.

### III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 20th day of September, 2018.

For the Nuclear Regulatory Commission.

**David C. Cullison,**

*NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-20792 Filed 9-24-18; 8:45 am]

**BILLING CODE 7590-01-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2017-0187]

### Proposed Revisions to Standard Review Plan Section 14.3.3, Piping Systems and Components—Inspections, Tests, Analyses, and Acceptance Criteria

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Standard review plan-draft section revision; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is re-noticing the solicitation for public comment published in the **Federal Register** on September 11, 2017, on NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” SRP Section 14.3.3, “Piping Systems and Components—Inspections, Tests, Analyses, and Acceptance Criteria.”

**DATES:** Comments must be filed no later than November 26, 2018. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

**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-2017-0187. Address questions about docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto: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:

Mark D. Notich, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-3053, email: [Mark.Notich@nrc.gov](mailto:Mark.Notich@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

## I. Obtaining Information and Submitting Comments

### A. Obtaining Information

Please refer to Docket ID NRC-2017-0187 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-2017-0187.

- *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 “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The draft revision and current revision to NUREG-0800, Section 14.3.3, “Piping Systems and Components—Inspections, Tests, Analyses, and Acceptance Criteria,” is available in ADAMS under Accession No. ML18088A069 and ML070660622. The redline-strikeout version comparing the draft revision 1 and the current version of revision 0 is available in ADAMS under Accession No. ML18092A046.

- *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-2017-0187 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. Further Information

The NRC seeks public comment on the proposed SRP-draft section revision of Section 14.3.3, “Piping Systems and Components—Inspections, Tests, Analyses, and Acceptance Criteria.” This re-notice includes revisions initiated by the staff to address editorial issues and provide further clarification on particular issues. This revision supersedes the previous revision issued on September 11, 2017, and the staff will not be addressing previously submitted comments. Following NRC staff evaluation of public comments, the NRC intends to finalize SRP Section 14.3.3, Revision 1 in ADAMS and post it on the NRC’s public website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/>. The SRP is guidance for the NRC staff. The SRP is not a substitute for the NRC regulations, and compliance with the SRP is not required.

## III. Backfitting and Issue Finality

Issuance of this draft SRP, if finalized, would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule), or otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. The staff’s position is based upon the following considerations.

1. *The draft SRP positions, if finalized, do not constitute backfitting, inasmuch as the SRP is guidance directed to the NRC staff with respect to its regulatory responsibilities.*

The SRP provides interim guidance to the staff on how to review an application for NRC regulatory approval in the form of licensing. Changes in staff guidance intended for use by only the staff are not matters that constitute backfitting as that term is defined in 10 CFR 50.109(a)(1) or involve the issue finality provisions of 10 CFR part 52.

2. *Backfitting and issue finality—with certain exceptions discussed below—do not apply to current or future applicants.*

Applicants and potential applicants are not, with certain exceptions, the subject of either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions under 10 CFR part 52 were intended to apply to every NRC action which substantially changes the expectations of current and future applicants.

The exceptions to this general principle are applicable whenever a 10 CFR part 50 operating license applicant references a construction permit or a 10

CFR part 52 combined license applicant references a license (e.g., an early site permit) and/or an NRC regulatory approval (e.g., a design certification rule) for which specified issue finality provisions apply.

The NRC staff does not currently intend to impose the positions represented in the draft SRP section in a manner that constitutes backfitting or is inconsistent with any issue finality provision in 10 CFR part 52. If in the future the NRC staff seeks to impose a position stated in this draft SRP section in a manner that would constitute backfitting or be inconsistent with these issue finality provisions, the NRC staff must make the showing as set forth in the Backfit Rule or address the regulatory criteria for set forth in the applicable issue finality provision, as applicable, that would allow the staff to impose the position.

3. *The staff has no intention to impose the draft SRP positions on existing nuclear power plant licenses either now or in the future (absent a voluntary request for a change from the licensee, holder of a regulatory approval, or a design certification applicant).*

The NRC staff does not intend to impose or apply the positions described in this draft SRP section to existing (already issued) licenses (e.g., operating licenses and combined licenses) and regulatory approvals. Hence, this draft SRP guidance—even if considered guidance subject to the Backfit rule or the issue finality provisions in 10 CFR part 52—need not be evaluated as if it were a backfit or as being inconsistent with these issue finality provisions. If, in the future, the NRC staff seeks to impose a position in this draft SRP section on holders of already issued licenses in a manner that would constitute backfitting or does not provide issue finality as described in the applicable issue finality provision, then the staff must make the showing as set forth in the Backfit Rule or address the criteria set forth in the applicable issue finality provision, as applicable, that would allow the staff to impose the position.

Dated at Rockville, Maryland, this 20th day of September 2018.

For the Nuclear Regulatory Commission.

**Jennivine K. Rankin,**

*Acting Chief, Licensing Branch 3, Division of Licensing, Siting, and Environmental Analysis, Office of New Reactors.*

[FR Doc. 2018–20826 Filed 9–24–18; 8:45 am]

**BILLING CODE 7590-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84195; File No. SR–NYSEArca–2018–54]

### Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Commentary .01 to NYSE Arca Rule 8.600–E Relating to Certain Generic Listing Standards for Managed Fund Shares

September 19, 2018.

On July 18, 2018, NYSE Arca, Inc. (“NYSE Arca” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> a proposed rule change to amend Commentary .01 to NYSE Arca Rule 8.600–E relating to certain generic listing standards for Managed Fund Shares. The proposed rule change was published for comment in the **Federal Register** on August 7, 2018.<sup>3</sup> The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act<sup>4</sup> provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is September 21, 2018. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,<sup>5</sup> designates November 5, 2018, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>3</sup> See Securities Exchange Act Release No. 83759 (August 1, 2018), 83 FR 38753.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> *Id.*

proposed rule change (File Number SR–NYSEArca–2018–54).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>6</sup>

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–20769 Filed 9–24–18; 8:45 am]

BILLING CODE 8011–01–P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84215; File No. SR–BX–2018–044]

### Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Conform the Exchange's By-Law Provisions Regarding the Chief Regulatory Officer to Those of Its Affiliate, Nasdaq PHLX LLC

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> notice is hereby given that on September 6, 2018, Nasdaq BX, Inc. (“BX” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to conform the Exchange's By-Law provisions regarding the Chief Regulatory Officer to those of its affiliate, Nasdaq PHLX LLC.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqbx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these

statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange proposes to amend its By-Laws at Article V, Section 5.10 to conform its provisions regarding the Exchange's Chief Regulatory Officer (“CRO”) to those of its affiliate, Nasdaq PHLX LLC (“Phlx”).<sup>3</sup> By-Law Article V, Section 5.10 presently requires that an officer of the Exchange<sup>4</sup> with the position of Executive Vice President or Senior Vice President be designated as the CRO of the Exchange. The Exchange now proposes to remove the requirement that the CRO be an Executive Vice President or Senior Vice President of the Exchange. The Exchange believes that this requirement is unnecessary and notes that there may be officers of the Exchange who are well qualified to serve in the CRO role, but who may not hold the position of an Executive Vice President or Senior Vice President.<sup>5</sup> The Exchange does not seek to amend any of the current responsibilities of the CRO as set forth in Section 5.10;<sup>6</sup> rather, the proposed changes are intended to give the Exchange more flexibility to attract and retain well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President of the Exchange. As noted above, the Exchange desires to conform the requirements to become CRO in its By-Laws to those in the By-Laws of Phlx, which do not contain a similar restriction in Article IV, Section 4–7 of its By-Laws that its CRO be an Executive

<sup>3</sup> See Phlx By-Law Article IV, Section 4–7 (Chief Regulatory Officer).

<sup>4</sup> In Exhibit 5, the references to “Corporation” mean the Exchange.

<sup>5</sup> The Exchange notes that Phlx's CRO currently holds the position of Vice President.

<sup>6</sup> The CRO's responsibilities include general supervision of the regulatory operations of the Exchange, including responsibility for overseeing the Exchange's surveillance, examination, and enforcement functions and for administering any regulatory services agreements with another SRO to which the Exchange is a party. In addition, the CRO shall meet with the Regulatory Oversight Committee of the Exchange in executive session at regularly scheduled meetings of such committee, and at any time upon request of the CRO or any member of the Regulatory Oversight Committee. Unlike Phlx, the Exchange's By-Laws provide that the CRO may also serve as the General Counsel of the Exchange. See By-Law Article V, Section 5.10.

Vice President or Senior Vice President of Phlx.<sup>7</sup>

##### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>8</sup> in general, and furthers the objectives of Section 6(b)(1) of the Act,<sup>9</sup> in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that this proposal furthers the objectives of Section 6(b)(5) of the Act,<sup>10</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposed changes will remove the requirement currently in Article V, Section 5.10 of the Exchange's By-Laws that the CRO be an Executive Vice President or Senior Vice President of the Exchange. As discussed above, the current responsibilities of the CRO as provided in Article V, Section 5.10 remain unchanged under this proposal, and the CRO will continue to have general oversight of the regulatory operations of the Exchange and be obligated to meet regularly with the Regulatory Oversight Committee. The proposed rule change is intended to provide the Exchange with greater flexibility to attract and retain capable individuals who are well qualified to serve in the CRO role. In addition, the proposed amendments will have the additional benefit of bringing the Exchange's requirements on the CRO role into greater conformity with those of its affiliate, Phlx, thereby creating equivalent standards among the affiliated exchanges owned by Nasdaq, Inc. (“HoldCo”).<sup>11</sup> As such, the Exchange believes that its proposal will bring greater consistency to its rules, which is beneficial to both investors and the public interest.

<sup>7</sup> See note 5 above.

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(1).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>11</sup> The Nasdaq Stock Market LLC (“NSM”), Nasdaq ISE, LLC (“ISE”), Nasdaq GEMX, LLC (“GEMX”), and Nasdaq MRX, LLC will file similar proposals to conform their By-Laws with Phlx's By-Laws. ISE, GEMX, MRX, NSM, BX, and Phlx will hereinafter be referred to collectively as “Affiliated Exchanges.”

<sup>6</sup> 17 CFR 200.30–3(a)(31).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

### 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 proposed rule change does not address competitive issues but relates to the administration and functioning of the Exchange by allowing the Exchange greater flexibility in attracting and retaining well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>12</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>13</sup>

A proposed rule change filed under Rule 19b-4(f)(6)<sup>14</sup> normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)<sup>15</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Exchange notes that waiver of the operative delay will allow it to amend its By-Laws by September 26, 2018. The Exchange states that the boards of the Affiliated Exchanges will collectively meet on that

date to address, among other matters, certain annual corporate "housekeeping items," which the Exchange states has historically included Exchange officer appointments. As such, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.<sup>16</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-BX-2018-044 on the subject line.

#### Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2018-044. 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

<sup>16</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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-BX-2018-044 and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Brent J. Fields,**

Secretary.

[FR Doc. 2018-20762 Filed 9-24-18; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84200; File No. SR-NASDAQ-2018-076]

### Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Fees at Rule 7014

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup>, and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 13, 2018, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

<sup>17</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>12</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>13</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>14</sup> 17 CFR 240.19b-4(f)(6).

<sup>15</sup> 17 CFR 240.19b-4(f)(6)(iii).

## I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the its fees at Rule 7014 to: (i) Eliminate the requirement that a member be a market maker to participate in the Qualified Market Maker ("QMM") Program; and (ii) eliminate the additional \$0.0002 per share executed credit under the NBBO Program.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaq.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

Rule 7014 provides various Market Quality Incentive Programs available to members. The purpose of the proposed rule change is to amend Rule 7014 to: (i) Eliminate the requirement that a member be a market maker to participate in the QMM Program; and (ii) eliminate the additional \$0.0002 per share executed credit under the NBBO Program.

The Exchange initially filed the proposed pricing changes on September 4, 2018 (SR-NASDAQ-2018-071). On September 13, 2018, the Exchange withdrew that filing and submitted this filing, which makes a technical change to the proposed rule text.

#### First Change

The purpose of the first proposed rule [sic] change is to eliminate the requirement that a member be a market maker to participate in the QMM Program. A QMM is a member that makes a significant contribution to market quality by providing liquidity at the national best bid and offer ("NBBO") in a large number of stocks

for a significant portion of the day. In addition, the member must avoid imposing the burdens on Nasdaq and its market participants that may be associated with excessive rates of entry of orders away from the inside and/or order cancellation. The designation reflects the QMM's commitment to provide meaningful and consistent support to market quality and price discovery by extensive quoting at the NBBO in a large number of securities. In return for its contributions, certain financial benefits are provided to a QMM with respect to its order activity, as described under Rule 7014(e). These benefits include a lower rate charged for executions of orders in securities priced at \$1 or more per share that access liquidity on the Nasdaq Market Center.

Rule 7014(d) provides the qualification criteria a member must meet to be eligible for the QMM Program. Specifically, to be designated a QMM, a member must meet the following criteria: (1) The member is not assessed any "Excess Order Fee" under Rule 7018 during the month; (2) the member quotes at the NBBO at least 25% of the time during regular market hours in an average of at least 1,000 securities per day during the month; and (3) the member is a registered Nasdaq market maker.<sup>3</sup> The Exchange is proposing to eliminate the requirement that a member be a Nasdaq market maker to be designated as a QMM. As a consequence, any member may participate in the program if it meets the other qualification criteria of the rule.

#### Second Change

The purpose of the second proposed rule [sic] change is to eliminate the additional \$0.0002 per share executed credit under the NBBO Program at Rule 7014(g). The NBBO Program provides two rebates per share executed. The Exchange is proposing to eliminate the \$0.0002 per share executed credit, which is provided to a member for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity priced at \$1 or more. Under Rule 7014(g), to qualify for the additional \$0.0002 per share executed credit for

displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity priced at \$1 or more, a member must (i) execute shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represents 0.5% or more of Consolidated Volume<sup>4</sup> during the month, and (ii) has a ratio of at least 25% NBBO liquidity provided<sup>5</sup> to liquidity provided during the month. The Exchange has observed that no members have qualified for this credit and is consequently proposing to eliminate it.

#### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>6</sup> in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,<sup>7</sup> in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."<sup>8</sup>

Likewise, in *NetCoalition v. Securities and Exchange Commission*<sup>9</sup>

<sup>4</sup> Consolidated Volume is defined as the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member's trading activity the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member's trading activity. See Rule 7018(a).

<sup>5</sup> NBBO liquidity provided means liquidity provided from orders (other than Designated Retail Orders, as defined in Nasdaq Rule 7018), that establish the NBBO, and displayed a quantity of at least one round lot at the time of execution.

<sup>6</sup> 15 U.S.C. 78f(b).

<sup>7</sup> 15 U.S.C. 78f(b)(4) and (5).

<sup>8</sup> Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

<sup>9</sup> *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

<sup>3</sup> In 2015, the Exchange adopted the requirement under Rule 7014(d) that a member must be a market maker to be designated a QMM. See Securities Exchange Act Release No. 74725 (April 14, 2015), 80 FR 21778 (April 20, 2015) (SR-NASDAQ-2015-032). Prior to the change, a QMM need not have been a Nasdaq market maker. Thus, the QMM designation does not by itself impose a two-sided quotation obligation or convey any of the benefits associated with being a registered market maker. This is currently the case and it will continue to be the case with the elimination of the market maker requirement.

(“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.<sup>10</sup> As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”<sup>11</sup>

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’ . . . .”<sup>12</sup>

#### First Change

The Exchange believes that the fees and credits of the QMM Program remain reasonable because the Exchange is not proposing to amend them. Thus, the basis set forth when the fees were adopted remain [sic] valid. The proposed elimination of the market maker requirement is reasonable, an equitable allocation and is not unfairly discriminatory because the Exchange seeks to broaden participation in the program. When the Exchange limited the QMM Program to market makers, it noted that market makers had provided the vast majority of participation in the program and were the only market participant [sic] utilizing the program at the time.<sup>13</sup> The Exchange now seeks broader participation in the program by allowing any Nasdaq member to participate in the QMM Program that qualifies under the remaining criteria. The Exchange believes that circumstances have changed over the three years since it last allowed non-Nasdaq market makers to participate in the program, such that non-market makers may have interest in meeting the criteria required to receive the fees and credits under the QMM Program. Allowing broader participation in the QMM Program may increase the market-improving participation in the QMM Program, to the extent the number of

members participating in the program increase [sic]. As a consequence, the proposed change is reasonable, an equitable allocation and will not discriminate in any way.

#### Second Change

The Exchange believes that elimination of the \$0.0002 per share executed NBBO credit is reasonable because it eliminates a credit that the Exchange has determined to be unnecessary. In particular, the credit has not provided adequate incentive to members to meet the related qualifying requirements. The Exchange notes that the \$0.0004 per share executed NBBO Program rebate will remain, thus members will continue to have the opportunity to qualify for significant rebates under the NBBO Program.

The Exchange believes that elimination of the \$0.0002 per share executed NBBO credit is an equitable allocation and is not unfairly discriminatory because no member currently qualifies for the credit. Thus, eliminating the credit will not discriminate in any manner and the proposed change will be applied equitably among all members. Moreover, elimination of the credit from rule book will allow the Exchange to consider new incentives.

#### 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. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed changes to the incentive programs under Rule 7014 do not impose a burden on competition because the Exchange’s

execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. Elimination of the market maker qualification requirement from the QMM Program may promote competition among trading venues to the extent that allowing broader participation in the program makes the Exchange a more attractive venue on which to participate. The proposed elimination of the \$0.0002 per share executed NBBO credit will not place any burden on competition because no members currently qualify for the credit. As noted above, the credit has not served its purpose of incentivizing members to provide the market-improving participation required by the credit’s qualification criteria. Consequently, removal of the credit should not affect competition among market participants or market venues whatsoever.

#### C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.<sup>14</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

<sup>14</sup> 15 U.S.C. 78s(b)(3)(A)(ii).

<sup>10</sup> See *NetCoalition*, at 534–535.

<sup>11</sup> *Id.* at 537.

<sup>12</sup> *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

<sup>13</sup> *Supra* note 3.

• Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR–NASDAQ–2018–076 on the subject line.

#### Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2018–076. 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–NASDAQ–2018–076, and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>15</sup>

**Eduardo A. Aleman,**  
Assistant Secretary.

[FR Doc. 2018–20770 Filed 9–24–18; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84203; File No. SR–ISE–2018–79]

### Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Conform By-Law's CRO Provisions to Those of an Affiliate Exchange

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> notice is hereby given that on September 6, 2018, Nasdaq ISE, LLC (“ISE” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to conform the Exchange's By-Law provisions regarding the Chief Regulatory Officer to those of its affiliate, Nasdaq PHLX LLC (“Phlx”).

The text of the proposed rule change is available on the Exchange's website at <http://ise.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange proposes to amend its By-Laws at Article IV, Section 7 to conform its provisions regarding the Exchange's Chief Regulatory Officer (“CRO”) to those of its affiliate, Nasdaq PHLX LLC (“Phlx”).<sup>3</sup> By-Law Article IV, Section 7 presently requires that an officer of the Exchange<sup>4</sup> with the position of Executive Vice President or Senior Vice President be designated as the CRO of the Exchange. The Exchange now proposes to remove the requirement that the CRO be an Executive Vice President or Senior Vice President of the Exchange. The Exchange believes that this requirement is unnecessary and notes that there may be officers of the Exchange who are well qualified to serve in the CRO role, but who may not hold the position of an Executive Vice President or Senior Vice President.<sup>5</sup> The Exchange does not seek to amend any of the current responsibilities of the CRO as set forth in Section 7;<sup>6</sup> rather, the proposed changes are intended to give the Exchange more flexibility to attract and retain well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President of the Exchange. As noted above, the Exchange desires to conform the requirements to become CRO in its By-Laws to those in the By-Laws of Phlx, which do not contain a similar restriction in Article IV, Section 4–7 of its By-Laws that its CRO be an Executive Vice President or Senior Vice President of Phlx.<sup>7</sup>

##### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

<sup>3</sup> See Phlx By-Law Article IV, Section 4–7 (Chief Regulatory Officer).

<sup>4</sup> In Exhibit 5, the references to “Company” mean the Exchange.

<sup>5</sup> The Exchange notes that Phlx's CRO currently holds the position of Vice President.

<sup>6</sup> The CRO's responsibilities include general supervision of the regulatory operations of the Exchange, including responsibility for overseeing the Exchange's surveillance, examination, and enforcement functions and for administering any regulatory services agreements with another SRO to which the Exchange is a party. In addition, the CRO shall meet with the Regulatory Oversight Committee of the Exchange in executive session at regularly scheduled meetings of such committee, and at any time upon request of the CRO or any member of the Regulatory Oversight Committee. Unlike Phlx, the Exchange's By-Laws provide that the CRO may also serve as the General Counsel of the Exchange. See By-Law Article IV, Section 7.

<sup>7</sup> See note 5 above.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>15</sup> 17 CFR 200.30–3(a)(12).

of the Act,<sup>8</sup> in general, and furthers the objectives of Section 6(b)(1) of the Act,<sup>9</sup> in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that this proposal furthers the objectives of Section 6(b)(5) of the Act,<sup>10</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposed changes will remove the requirement currently in Article IV, Section 7 of the Exchange's By-Laws that the CRO be an Executive Vice President or Senior Vice President of the Exchange. As discussed above, the current responsibilities of the CRO as provided in Article IV, Section 7 remain unchanged under this proposal, and the CRO will continue to have general oversight of the regulatory operations of the Exchange and be obligated to meet regularly with the Regulatory Oversight Committee. The proposed rule change is intended to provide the Exchange with greater flexibility to attract and retain capable individuals who are well qualified to serve in the CRO role. In addition, the proposed amendments will have the additional benefit of bringing the Exchange's requirements on the CRO role into greater conformity with those of its affiliate, Phlx, thereby creating equivalent standards among the affiliated exchanges owned by Nasdaq, Inc. ("HoldCo").<sup>11</sup> As such, the Exchange believes that its proposal will bring greater consistency to its rules, which is beneficial to both investors and the public interest.

#### *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

proposed rule change does not address competitive issues but relates to the administration and functioning of the Exchange by allowing the Exchange greater flexibility in attracting and retaining well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

#### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>12</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>13</sup>

A proposed rule change filed under Rule 19b-4(f)(6)<sup>14</sup> normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)<sup>15</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Exchange notes that waiver of the operative delay will allow it to amend its By-Laws by September 26, 2018. The Exchange states that the boards of the Affiliated Exchanges will collectively meet on that date to address, among other matters, certain annual corporate "housekeeping items," which the Exchange states has historically included Exchange officer appointments. As such, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest.

<sup>12</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>13</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>14</sup> 17 CFR 240.19b-4(f)(6).

<sup>15</sup> 17 CFR 240.19b-4(f)(6)(iii).

Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.<sup>16</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### *Electronic Comments*

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-ISE-2018-79 on the subject line.

##### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-ISE-2018-79. 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,

<sup>16</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(1).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>11</sup> The Nasdaq Stock Market LLC ("NSM"), Nasdaq BX, Inc. ("BX"), Nasdaq GEMX, LLC ("GEMX"), and Nasdaq MRX, LLC ("MRX") will file similar proposals to conform their By-Laws with Phlx's By-Laws. ISE, GEMX, MRX, NSM, BX, and Phlx will hereinafter be referred to collectively as "Affiliated Exchanges."

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-ISE-2018-79 and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Eduardo A. Aleman,**  
Assistant Secretary.

[FR Doc. 2018-20759 Filed 9-24-18; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84204; File No. SR-MRX-2018-29]

### Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Conform By-Law's CRO Provisions To Those of an Affiliate Exchange

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 6, 2018, Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to conform the Exchange's By-Law provisions regarding the Chief Regulatory Officer to those of its affiliate, Nasdaq PHLX LLC ("Phlx").

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqmrxcchwallstreet.com/>, at

the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange proposes to amend its By-Laws at Article IV, Section 7 to conform its provisions regarding the Exchange's Chief Regulatory Officer ("CRO") to those of its affiliate, Nasdaq PHLX LLC ("Phlx").<sup>3</sup> By-Law Article IV, Section 7 presently requires that an officer of the Exchange<sup>4</sup> with the position of Executive Vice President or Senior Vice President be designated as the CRO of the Exchange. The Exchange now proposes to remove the requirement that the CRO be an Executive Vice President or Senior Vice President of the Exchange. The Exchange believes that this requirement is unnecessary and notes that there may be officers of the Exchange who are well qualified to serve in the CRO role, but who may not hold the position of an Executive Vice President or Senior Vice President.<sup>5</sup> The Exchange does not seek to amend any of the current responsibilities of the CRO as set forth in Section 7;<sup>6</sup> rather, the proposed

<sup>3</sup> See Phlx By-Law Article IV, Section 4-7 (Chief Regulatory Officer).

<sup>4</sup> In Exhibit 5, the references to "Company" mean the Exchange.

<sup>5</sup> The Exchange notes that Phlx's CRO currently holds the position of Vice President.

<sup>6</sup> The CRO's responsibilities include general supervision of the regulatory operations of the Exchange, including responsibility for overseeing the Exchange's surveillance, examination, and enforcement functions and for administering any regulatory services agreements with another SRO to which the Exchange is a party. In addition, the CRO shall meet with the Regulatory Oversight Committee of the Exchange in executive session at regularly scheduled meetings of such committee, and at any time upon request of the CRO or any member of the Regulatory Oversight Committee. Unlike Phlx, the Exchange's By-Laws provide that

changes are intended to give the Exchange more flexibility to attract and retain well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President of the Exchange. As noted above, the Exchange desires to conform the requirements to become CRO in its By-Laws to those in the By-Laws of Phlx, which do not contain a similar restriction in Article IV, Section 4-7 of its By-Laws that its CRO be an Executive Vice President or Senior Vice President of Phlx.<sup>7</sup>

###### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>8</sup> in general, and furthers the objectives of Section 6(b)(1) of the Act,<sup>9</sup> in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that this proposal furthers the objectives of Section 6(b)(5) of the Act,<sup>10</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposed changes will remove the requirement currently in Article IV, Section 7 of the Exchange's By-Laws that the CRO be an Executive Vice President or Senior Vice President of the Exchange. As discussed above, the current responsibilities of the CRO as provided in Article IV, Section 7 remain unchanged under this proposal, and the CRO will continue to have general oversight of the regulatory operations of the Exchange and be obligated to meet regularly with the Regulatory Oversight Committee. The proposed rule change is intended to provide the Exchange with greater flexibility to attract and retain capable individuals who are well qualified to serve in the CRO role. In addition, the proposed amendments will have the additional benefit of bringing the Exchange's requirements on the CRO role into greater conformity with those of its affiliate, Phlx, thereby

the CRO may also serve as the General Counsel of the Exchange. See By-Law Article IV, Section 7.

<sup>7</sup> See note 5 above.

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(1).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>17</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.



creating equivalent standards among the affiliated exchanges owned by Nasdaq, Inc. (“HoldCo”).<sup>11</sup> As such, the Exchange believes that its proposal will bring greater consistency to its rules, which is beneficial to both investors and the public interest.

#### *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 proposed rule change does not address competitive issues but relates to the administration and functioning of the Exchange by allowing the Exchange greater flexibility in attracting and retaining well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President.

#### *C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>12</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>13</sup>

A proposed rule change filed under Rule 19b-4(f)(6)<sup>14</sup> normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)<sup>15</sup> permits the

<sup>11</sup> The Nasdaq Stock Market LLC (“NSM”), Nasdaq BX, Inc. (“BX”), Nasdaq ISE, LLC (“ISE”), and Nasdaq GEMX, LLC (“GEMX”) will file similar proposals to conform their By-Laws with Phlx’s By-Laws. ISE, GEMX, MRX, NSM, BX, and Phlx will hereinafter be referred to collectively as “Affiliated Exchanges.”

<sup>12</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>13</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>14</sup> 17 CFR 240.19b-4(f)(6).

<sup>15</sup> 17 CFR 240.19b-4(f)(6)(iii).

Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Exchange notes that waiver of the operative delay will allow it to amend its By-Laws by September 26, 2018. The Exchange states that the boards of the Affiliated Exchanges will collectively meet on that date to address, among other matters, certain annual corporate “housekeeping items,” which the Exchange states has historically included Exchange officer appointments. As such, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.<sup>16</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-MRX-2018-29 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-MRX-2018-29. This file number should be included on the

<sup>16</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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 a.m. and 3 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-MRX-2018-29 and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Eduardo A. Aleman,**  
Assistant Secretary.

[FR Doc. 2018-20760 Filed 9-24-18; 8:45 am]

**BILLING CODE 8011-01-P**

## **SECURITIES AND EXCHANGE COMMISSION**

### **Sunshine Act Meetings**

**TIME AND DATE:** 2:00 p.m. on Thursday, September 27, 2018.

**PLACE:** Closed Commission Hearing Room 10800.

**STATUS:** This meeting will be closed to the public.

#### **MATTERS TO BE CONSIDERED:**

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has

<sup>17</sup> 17 CFR 200.30-3(a)(12).

certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Peirce, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

**CONTACT PERSON FOR MORE INFORMATION:**

For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551-5400.

Dated: September 20, 2018.

**Brent J. Fields,**  
Secretary.

[FR Doc. 2018-20899 Filed 9-21-18; 11:15 am]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-84227; File No. SR-BX-2018-045]

**Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Equity Rule 6950 Series Concerning the Order Audit Trail System To Make Conforming and Technical Changes**

September 20, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 12, 2018, Nasdaq BX, Inc. (“BX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” rule change pursuant to Section 19(b)(3)(A) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder.<sup>4</sup> 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 the [sic] Rule 6950 Series concerning the Order Audit Trail System to make conforming and technical changes.

The text of the proposed rule change is available on the Exchange’s website at <http://nasdaqbx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

**II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange is proposing to amend the Equity Rule 6950 Series<sup>5</sup> concerning the Order Audit Trail System to: (1) Renumber the whole Equity Rule 6950 Series to conform it to the numbering convention used by the Nasdaq Stock Market LLC (“Nasdaq”) and FINRA; (2) amend Equity Rule 7410A to expand two exemptions and to make technical changes to text under the Rule; (3) delete inapplicable text from Equity Rules 7430A, 7440A and 7450A and make other conforming changes to these Rules; (4) reorganize rule text under Equity Rule 7450A; (5) delete current Equity Rules 6957 and 6958.

The Exchange’s Equity Rule 6950 Series imposes an obligation on Exchange members to record in electronic form and report to FINRA on a daily basis certain information with

respect to orders originated, received, transmitted, modified, canceled, or executed by members in Nasdaq- and Exchange-listed stocks. FINRA’s Order Audit Trail System (“OATS”) captures this order information and integrates it with quote and transaction information to create a time-sequenced record of orders, quotes, and transactions. This information is used by FINRA staff to conduct surveillance and investigations of members for potential violation of Exchange rules and federal securities laws.

The Exchange adopted the Equity Rule 6950 Series to copy Nasdaq and FINRA OATS rules, where appropriate. As a general principle, the Exchange endeavors to keep its rules worded and structured as closely as possible to the FINRA rules on which they are based, including FINRA’s OATS rules under its Rule 7000 Series. In instances where the FINRA rules are inapplicable to the Exchange, such as FINRA Rule 7410(o)(2), which concerns an exception to the definition of a Reporting Member relating to members operating on equities floors, the Exchange has not copied those FINRA rules. Generally, the Exchange also seeks to keep the Equity Rule 6950 Series consistent with Nasdaq’s Rule 7400A Series, which should also be materially identical to the related rules of the Exchange. The proposed changes will harmonize Exchange rules with analogous Nasdaq and FINRA rules, which have been amended since the Exchange first adopted its rules.

First Change

The Exchange is proposing to renumber the Equity Rule 6950 Series to a new Equity Rule 7000A Series, which is identical to how Nasdaq presents its OATS rules. This will allow the Exchange’s OATS rules to follow the numbering convention used by Nasdaq and FINRA. Like Nasdaq, the Exchange is proposing to add an “A” to each of the rules so that they do not conflict with the existing Equity Rule 7000 Series within the Exchange’s rule book yet also follow FINRA’s numbering convention. FINRA’s OATS rules are under the FINRA Rule 7400 Series and individual rule numbers align with those of Nasdaq’s OATS rules and those proposed by the Exchange. As part of this change, the Exchange is also updating references to rules in the Equity Rule 6950 Series to the renumbered rules in the Equity Rule 7000A Series. Relatedly, the Exchange is correcting citations in Equity Rules 7430A, 7440A, and 7450A that currently reference NASD rule [sic] that have been renumbered as FINRA rules.

<sup>5</sup> The term “Equity Rules” means the numbered rules set forth in the Exchange Manual denominated as the 0100, 1000, 2000, 3000, 4000, 5000, 6000, 7000, 8000, 9000, 10000, and 11000 Series Rules. See Equity Rule 0120(p). The Exchange is proposing to make it clear in the proposed rules that references to rules of the Exchange are “Equity Rules.”

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

## Second Change

The Exchange is amending Equity Rule 7410A to conform it to the rules of Nasdaq. The Exchange is proposing to add new text as paragraph (a) noting that terms used in the Rule have the same meanings as are ascribed to those terms in the Exchange's By-Laws and in its other rules, unless otherwise noted, which is identical to Nasdaq's Rule 7410A. Consequently, the Exchange is renumbering current paragraphs (a)–(n) as paragraphs (b)–(o). The Exchange is also amending Equity Rule 7410A to make technical changes that harmonize the definitions of “Electronic Communication Network,” “Index Arbitrage Trade,” “Intermarket Sweep Order,” and “Program Trade” with the definitions of those terms in the Nasdaq Rules.<sup>6</sup>

The Exchange is also proposing to adopt the same limited exemption from OATS order data recordation requirements provided under Nasdaq Rule 7410A(k) for BX members that are registered market makers in standardized options on any market. Equity Rule 7410A(j) defines the term “Order” and provides a limited exemption from the definition for a proprietary transaction originated by a trading desk in the ordinary course of a member's market making activities. The Exchange is proposing to adopt a second limited exemption currently available under Nasdaq's analogous definition of “Order.”<sup>7</sup> That limited exemption excludes from the definition of an “Order” a *bona fide* hedge transaction involving a Nasdaq-listed equity security originated by a trading desk in the ordinary course of the member's options market making activities.<sup>8</sup> As noted by Nasdaq in adopting the exemption, OATS was designed to provide an accurate, time-sequenced record of orders and transactions, beginning with the receipt of an equity order at the first point of contact between the broker-dealer and the customer or counterparty and further documenting the life of the equity order

<sup>6</sup> The Exchange is not adopting the definition of “NMS Stock” found under Nasdaq Rule 7410A(j). The term is not used in the BX OATS rules. In addition, the term is not used in the Nasdaq OATS rules. The term is used in FINRA Rule 7410(k) defining “Order Audit Trail System,” whereas BX and Nasdaq instead reference Exchange and Nasdaq listed securities under Equity Rule 7410A(k) and Nasdaq listed securities under Nasdaq Rule 7410A(l).

<sup>7</sup> See Nasdaq Rule 7410A(k).

<sup>8</sup> The Exchange notes that Nasdaq capitalizes the term “Bona Fide Hedge Transaction” in Nasdaq Rule 7410A(k), although the term is not defined in Nasdaq's rules. The Exchange believes that capitalizing the term was an error and is therefore not capitalizing the term in Equity Rule 7410A(k).

through the process of execution.<sup>9</sup> The proposed rule change does not impact the customer protection orientation of OATS since, by definition, *bona fide* hedging transactions in equity securities that are undertaken by options market makers do not involve customer orders in those equity securities. Rather, *bona fide* hedging transactions in equity securities are undertaken by an options market maker to hedge against the firm risk that it creates through its conduct as a registered options market maker. Accordingly, submitting *bona fide* hedging transactions to OATS recording requirements provides no customer protection or equivalent regulatory benefit. It is also very expensive for firms that are not currently FINRA members or that do not currently trade Exchange or Nasdaq equities to develop and maintain the compliance systems and compliance staff required to continuously monitor the daily transmission of OATS data. For these reasons, the Exchange is proposing to adopt such an exemption, available to its options market makers.

The Exchange is proposing to amend Equity Rule 7410A(n)(1) to harmonize the rule with FINRA Rule 7410(o)(1)(A) and Nasdaq Rule 7410A(o)(1)(A). Equity Rule 7410A(n) defines a “Reporting Member” as a member that receives or originates an order and has an obligation to record and report information under Equity Rules 7440A and 7450A. The Rule also provides an exception to the general definition of a “Reporting Member” if the member meets four conditions.<sup>10</sup> The first condition in subparagraph (n)(1), which is the only condition at issue in this proposal, is that currently the member engages in a non-discretionary order routing process, pursuant to which it immediately routes, by electronic or other means, all of its orders to a single receiving Reporting Member. On May 12, 2014, FINRA amended FINRA Rule 7410(o)(1)(A) to allow a member to satisfy this condition by permitting a member to alternatively route its orders to two receiving Reporting Members, if two related requirements were met.<sup>11</sup> First, the orders must be routed by the member to each receiving Reporting Member on a pre-determined schedule approved by FINRA. Second, the FINRA member's orders must be routed to two receiving Reporting Members pursuant

<sup>9</sup> See Securities Exchange Act Release No. 59369 (February 6, 2009), 74 FR 7278 (February 13, 2009) (SR–NASDAQ–2008–097).

<sup>10</sup> The four conditions are provided under Equity Rules 7410A(n)(1)–(4).

<sup>11</sup> See Securities Exchange Act Release No. 72191 (May 20, 2014), 79 FR 30219 (May 27, 2014) (SR–FINRA–2014–024).

to the schedule for a time period not to exceed one year. Under FINRA's rule as amended, FINRA members may continue to rely on the exception from the definition of Reporting Member if it [sic] routes all of its [sic] orders to a single Reporting Member, provided the other conditions of the exception are met. Consequently, BX is also keeping its existing single receiving Reporting Member exception and adding a second exception for two receiving Reporting Members. FINRA noted in adopting the change that the rule was intended to accommodate introducing firms that transition to a different clearing firm over time and, during the transition, route their orders [sic] two different clearing firms, both of which report the introducing firm's information to OATS during the transition time. Nasdaq recently amended its rule to incorporate this change.<sup>12</sup> The Exchange believes that this additional limited exception is appropriate for its members, which likewise may encounter a transition to a different clearing firm whereby a member would no longer be eligible for the exception to the definition of Reporting Member. Accordingly, the Exchange is proposing to adopt the FINRA rule text under Equity Rule 7410A(n)(1)(B).

## Third Change

The Exchange is proposing to amend Equity Rules 7430A(a), 7440A(a) and 7450A(a) to delete text concerning FINRA's process of transitioning certain NASD rules into a new FINRA rulebook because this transition period has ended and the text is obsolete. The Exchange is also proposing to make technical changes that update citations to the appropriate FINRA rules under Equity Rules 7430A(a), 7440A(a) and 7450A(a).<sup>13</sup> Consistent with Nasdaq Rule 7440A(d)(2), the Exchange is proposing to add new Equity Rule 7440A(d)(2), which provides that references to FINRA Rules 5320, 7440, and 7450 shall be construed as references to Equity Rules IM–2110–2, 7440A, and 7450A, respectively. Last, the Exchange is making minor clarifying changes under Equity Rules 7440A(d)(1) and (2) to make it clear that certain rules

<sup>12</sup> See Securities Exchange Act Release No. 83115 (April 26, 2018), 83 FR 19384 (May 2, 2018) (SR–NASDAQ–2018–030).

<sup>13</sup> The Exchange notes that Rule 7450A(b) requires both Proprietary Trading Firms as well as their associated persons to comply with FINRA Rule 7450 in limited circumstances, whereas Nasdaq's Rule 7450A only requires compliance by Proprietary Trading Firms. The Exchange believes that this is an omission in the Nasdaq rule and is accordingly not adjusting the Exchange rule.

noted thereunder are references to FINRA rules.

#### Fourth Change

The Exchange is proposing to delete paragraph (c) from current Equity Rule 6954 (which will be renumbered Equity Rule 7440A and paragraph (d) from current Equity Rule 6955 (which will be renumbered Equity Rule 7450A), and move the text to Equity Rules 7440A(a) and 7450A(a), respectively, with minor technical differences to correct citations.<sup>14</sup> The Rules explain that the Exchange and FINRA are parties to the FINRA Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions on behalf of the Exchange. The Rules also note that members are complying with current Equity Rules 6954 and 6955 by complying with NASD Rules 6954 and 6955, respectively. Nasdaq places the same text as current Equity Rules 6954(d) and 6955(d) under Nasdaq Rules 7440A(a) and 7450A(a), respectively. Thus, the Exchange is moving the text, as amended, under Equity Rules 7440A(a) and 7450A(a). As a consequence, the Exchange is changing the lettering of paragraphs (d) and (e) of current Equity Rule 6954 to paragraphs (c) and (d), respectively, of Equity Rule 7440A, and the lettering of paragraph (e) of current Equity Rule 6955 to paragraph (d) of Equity Rule 7450A.

#### Fifth Change

The Exchange is proposing to delete current Equity Rules 6957 and 6958. Equity Rule 6957 concerns compliance with NASD Rule 6954. NASD Rule 6954 provided the effective dates of requirements of the Order Audit Trail System, all of which have passed. FINRA has deleted NASD Rule 6954 and consequently, the Exchange is proposing to delete Equity Rule 6957.

The Exchange is proposing to delete current Equity Rule 6958, which will be renumbered Equity Rule 7470A and held in reserve. Current Equity Rule 6958 provided an exemption from the order recording and data transmission requirements of current Equity Rules 6954 and 6955, which are OATS rules applicable to manual orders. The exemption has not been requested by any Exchange member to date and the Exchange does not believe that

Exchange members are likely to need the exemption, since the vast majority of such members to which the rule applies are electronic proprietary trading firms that would not qualify for the exemption.<sup>15</sup> Thus, the Exchange is proposing to eliminate the rule text under Equity Rule 6958 from its rule book, renumber the rule to Equity Rule 7470A, and hold the rule in reserve.

#### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>16</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act,<sup>17</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by harmonizing the Exchange's OATS rules with those of FINRA, on which they are based, and with those of Nasdaq, which they should largely match. Consequently, the proposed change will conform Exchange Rules to changes made to corresponding FINRA and Nasdaq rules, thus promoting consistent regulatory standards with respect to rules that FINRA enforces pursuant to its Regulatory Services Agreements with the Exchange and Nasdaq. With respect to the proposed amendment to Equity Rule 7410A(n)(1), the exemption will provide Exchange members with the same flexibility to transition to a new clearing firm that both Nasdaq and FINRA members currently enjoy. The rule is intended to accommodate introducing firms that transition to a different clearing firm over time and, during the transition, route their orders to two different clearing firms, both of which report the introducing firm's information to OATS during the transition time. Adopting the new and amended rule text under Equity Rule 7410A will also align the Exchange rulebook with Nasdaq's and FINRA's, thereby reducing complexity from FINRA's work under a regulatory services agreement with the Exchange.

The Exchange believes that adopting the new limited exception to the definition of "Order" is consistent with the Act because it provides a very narrow exemption from reporting transactions that are done to manage risk and facilitate options market making. *Bona fide* hedging transactions

in equity securities that are undertaken by options market makers do not involve customer orders in those equity securities and thus do not implicate customer protection issues. Moreover, information regarding *bona fide* hedging transactions retained by a registered BX Options Market market maker is otherwise available to FINRA and BX Regulation through the Exchange's electronic delivery systems, upon request. This information includes trade reporting data, including order time and sales data captured by the Exchange system.

With respect to the proposed technical corrections to the rules, the Exchange believes that these changes are consistent with the Act because they will prevent investor confusion that may be caused by including in the Rules incorrect rule citations, defunct rule text and expired exemptions.

#### 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 proposed rule change align [sic] the Exchange's rules with those of Nasdaq and FINRA, which will assist FINRA in its oversight work done pursuant to a regulatory services agreement. The proposed changes also provide uniform standards with which market participants must comply. Consequently, the Exchange does not believe that the proposed changes implicate competition at all.

#### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>18</sup> and Rule 19b-4(f)(6) thereunder.<sup>19</sup>

<sup>18</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>19</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to

<sup>14</sup> The Exchange is not including text from current Equity Rules 6954(c) and 6955(d), which notes that members are complying with these rules by complying with the related FINRA rules, in Equity Rules 7440A(a) and 7450A(a). The Exchange believes these sentences are duplicative of the first sentence of Equity Rules 7440A(a) and 7450A(a). The Exchange notes that Nasdaq's Rules 7440A(a) and 7450A(a) include this duplicative text.

<sup>15</sup> The Exchange notes that Nasdaq does not have an analogous rule, having eliminated similar text recently for the same reasons. See note 10 [sic], *supra*.

<sup>16</sup> 15 U.S.C. 78f(b).

<sup>17</sup> 15 U.S.C. 78f(b)(5).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### *Electronic Comments*

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-BX-2018-045 on the subject line.

##### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-BX-2018-045. 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.

file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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-BX-2018-045 and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>20</sup>

**Brent J. Fields,**  
*Secretary.*

[FR Doc. 2018-20898 Filed 9-24-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84214; File No. SR-NASDAQ-2018-072]

### Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Conform the Exchange's By-Law Provisions Regarding the Chief Regulatory Officer to Those of Its Affiliate, Nasdaq PHLX LLC

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 6, 2018, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to a proposal [sic] to conform the Exchange's By-Law provisions regarding the Chief Regulatory Officer to those of its affiliate, Nasdaq PHLX LLC ("Phlx"). The text of the proposed rule change is available on the Exchange's website at <http://nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

<sup>20</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange proposes to amend its By-Laws at Article IV, Section 7 to conform its provisions regarding the Exchange's Chief Regulatory Officer ("CRO") to those of its affiliate, Nasdaq PHLX LLC ("Phlx").<sup>3</sup> By-Law Article IV, Section 7 presently requires that an officer of the Exchange<sup>4</sup> with the position of Executive Vice President or Senior Vice President be designated as the CRO of the Exchange. The Exchange now proposes to remove the requirement that the CRO be an Executive Vice President or Senior Vice President of the Exchange. The Exchange believes that this requirement is unnecessary and notes that there may be officers of the Exchange who are well qualified to serve in the CRO role, but who may not hold the position of an Executive Vice President or Senior Vice President.<sup>5</sup> The Exchange does not seek to amend any of the current responsibilities of the CRO as set forth in Section 7;<sup>6</sup> rather, the proposed changes are intended to give the Exchange more flexibility to attract and retain well qualified officers to the role

<sup>3</sup> See Phlx By-Law Article IV, Section 4-7 (Chief Regulatory Officer).

<sup>4</sup> In Exhibit 5, the references to "Company" mean the Exchange.

<sup>5</sup> The Exchange notes that Phlx's CRO currently holds the position of Vice President.

<sup>6</sup> The CRO's responsibilities include general supervision of the regulatory operations of the Exchange, including responsibility for overseeing the Exchange's surveillance, examination, and enforcement functions and for administering any regulatory services agreements with another SRO to which the Exchange is a party. In addition, the CRO shall meet with the Regulatory Oversight Committee of the Exchange in executive session at regularly scheduled meetings of such committee, and at any time upon request of the CRO or any member of the Regulatory Oversight Committee. Unlike Phlx, the Exchange's By-Laws provide that the CRO may also serve as the General Counsel of the Exchange. See By-Law Article IV, Section 7.

of CRO that are not designated as an Executive Vice President or Senior Vice President of the Exchange. As noted above, the Exchange desires to conform the requirements to become CRO in its By-Laws to those in the By-Laws of Phlx, which do not contain a similar restriction in Article IV, Section 4–7 of its By-Laws that its CRO be an Executive Vice President or Senior Vice President of Phlx.<sup>7</sup>

## 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>8</sup> in general, and furthers the objectives of Section 6(b)(1) of the Act,<sup>9</sup> in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that this proposal furthers the objectives of Section 6(b)(5) of the Act,<sup>10</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposed changes will remove the requirement currently in Article IV, Section 7 of the Exchange's By-Laws that the CRO be an Executive Vice President or Senior Vice President of the Exchange. As discussed above, the current responsibilities of the CRO as provided in Article IV, Section 7 remain unchanged under this proposal, and the CRO will continue to have general oversight of the regulatory operations of the Exchange and be obligated to meet regularly with the Regulatory Oversight Committee. The proposed rule change is intended to provide the Exchange with greater flexibility to attract and retain capable individuals who are well qualified to serve in the CRO role. In addition, the proposed amendments will have the additional benefit of bringing the Exchange's requirements on the CRO role into greater conformity with those of its affiliate, Phlx, thereby creating equivalent standards among the affiliated exchanges owned by Nasdaq, Inc. ("HoldCo").<sup>11</sup> As such, the

Exchange believes that its proposal will bring greater consistency to its rules, which is beneficial to both investors and the public interest.

### 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 proposed rule change does not address competitive issues but relates to the administration and functioning of the Exchange by allowing the Exchange greater flexibility in attracting and retaining well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>12</sup> and subparagraph (f)(6) of Rule 19b–4 thereunder.<sup>13</sup>

A proposed rule change filed under Rule 19b–4(f)(6)<sup>14</sup> normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)<sup>15</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day

MRX, LLC ("MRX") will file similar proposals to conform their By-Laws with Phlx's By-Laws. ISE, GEMX, MRX, NSM, BX, and Phlx will hereinafter be referred to collectively as "Affiliated Exchanges."

<sup>12</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>13</sup> 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>14</sup> 17 CFR 240.19b–4(f)(6).

<sup>15</sup> 17 CFR 240.19b–4(f)(6)(iii).

operative delay so that the proposed rule change may become operative immediately upon filing. The Exchange notes that waiver of the operative delay will allow it to amend its By-Laws by September 26, 2018. The Exchange states that the boards of the Affiliated Exchanges will collectively meet on that date to address, among other matters, certain annual corporate "housekeeping items," which the Exchange states has historically included Exchange officer appointments. As such, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.<sup>16</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

### Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR–NASDAQ–2018–072 on the subject line.

### Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2018–072. 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

<sup>16</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>7</sup> See note 5 above.

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(1).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>11</sup> Nasdaq BX, Inc. ("BX"), Nasdaq ISE, LLC ("ISE"), Nasdaq GEMX, LLC ("GEMX"), and Nasdaq

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-NASDAQ-2018-072 and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Brent J. Fields,**  
Secretary.

[FR Doc. 2018-20768 Filed 9-24-18; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33242; 812-14895]

### Variant Alternative Income Fund and Variant Investments, LLC

September 20, 2018.

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c-3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d-1 under the Act.

**SUMMARY OF APPLICATION:** Applicants request an order to permit certain

registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based distribution and/or service fees, early withdrawal charges ("EWCs") and early repurchase fees.

**APPLICANTS:** Variant Alternative Income Fund (the "Initial Fund") and Variant Investments, LLC (the "Adviser").

**FILING DATES:** The application was filed on April 13, 2018, and amended on August 3, 2018.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the requested relief 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 October 11, 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: 10250 SW Greenburg Road, Suite 215, Portland, OR 97223.

**FOR FURTHER INFORMATION CONTACT:** Jean E. Minarick, Senior Counsel, at (202) 551-6811, or Kaitlin C. Bottock, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

### Applicants' Representations

1. The Initial Fund is a Delaware statutory trust that is registered under the Act as a non-diversified, closed-end management investment company. The Initial Fund's primary investment objective is to provide a high level of current income. Capital appreciation will be considered a secondary objective.

2. The Adviser, a Delaware limited liability company, is registered as an

investment adviser under the Investment Advisers Act of 1940, as amended. The Adviser will serve as investment adviser to the Initial Fund.

3. The applicants seek an order to permit the Initial Fund to issue multiple classes of shares and to impose asset-based distribution and/or service fees and EWCs.

4. Applicants request that the order also apply to any continuously offered registered closed-end management investment company that has been previously organized or that may be organized in the future for which the Adviser, or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,<sup>1</sup> acts as investment adviser and which operates as an interval fund pursuant to rule 23c-3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e-4 under the Securities Exchange Act of 1934 ("Exchange Act") (each, a "Future Fund" and together with the Initial Fund, the "Funds").<sup>2</sup>

5. The Initial Fund anticipates making a continuous public offering of beneficial interest in connection with its registration statement. Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange nor quoted on any quotation medium. The Funds do not expect there to be a secondary trading market for their shares.

6. If the requested relief is granted, the Initial Fund anticipates offering Institutional Class Shares and Investor Class Shares. Each of the Institutional Class Shares and Investor Class Shares will have their own fee and expense structure. The Funds may in the future offer additional classes of shares and/or another sales charge structure. Because of the different distribution fees, services and any other class expenses that may be attributable to each class of shares, the net income attributable to, and the dividends payable on, each class of shares may differ from each other.

7. Applicants state that, from time to time, the Fund may create additional classes of shares, the terms of which may differ from the initial classes

<sup>1</sup> A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

<sup>2</sup> Any Fund relying on this relief in the future will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each entity presently intending to rely on the requested relief is listed as an applicant.

<sup>17</sup> 17 CFR 200.30-3(a)(12).

pursuant to and in compliance with rule 18f-3 under the Act.

8. Applicants state that shares of a Fund may be subject to an early repurchase fee ("Early Repurchase Fee") at a rate of no greater than 2% of the shareholder's repurchase proceeds if the interval between the date of purchase of the shares and the valuation date with respect to the repurchase of those shares is less than one year. Any Early Repurchase Fees will apply equally to all classes of shares of a Fund, consistent with section 18 of the Act and rule 18f-3 thereunder. To the extent a Fund determines to waive, impose scheduled variations of, or eliminate any Early Repurchase Fee, it will do so consistently with the requirements of rule 22d-1 under the Act as if the Early Repurchase Fee were a CDSL (defined below) and as if the Fund were an open-end investment company and the Fund's waiver of, scheduled variation in, or elimination of, any such Early Repurchase Fee will apply uniformly to all shareholders of the Fund regardless of class. Applicants state that the Initial Fund does not intend to impose an Early Repurchase Fee.

9. Applicants state that the Initial Fund has adopted a fundamental policy to repurchase a specified percentage of its shares at net asset value on a quarterly basis. Such repurchase offers will be conducted pursuant to rule 23c-3 under the Act. Any Future Funds will likewise adopt fundamental investment policies and make periodic repurchase offers to its shareholders in compliance with rule 23c-3 or will provide periodic liquidity with respect to its shares pursuant to rule 13e-4 under the Exchange Act.<sup>3</sup> Any repurchase offers made by the Funds will be made to all holders of shares of each such Fund.

10. Applicants represent that any asset-based service and/or distribution fees for each class of shares of the Funds will comply with the provisions of the FINRA Rule 2341(d) ("FINRA Sales Charge Rule").<sup>4</sup> Applicants also represent that each Fund will disclose in its prospectus the fees, expenses and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multiple class funds under Form N-1A. As is required for open-end funds, each Fund

will disclose its expenses in shareholder reports, and describe any arrangements that result in breakpoints in or elimination of sales loads in its prospectus.<sup>5</sup> In addition, applicants will comply with applicable enhanced fee disclosure requirements for fund of funds, including registered funds of hedge funds.<sup>6</sup>

11. Each of the Funds will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to the Fund. In addition, each Fund will contractually require that any distributor of the Fund's shares comply with such requirements in connection with the distribution of such Fund's shares.

12. Each Fund will allocate all expenses incurred by it among the various classes of shares based on the net assets of that Fund attributable to each class, except that the net asset value and expenses of each class will reflect the expenses associated with the distribution plan of that class (if any), service fees attributable to that class (if any), including transfer agency fees, and any other incremental expenses of that class. Expenses of a Fund allocated to a particular class of shares will be borne on a pro rata basis by each outstanding share of that class. Applicants state that each Fund will comply with the provisions of rule 18f-3 under the Act as if it were an open-end investment company.

13. Applicants state that each Fund may impose an EWC on shares submitted for repurchase that have been held less than a specified period and may waive the EWC for certain categories of shareholders or transactions to be established from time to time. Applicants state that each Fund will apply the EWC (and any waivers or scheduled variations, or elimination of

the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d-1 under the Act as if the Funds were open-end investment companies.

14. Each Fund operating as an interval fund pursuant to rule 23c-3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with such Fund's periodic repurchase offers, exchange their shares of the Fund for shares of the same class of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c-3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, "Other Funds"). Shares of a Fund operating pursuant to rule 23c-3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c-3 under the Act. Any exchange option will comply with rule 11a-3 under the Act, as if the Fund were an open-end investment company subject to rule 11a-3. In complying with rule 11a-3, each Fund will treat an EWC as if it were a contingent deferred sales load ("CDSL").

### Applicants' Legal Analysis

#### *Multiple Classes of Shares*

1. Section 18(a)(2) of the Act provides that a closed-end investment company may not issue or sell a senior security that is a stock unless certain requirements are met. Applicants state that the creation of multiple classes of shares of the Funds may violate section 18(a)(2) because the Funds may not meet such requirements with respect to a class of shares that may be a senior security.

2. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of shares of the Funds may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

3. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of

<sup>3</sup> Applicants submit that rule 23c-3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to Rule 415 under the Securities Act of 1933, as amended.

<sup>4</sup> Any reference to the FINRA Sales Charge Rule includes any successor or replacement to the FINRA Sales Charge Rule.

<sup>5</sup> See Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

<sup>6</sup> Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). See also Rules 12d1-1, *et seq.* of the Act.



shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

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 provision of the Act, or from any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(a)(2), 18(c) and 18(i) to permit the Funds to issue multiple classes of shares.

5. Applicants submit that the proposed allocation of expenses relating to distribution and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its securities and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f-3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f-3 as if it were an open-end investment company.

#### *Early Withdrawal Charges*

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c-3 under the Act permits an "interval fund" to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c-3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to

the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c-3 to the extent necessary for the Funds to impose EWCs on shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c-10 under the Act. Rule 6c-10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c-10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c-10 under the Act as if the rule were applicable to closed-end investment companies. The Funds will disclose EWCs in accordance with the requirements of Form N-1A concerning CDSLs.

#### *Asset-Based Distribution and/or Service Fees*

1. Section 17(d) of the Act and rule 17d-1 under the Act prohibit an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d-1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis

different from or less advantageous than that of other participants.

2. Rule 17d-3 under the Act provides an exemption from section 17(d) and rule 17d-1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b-1 under the Act. Applicants request an order under section 17(d) and rule 17d-1 under the Act to the extent necessary to permit the Fund to impose asset-based distribution and/or service fees. Applicants have agreed to comply with rules 12b-1 and 17d-3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based distribution fees.

3. For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' imposition of asset-based distribution and/or service fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

#### **Applicants' Condition**

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c-10, 12b-1, 17d-3, 18f-3, 22d-1, and, where applicable, 11a-3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the FINRA Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

**Brent J. Fields,**  
*Secretary.*

[FR Doc. 2018-20820 Filed 9-24-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84202; File No. SR-GEMX-2018-31]

### Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Conform By-Law's CRO Provisions to Those of an Affiliate Exchange

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 6, 2018, Nasdaq GEMX, LLC ("GEMX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to conform the Exchange's By-Law provisions regarding the Chief Regulatory Officer to those of its affiliate, Nasdaq PHLX LLC ("Phlx").

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqgemx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange proposes to amend its By-Laws at Article IV, Section 7 to conform its provisions regarding the Exchange's Chief Regulatory Officer ("CRO") to those of its affiliate, Nasdaq PHLX LLC ("Phlx").<sup>3</sup> By-Law Article IV, Section 7 presently requires that an officer of the Exchange<sup>4</sup> with the position of Executive Vice President or Senior Vice President be designated as the CRO of the Exchange. The Exchange now proposes to remove the requirement that the CRO be an Executive Vice President or Senior Vice President of the Exchange. The Exchange believes that this requirement is unnecessary and notes that there may be officers of the Exchange who are well qualified to serve in the CRO role, but who may not hold the position of an Executive Vice President or Senior Vice President.<sup>5</sup> The Exchange does not seek to amend any of the current responsibilities of the CRO as set forth in Section 7;<sup>6</sup> rather, the proposed changes are intended to give the Exchange more flexibility to attract and retain well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President of the Exchange. As noted above, the Exchange desires to conform the requirements to become CRO in its By-Laws to those in the By-Laws of Phlx, which do not contain a similar restriction in Article IV, Section 4-7 of its By-Laws that its CRO be an Executive Vice President or Senior Vice President of Phlx.<sup>7</sup>

##### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

of the Act,<sup>8</sup> in general, and furthers the objectives of Section 6(b)(1) of the Act,<sup>9</sup> in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that this proposal furthers the objectives of Section 6(b)(5) of the Act,<sup>10</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposed changes will remove the requirement currently in Article IV, Section 7 of the Exchange's By-Laws that the CRO be an Executive Vice President or Senior Vice President of the Exchange. As discussed above, the current responsibilities of the CRO as provided in Article IV, Section 7 remain unchanged under this proposal, and the CRO will continue to have general oversight of the regulatory operations of the Exchange and be obligated to meet regularly with the Regulatory Oversight Committee. The proposed rule change is intended to provide the Exchange with greater flexibility to attract and retain capable individuals who are well qualified to serve in the CRO role. In addition, the proposed amendments will have the additional benefit of bringing the Exchange's requirements on the CRO role into greater conformity with those of its affiliate, Phlx, thereby creating equivalent standards among the affiliated exchanges owned by Nasdaq, Inc. ("HoldCo").<sup>11</sup> As such, the Exchange believes that its proposal will bring greater consistency to its rules, which is beneficial to both investors and the public interest.

#### 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

<sup>3</sup> See Phlx By-Law Article IV, Section 4-7 (Chief Regulatory Officer).

<sup>4</sup> In Exhibit 5, the references to "Company" mean the Exchange.

<sup>5</sup> The Exchange notes that Phlx's CRO currently holds the position of Vice President.

<sup>6</sup> The CRO's responsibilities include general supervision of the regulatory operations of the Exchange, including responsibility for overseeing the Exchange's surveillance, examination, and enforcement functions and for administering any regulatory services agreements with another SRO to which the Exchange is a party. In addition, the CRO shall meet with the Regulatory Oversight Committee of the Exchange in executive session at regularly scheduled meetings of such committee, and at any time upon request of the CRO or any member of the Regulatory Oversight Committee. Unlike Phlx, the Exchange's By-Laws provide that the CRO may also serve as the General Counsel of the Exchange. See By-Law Article IV, Section 7.

<sup>7</sup> See note 5 above.

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(1).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>11</sup> The Nasdaq Stock Market LLC ("NSM"), Nasdaq BX, Inc. ("BX"), Nasdaq ISE, LLC ("ISE"), and Nasdaq MRX, LLC ("MRX") will file similar proposals to conform their By-Laws with Phlx's By-Laws. ISE, GEMX, MRX, NSM, BX, and Phlx will hereinafter be referred to collectively as "Affiliated Exchanges."

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

proposed rule change does not address competitive issues but relates to the administration and functioning of the Exchange by allowing the Exchange greater flexibility in attracting and retaining well qualified officers to the role of CRO that are not designated as an Executive Vice President or Senior Vice President.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>12</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>13</sup>

A proposed rule change filed under Rule 19b-4(f)(6)<sup>14</sup> normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)<sup>15</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Exchange notes that waiver of the operative delay will allow it to amend its By-Laws by September 26, 2018. The Exchange states that the boards of the Affiliated Exchanges will collectively meet on that date to address, among other matters, certain annual corporate "housekeeping items," which the Exchange states has historically included Exchange officer appointments. As such, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest.

<sup>12</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>13</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>14</sup> 17 CFR 240.19b-4(f)(6).

<sup>15</sup> 17 CFR 240.19b-4(f)(6)(iii).

Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.<sup>16</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-GEMX-2018-31 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-GEMX-2018-31. 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,

<sup>16</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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-GEMX-2018-31 and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2018-20758 Filed 9-24-18; 8:45 am]

BILLING CODE 8011-01-P

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-84209; File No. SR-NASDAQ-2018-073]

**Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7021**

September 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 6, 2018, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes to amend Rule 7021 to address the transition of reports available on Report Center to a new underlying platform, and to make technical and clarifying changes.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at

<sup>17</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

the Commission's Public Reference Room.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange is proposing to amend Rule 7021, concerning the Report Center, to address the transition of reports available on Report Center to a new underlying platform, and to make technical and clarifying changes. Report Center provides members with various reports containing information concerning the member's own historical quoting and trading activity on Nasdaq and the FINRA/Nasdaq Trade Reporting Facility, which is located in Carteret, NJ ("TRF Carteret"). The Exchange will begin operating a second trade reporting facility, FINRA/Nasdaq TRF Chicago ("TRF Chicago"), in September of 2018.<sup>3</sup> The purpose of this proposed rule change is to inform members of the transition to the new underlying platform, to clarify the contents of certain reports in light of the new TRF Chicago, and to make clarifying changes concerning how the fee is assessed.

The Exchange is beginning a process of replacing the underlying platform of Report Center with a new platform, Report HQ. Report HQ will be more robust and user friendly, and thus an improvement over the existing Report Center platform. Nasdaq is not proposing to change the fees assessed for the reports under Rule 7021 or assess an additional fee for access to the Rule 7021 reports on Report HQ. Nasdaq is beginning the transition with reports that may include TRF data, which are certain Historical Research Reports under Rule 7021(b) and the Market Recap report under Rule 7021(d). These reports will be available on both

platforms concurrent with the launch of the TRF Chicago, which is currently scheduled for September 2018. In light of the timing of the TRF Chicago and the transition to the Report HQ,<sup>4</sup> Nasdaq will not be adding TRF Chicago data to the Historical Research Reports and Market Recap reports available on Report Center, but will make TRF Chicago data in those reports available through the Report HQ platform. The remaining reports available under Rule 7021 do not include TRF data and consequently will be identical on each platform as they are transferred over the course of the transition.<sup>5</sup>

Any member may have access to the Report HQ platform upon request. Specifically, an existing Report Center subscriber must submit a Report HQ Request Form available at <https://www.nasdaqtrader.com/EASP/TraderEASP.aspx?id=ReportHQSignUp>. Nasdaq will then verify the account and send the member a registration link.<sup>6</sup> Upon completion of the registration process, the member will be able to access both platforms to access reports, and will not be charged any additional fees for these reports. If a member does not have an existing Report Center subscription and requests Report HQ access to the Rule 7021 reports using the process described immediately above, Nasdaq will create a login to the Report Center platform in addition to a Report HQ login for the member, and the member will be charged the current monthly \$250 per entitled user, per MPID<sup>7</sup> fee under Rule 7021. This registration process ensures that customers are able to access the whole breadth of reports available and covered by Rule 7021. Any new subscriber to Report Center will receive both a Report Center and Report HQ login. Last, during the process of transitioning reports from Report Center to Report HQ, subscribers will be able to access up to a total of 100 reports under (b)–(f) of the rule on each platform. This will effectively double the number of reports available for a subscription for the duration of the transition. All

<sup>4</sup> In this regard, Nasdaq notes that it is beginning the transition to Report HQ with the only reports that include TRF data. Thus the Exchange is avoiding the time and expense of programming new reports for the Report Center platform, which will become defunct upon completion of the transition.

<sup>5</sup> The Exchange will provide prior notice via Equity Trader Alerts of the availability of the reports under Rule 7021 on Report HQ.

<sup>6</sup> See [https://business.nasdaq.com/media/NasdaqReportHQ\\_tcm5044-43704.pdf](https://business.nasdaq.com/media/NasdaqReportHQ_tcm5044-43704.pdf).

<sup>7</sup> The Exchange is proposing to clarify under Rule 7021 that the fee is assessed per entitled user, per MPID, because under the Nasdaq Report Center each entitled user is entitled to reports for a single MPID.

members may access the Rule 7021 reports on Report HQ upon completion of the Report HQ registration process noted above.

The Exchange is also proposing to remove Monthly Summaries from Rule 7021, and hold Rule 7021(a) in reserve. No member has accessed Monthly Summaries in over a year and Nasdaq does not currently provide the report in Report Center. The Exchange believes that the report is no longer useful to members and consequently is proposing to eliminate the report from Rule 7021.

Last, the Exchange is proposing to make two clarifying changes to Rule 7021. First, as noted above, accessing reports under (b)–(f) do count toward the cap under Rule 7021. In this regard, when the Exchange added several reports to the Rule in 2014,<sup>8</sup> it noted that the following reports count toward the report cap: Nasdaq Order Execution and Routing; Market Recap; QView Historical Reports; and Real-Time Registered Market Maker Report. These reports are found under paragraphs (c)–(f) of the Rule. In the 2014 filing, the Exchange also added text that made it clear that the newly-added reports under (g)–(k) do not count toward the report cap.<sup>9</sup> The Exchange is proposing to make it clear that the reports under (b)–(f) are counted toward the monthly cap. Second, the Exchange is making it clear that the monthly fee under Rule 7021 is assessed per entitled user, per MPID. Currently under Rule 7021, a member is billed by each entitled user, *i.e.*, a user ID, which is tied to a single MPID of the member. The 100 report limit is tied to a user ID. In practice, a member may have multiple user IDs so that they may access reports concerning multiple MPIDs. Report HQ has simplified access to reports by not requiring multiple user IDs, but rather allows a single user ID per person, who then may be given access to reports for multiple MPIDs (each for the \$250 monthly fee). Thus, Report HQ will simplify access to the reports under Rule 7021, but will not alter the fee or what reports are provided in return for the fee. During the transition, a Report Center subscription will provide the user with access to the reports for the same MPID for Report HQ, as described above.

#### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

<sup>8</sup> See Securities Exchange Act Release No. 73815 (December 11, 2014), 79 FR 75223 (December 17, 2014) (SR–NASDAQ–2014–121).

<sup>9</sup> *Id.*

<sup>3</sup> See Securities Exchange Act Release No. 83559 (June 29, 2018), 83 FR 31589 (July 6, 2018) (SR–FINRA–2018–013).

of the Act,<sup>10</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act,<sup>11</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by allowing the Exchange to upgrade its systems, which will benefit members that use Report Center to access the reports found under Rule 7021. As noted above, Report HQ will be more robust and user friendly, and thus an improvement over the existing Report Center platform. The Exchange notes that all members may access the reports available through Report HQ without additional cost in addition to the existing fees. Nasdaq is not proposing to change the fees assessed for the reports under Rule 7021 or assess an additional fee for access to the Rule 7021 reports on Report HQ. The proposed rule change will not change the content of any of the reports under Rule 7021, other than the addition of TRF Chicago data and the deletion of an unused report that is not currently offered, as discussed above. Moreover, the Exchange is proposing to allow members to access 100 reports under Rule 7021(b)–(f) on either system. To access these reports, member need only complete the registration process, which is provided in a non-discriminatory manner. As noted above, if a member does not have an existing Report Center subscription and requests Report HQ access to the Rule 7021 reports using the process described above, Nasdaq will create a login to the Report Center platform in addition to a Report HQ login for the member, and the member will be charged the current monthly \$250 per entitled user fee. Thus, all members receiving the same reports under Rule 7021 will be assessed the same fee. The Exchange notes that providing members with a cap of 100 reports under Rule 7021(b)–(f) on each system will allow firms to more easily transition between the systems. The Exchange believes that the proposed clarifying changes protect investors and the public interest by removing ambiguities from the rule, which may cause market participant confusion over how the fee is assessed and what is included in the 100 report monthly limit. Last, the Exchange believes that removal of the Monthly Summaries report from Rule 7021 further perfects the Exchange's rule book and is consistent with the protection of

investors because the Exchange is eliminating an unused report from its rule. As noted above, no member has accessed Monthly Summaries in over a year and Nasdaq does not currently provide the report in Report Center. Keeping the Monthly Summaries text under Rule 7021 would lead to investor confusion over what reports are available under the rule. Accordingly, the Exchange believes that it is consistent with the purposes of the Act to delete the text.

The Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act<sup>12</sup> in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and it does not unfairly discriminate between customers, issuers, brokers or dealers. The Exchange is proposing a transition process that will not affect the fee assessed for the reports under Rule 7021. In this regard, the Exchange notes that all members receiving the reports under Rule 7021 will be assessed the same fee. Accordingly, the Exchange believes that the proposed change is an equitable allocation of a reasonable fee and does not unfairly discriminate.

#### *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, but it is rather pro-competitive. The proposal is reflective of the Exchange's efforts to upgrade its systems to improve the experience of its members. The Exchange is not increasing fees nor limiting the information available to members through a subscription under Rule 7021 other than the elimination of an unused report. Moreover, the proposed rule change will ensure that all members receiving the same reports under Rule 7021 will be assessed the same fee regardless of the platform used to access the report. To the extent that the upgraded platform improves the experience of members, it may make the Exchange a more attractive venue, which will help to retain existing members and potentially attract new members. Consequently, other trading venues may be compelled to improve their services in response.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

#### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>13</sup> and Rule 19b-4(f)(6) thereunder.<sup>14</sup>

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act<sup>15</sup> normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)<sup>16</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. Waiver of the operative delay would allow the Exchange to provide members with access to TRF Chicago data through Report HQ and make related changes to Rule 7021 concurrent with the launch of TRF Chicago in September 2018. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.<sup>17</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the

<sup>13</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>14</sup> 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

<sup>15</sup> 17 CFR 240.19b-4(f)(6).

<sup>16</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>17</sup> For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>10</sup> 15 U.S.C. 78f(b).

<sup>11</sup> 15 U.S.C. 78f(b)(5).

<sup>12</sup> 15 U.S.C. 78f(b)(4).

public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### *Electronic Comments*

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NASDAQ-2018-073 on the subject line.

##### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2018-073. 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-NASDAQ-2018-073, and should be submitted on or before October 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>18</sup>

**Brent J. Fields,**  
*Secretary.*

[FR Doc. 2018-20761 Filed 9-24-18; 8:45 am]

**BILLING CODE 8011-01-P**

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## SMALL BUSINESS ADMINISTRATION

### Reporting and Recordkeeping Requirements Under OMB Review

**AGENCY:** Small Business Administration.  
**ACTION:** 30-Day notice.

**SUMMARY:** The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public of that submission.

**DATES:** Submit comments on or before October 25, 2018.

**ADDRESSES:** Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer*, Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer*, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Curtis Rich, Agency Clearance Officer, (202) 205-7030, [curtis.rich@sba.gov](mailto:curtis.rich@sba.gov).

*Copies:* A copy of the Form OMB 83-1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

**SUPPLEMENTARY INFORMATION:** Under this program, a small business concern without a past performance rating as a prime contractor in the Past Performance Information Retrieval System (PPIRS) may request a past performance rating in the Contractor Performance Assessment Reporting System (CPARS), if the small business is a first tier subcontractor under a covered Federal Government contract requiring a FAR 19.702(a). Ratings of subcontractor performance can be requested on

subcontracts that exceed the simplified acquisition threshold, or subcontracts for architecture-engineering services valued at \$35,000 or more as provided in FAR 42.1502.

#### Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

#### Summary of Information Collections

(1) *Title:* SBA Subcontractor Past Performance Pilot Initiative.

*Description of Respondents:* Prime Contractor.

*Form Number:* 2,465.

*Estimated Annual Respondents:* 2,520.

*Estimated Annual Responses:* 2,520.

*Estimated Annual Hour Burden:* 3,780.

**Curtis Rich,**

*Management Analyst.*

[FR Doc. 2018-20829 Filed 9-24-18; 8:45 am]

**BILLING CODE 8025-01-P**

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## DEPARTMENT OF STATE

[Public Notice 10557]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: “Underworld: Imagining the Afterlife” Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Underworld: Imagining the Afterlife,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum at the Getty Villa, Los Angeles, California, from on or about October 31, 2018, until on or about March 18, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.  
**FOR FURTHER INFORMATION CONTACT:** Elliot Chiu, Attorney-Adviser, Office of

<sup>18</sup> 17 CFR 200.30-3(a)(12).

the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/ PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 236-14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-20806 Filed 9-24-18; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF STATE

[Public Notice: 10563]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: “Andy Warhol—From A to B and Back Again” Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Andy Warhol—From A to B and Back Again,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Whitney Museum of American Art, New York, New York, from on or about November 12, 2018, until on or about March 31, 2019; the San Francisco Museum of Modern Art, San Francisco, California, from on or about May 18, 2019, until on or about September 2, 2019; and The Art Institute of Chicago, Chicago, Illinois, from on or about October 20, 2019, until on or about January 26, 2020; and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email:

[section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/ PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 236-14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-20824 Filed 9-24-18; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF STATE

[Public Notice: 10561]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: “Metaphysical Masterpieces 1916–1920: Morandi, Sironi, and Carrà” Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Metaphysical Masterpieces 1916–1920: Morandi, Sironi, and Carrà,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Center for Italian Modern Art, New York, New York, from on or about October 19, 2018, until on or about June 15, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/ PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat.

985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 236-14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-20813 Filed 9-24-18; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF STATE

[Public Notice 10528]

### 60-Day Notice of Proposed Information Collection: Statement of Registration

**ACTION:** Notice of request for public comment.

**SUMMARY:** The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

**DATES:** The Department will accept comments from the public up to *November 26, 2018*.

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

- **Web:** Persons with access to the internet may comment on this notice by going to [www.Regulations.gov](http://www.Regulations.gov). You can search for the document by entering “Docket Number: DOS-2018-0039” in the Search field. Then click the “Comment Now” button and complete the comment form.

- **Email:** [DDTCPublicComments@state.gov](mailto:DDTCPublicComments@state.gov).

- **Regular Mail:** Send written comments to: Directorate of Defense Trade Controls, Attn: Andrea Battista, 2401 E St. NW, Suite H-1205, Washington, DC 20522-0112.

You must include the subject (PRA 60 Day Comment), information collection title (Statement of Registration), and OMB control number (1405-0002) in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Direct requests for additional information regarding this collection to Andrea Battista, who may be reached at [BattistaAL@state.gov](mailto:BattistaAL@state.gov) or 202-663-3136.

**SUPPLEMENTARY INFORMATION:**

- *Title of Information Collection:* Statement of Registration.
- *OMB Control Number:* 1405–0002.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Directorate of Defense Trade Controls (DDTC).
- *Form Number:* DS–2032.
- *Respondents:* Respondents are any person/s who engages in the United States in the business of manufacturing or exporting or temporarily importing defense articles.
- *Estimated Number of Respondents:* 14,800.
- *Estimated Number of Responses:* 15,540.
- *Average Time per Response:* 1 hour to complete the registration; 5 minutes to amend the form as necessary.
- *Total Estimated Burden Time:* 14,862 hours.
- *Frequency:* Annually, with amendments as necessary.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

**Abstract of Proposed Collection**

Pursuant to Part 122 of the International Traffic in Arms Regulation (ITAR), and section 38 of the Arms Export Control Act, 22 U.S.C. 2778, any person who engages in the United States in the business of manufacturing or exporting or temporarily importing defense articles or furnishing defense services is required to register with the Department of State, Directorate of Defense Trade Controls (DDTC). Pursuant to Part 129 of the ITAR, any U.S. person wherever located, and any foreign person located in the United States or otherwise subject to the

jurisdiction of the United States, who engages in the business of brokering activities, is required to register with DDTC. DDTC uses the information provided by registrants to meet the mandates described in Part 122 and Part 129 of the ITAR. As appropriate, such information may be shared with other U.S. Government entities. This information is currently used in the review and action on registration requests and to ensure compliance with defense trade laws and regulations.

**Methodology**

Statement of Registration submissions are made via a completed DS–2032 which may be accessed from DDTC's website and submitted electronically.

**Anthony M. Dearth,**

*Chief of Staff, Directorate of Defense Trade Controls, U.S. Department of State.*

[FR Doc. 2018–20750 Filed 9–24–18; 8:45 am]

**BILLING CODE 4710–25-P**

**DEPARTMENT OF STATE**

[Public Notice: 10566]

**Notice of Determinations; Culturally Significant Objects Re-Imported for Exhibition—Determinations: “Art and China after 1989: Theater of the World” Exhibition**

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Art and China after 1989: Theater of the World,” re-imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are re-imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the San Francisco Museum of Modern Art, San Francisco, California, from on or about November 10, 2018, until on or about February 24, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:**

Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat.

985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 236–14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018–20823 Filed 9–24–18; 8:45 am]

**BILLING CODE 4710–05-P**

**DEPARTMENT OF STATE**

[Public Notice: 10559]

**Notice of Determinations; Culturally Significant Object Imported for Exhibition—Determinations: “Myth and Faith in Renaissance Florence” Exhibition**

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that a certain object to be included in the exhibition “Myth and Faith in Renaissance Florence,” imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at the Currier Museum of Art, Manchester, New Hampshire, from on or about October 13, 2018, until on or about January 21, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:**

Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28,



2000, and Delegation of Authority No. 236–14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018–20811 Filed 9–24–18; 8:45 am]

**BILLING CODE 4710–05–P**

2000, and Delegation of Authority No. 236–14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018–20812 Filed 9–24–18; 8:45 am]

**BILLING CODE 4710–05–P**

2000, and Delegation of Authority No. 236–14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018–20810 Filed 9–24–18; 8:45 am]

**BILLING CODE 4710–05–P**

## DEPARTMENT OF STATE

[Public Notice: 10560]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: “East Meets West: Jewels of the Maharajas From the Al Thani Collection” Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “East Meets West: Jewels of the Maharajas from the Al Thani Collection,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Fine Arts Museums of San Francisco, Legion of Honor Museum, San Francisco, California, from on or about November 3, 2018, until on or about February 24, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PA, SA–5, Suite 5H03, Washington, DC 20522–0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28,

## DEPARTMENT OF STATE

[Public Notice: 10558]

### Notice of Determinations; Culturally Significant Objects Re-Imported for Exhibition—Determinations: “Keir Collection of Art of the Islamic World” Exhibitions

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that two objects to be included in exhibitions of the Keir Collection of Art of the Islamic World, re-imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are re-imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the first object at the Dallas Museum of Art, in Dallas, Texas, and at possible additional exhibitions or venues yet to be determined, from on or about September 21, 2018, until on or about May 4, 2020, is in the national interest. I also determine that the exhibition or display of the second object at the Dallas Museum of Art, and at possible additional exhibitions or venues yet to be determined, from on or about September 21, 2018, until on or about October 13, 2020, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PA, SA–5, Suite 5H03, Washington, DC 20522–0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28,

## DEPARTMENT OF STATE

[Public Notice 10565]

### Meetings of the United States-Panama Environmental Affairs Council and Environmental Cooperation Commission

**ACTION:** Notice of meetings of the United States-Panama Environmental Affairs Council and Environmental Cooperation Commission and request for comments.

**SUMMARY:** The Department of State and the Office of the United States Trade Representative (USTR) are providing notice that the United States and Panama intend to hold the second meetings of the Environmental Affairs Council (the “Council”) and the Environmental Cooperation Commission (the “Commission”) on October 3, 2018. The public sessions for the Council and Commission will be held on October 3, 2018, in Panama City, Panama.

The purpose of the meetings is to review implementation of Chapter 17 (Environment) of the United States-Panama Trade Promotion Agreement (TPA) and the United States-Panama Environmental Cooperation Agreement (ECA).

The Department of State and USTR invite interested organizations and members of the public to attend the public sessions and to submit written comments or suggestions regarding topics to be discussed at the meetings.

If you would like to attend the public session, please notify Neal Morris and Laura Buffo at the email addresses listed below under the heading **ADDRESSES**. Please include your full name and any organization or group you represent.

In preparing comments, submitters are encouraged to refer to:

- Chapter 17 of the TPA, [https://ustr.gov/sites/default/files/uploads/agreements/fta/panama/asset\\_upload\\_file314\\_10400.pdf](https://ustr.gov/sites/default/files/uploads/agreements/fta/panama/asset_upload_file314_10400.pdf); and
- the ECA <http://www.state.gov/documents/organization/189455.pdf>.

These and other useful documents are available at <https://ustr.gov/trade-agreements/free-trade-agreements/panama-tpa> and at <http://>

[www.state.gov/e/oes/eqt/trade/panama/index.htm](http://www.state.gov/e/oes/eqt/trade/panama/index.htm).

**ADDRESSES:** Any written comments and suggestions should be submitted to both:

(1) Neal Morris, Office of Environmental Quality and Transboundary Issues, U.S. Department of State, by electronic mail at [MorrisND@state.gov](mailto:MorrisND@state.gov) with the subject line “U.S.-Panama EAC/ECC Meetings”;

and  
(2) Laura Buffo, Office of Environment and Natural Resources, Office of the United States Trade Representative, by electronic mail at [Laura\\_Buffo@ustr.eop.gov](mailto:Laura_Buffo@ustr.eop.gov) with the subject line “U.S.-Panama EAC/ECC Meetings.”

**DATES:** The public sessions of the Council and Commission meetings will be held on October 3, 2018. Please contact Neal Morris and Laura Buffo for the time and location of the meetings. We request comments and suggestions in writing no later than October 1, 2018, to facilitate consideration.

Persons with access to the internet may comment on this notice by going to [www.Regulations.gov](http://www.Regulations.gov). You can search for the document by entering “Docket Number: DOS-2018-0046” in the Search field. Then click the “Comment Now” button and complete the comment form.

**Brian Doherty,**

*Director, Office of Environmental Quality and Transboundary Issues, Department of State.*

[FR Doc. 2018-20803 Filed 9-24-18; 8:45 am]

**BILLING CODE 4710-09-P**

## DEPARTMENT OF STATE

[Public Notice: 10562]

### Notice of Determinations; Culturally Significant Object Imported for Exhibition—Determinations: “After Vesuvius: Treasures From the Villa dei Papiri” Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that a certain object to be included in the exhibition “After Vesuvius: Treasures from the Villa dei Papiri,” imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at The J. Paul Getty Museum at the Getty Villa, Pacific Palisades, California, from on or about June 26, 2019, until on or about October 28, 2019, and at possible additional exhibitions or venues yet to be

determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PA, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 236-14 of September 10, 2018.

**Jennifer Z. Galt,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-20814 Filed 9-24-18; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF STATE

[Public Notice: 10554]

### Bureau of Consular Affairs; Registration for the Diversity Immigrant (DV-2020) Visa Program

**ACTION:** Notice.

**SUMMARY:** This public notice provides information on how to apply for the DV-2020 Program and is issued pursuant to the Immigration and Nationality Act.

#### Program Overview

The Department of State annually administers the statutorily-mandated Diversity Immigrant Visa Program. Section 203(c) of the Immigration and Nationality Act (INA) provides for a class of immigrants known as “diversity immigrants,” from countries with historically low rates of immigration to the United States. For fiscal year 2020, 50,000 diversity visas (DVs) will be available. There is no cost to register for the DV Program.

Applicants who are selected in the lottery (“selectees”) must meet simple, but strict, eligibility requirements to qualify for a diversity visa. The Department of State determines selectees through a randomized

computer drawing. Diversity visa numbers are distributed among six geographic regions, and no single country may receive more than seven percent of the available DVs in any one year.

For DV-2020, natives of the following countries are not eligible to apply, because more than 50,000 natives of these countries immigrated to the United States in the previous five years:

Bangladesh, Brazil, Canada, China (mainland-born), Colombia, Dominican Republic, El Salvador, Haiti, India, Jamaica, Mexico, Nigeria, Pakistan, Peru, Philippines, South Korea, United Kingdom (except Northern Ireland) and its dependent territories, and Vietnam.

Persons born in Hong Kong SAR, Macau SAR, and Taiwan are eligible.

There are no changes in eligibility this year from the previous year.

#### Eligibility

**Requirement #1:** Individuals born in countries whose natives qualify may be eligible to enter.

If you were not born in an eligible country, there are two other ways you might be able to qualify:

- Was your spouse born in a country whose natives are eligible? If yes, you can claim your spouse’s country of birth—provided that both you and your spouse are named on the selected entry, are found eligible for and issued diversity visas, and enter the United States simultaneously.

- Were you born in a country whose natives are ineligible, but in which neither of your parents were born or legally resided at the time of your birth? If yes, you may claim the country of birth of one of your parents—provided that one of your parents was born in a country whose natives are eligible for the DV-2020 program. For more details on what this means, see the Frequently Asked Questions.

**Requirement #2:** Each applicant must meet the education/work experience requirement of the DV program by having either:

- At least a high school education or its equivalent, defined as successful completion of a 12-year course of formal elementary and secondary education; OR

- two years of work experience within the past five years in an occupation that requires at least two years of training or experience to perform. The Department of State will use the U.S. Department of Labor’s O\*Net Online database to determine qualifying work experience. For more information about qualifying work experience for the principal DV

applicant, see the Frequently Asked Questions.

*Do not submit an entry to the DV program unless you meet both of these requirements.*

### Entry Period

Applicants must submit entries for the DV-2020 DV program electronically at [dvlottery.state.gov](http://dvlottery.state.gov) between noon, Eastern Daylight Time (EDT) (GMT-4), Wednesday, October 3, 2018, and noon, Eastern Standard Time (EST) (GMT-5), Tuesday, November 6, 2018. Do not wait until the last week of the registration period to enter, as heavy demand may result in website delays. No late entries or paper entries will be accepted. The law allows only one entry per person during each registration period. The Department of State uses sophisticated technology to detect multiple entries. *Individuals with more than one entry will be disqualified.*

### Completing Your Electronic Entry for the DV-2020 Program

Submit your Electronic Diversity Visa Entry Form (E-DV Entry Form or DS-5501), online at [dvlottery.state.gov](http://dvlottery.state.gov). We will not accept incomplete entries. There is no cost to register for the DV Program.

We strongly encourage you to complete the entry form yourself, without a "visa consultant," "visa agent," or other facilitator who offers to help. If someone else helps you, you should be present when your entry is prepared so that you can provide the correct answers to the questions and retain the confirmation page and your unique confirmation number.

After you submit a complete entry, you will see a confirmation screen that contains your name and a unique confirmation number. Print this confirmation screen for your records. It is extremely important that you retain your confirmation page and unique confirmation number. Without this information, you will not be able to access the online system that will inform you of the status of your entry. You also should retain access to the email account listed in the E-DV. See the Frequently Asked Questions for more information about Diversity Visa scams.

Starting May 7, 2019, you will be able to check the status of your entry by returning to [dvlottery.state.gov](http://dvlottery.state.gov), clicking on *Entrant Status Check*, and entering your unique confirmation number and personal information. *Entrant Status Check* will be the sole means of informing you of your selection for DV-2020, providing instructions on how to proceed with your application, and

notifying you of your appointment for your immigrant visa interview. Please review the Frequently Asked Questions for more information about the selection process.

You must provide the following information to complete your E-DV entry:

1. Name—last/family name, first name, middle name—exactly as it appears on your passport. If you have one name, it must be entered in the last/family name field.
2. Gender—male or female.
3. Birth date—day, month, year.
4. City where you were born.
5. Country where you were born—Use the name of the country currently used for the place where you were born.
6. Country of eligibility for the DV Program—Your country of eligibility will normally be the same as your country of birth. Your country of eligibility is not related to where you live.

If you were born in a country that is not eligible, please review the Frequently Asked Questions to see if there is another way you may be eligible.

7. Entrant photograph(s)—Recent photographs (taken within the last six months) of yourself, your spouse, and all your children listed on your entry. See Submitting a Digital Photograph below for compositional and technical specifications. You do not need to include a photograph for a spouse or child who is already a U.S. citizen or a Lawful Permanent Resident, but you will not be penalized if you do. DV entry photographs must meet the same standards as U.S. visa photos. Your entry will be disqualified if your visa refused if the entry photographs for you and your family members do not fully meet these specifications or have been manipulated in any way. Submitting the same photograph that was submitted with a prior year's entry will result in disqualification. See Submitting a Digital Photograph for more information.

8. Mailing Address—

In Care Of  
Address Line 1  
Address Line 2 (optional)  
City/Town  
District/Country/Province/State  
Postal Code/Zip Code  
Country

9. Country where you live today.
10. Phone number (optional).
11. Email address—An email address to which you have direct access, and will continue to have direct access after we notify selectees in May of next year. If your entry is selected and you

respond to the notification of your selection through the *Entrant Status Check*, you will receive follow-up email communication from the Department of State notifying you that details of your immigrant visa interview are available on *Entrant Status Check*. The Department of State will never send you an email telling you that you have been selected for the DV program. See the Frequently Asked Questions for more information about the selection process.

12. Highest level of education you have achieved, as of today: (1) Primary school only, (2) Some High School, no degree, (3) High School degree, (4) Vocational School, (5) Some University Courses, (6) University Degree, (7) Some Graduate-Level Courses, (8) Master's Degree, (9) Some Doctoral-Level courses, and (10) Doctorate Degree. See the Frequently Asked Questions for more information about educational requirements.

13. Current marital status—(1) Unmarried, (2) Married and my spouse is NOT a U.S. citizen or U.S. Lawful Permanent Resident, (3) Married and my spouse IS a U.S. citizen or U.S. Lawful Permanent Resident, (4) Divorced, (5) Widowed, or (6) Legally Separated. Enter the name, date of birth, gender, city/town of birth, country of birth of your spouse, and a photograph of your spouse meeting the same technical specifications as your photo.

Failure to list your eligible spouse or, listing someone who is not your spouse, will result in disqualification of the principal applicant and refusal of all visas in the case at the time of the visa interview. You must list your spouse even if you currently are separated from him/her, unless you are legally separated. Legal separation is an arrangement under which a couple remain married but live apart, following a court order. If you and your spouse are legally separated, your spouse will not be able to immigrate with you through the Diversity Visa program. You will not be penalized if you choose to enter the name of a spouse from whom you are legally separated. If you are not legally separated by a court order, you must include your spouse even if you plan to be divorced before you apply for the Diversity Visa. Failure to list your eligible spouse is grounds for disqualification.

If your spouse is a U.S. citizen or Lawful Permanent Resident, do not list him/her in your entry. A spouse who is already a U.S. citizen or a Lawful Permanent Resident will not require or be issued a DV visa. Therefore, if you select "married and my spouse IS a U.S. citizen or U.S. LPR" on your entry, you will not be prompted to include further

information on your spouse. See the Frequently Asked Questions for more information about family members.

14. Number of children—List the name, date of birth, gender, city/town of birth, and country of birth for all living unmarried children under 21 years of age, regardless . Submit individual photographs of each of your children using the same technical specifications as your own photograph.

Be sure to include:

- All living natural children;
- all living children legally adopted by you; and,
- all living step-children who are unmarried and under the age of 21 on the date of your electronic entry, even if you are no longer legally married to the child's parent, and even if the child does not currently reside with you and/or will not immigrate with you.

Married children and children over the age of 21 are not eligible for the DV. However, the Child Status Protection Act protects children from “aging out” in certain circumstances. If you submit your DV entry before your unmarried child turns 21, and the child turns 21 before visa issuance, it is possible that he or she may be treated as though he or she were under 21 for visa-processing purposes.

A child who is already a U.S. citizen or a Lawful Permanent Resident will not require or be issued a diversity visa, and you will not be penalized for either including or omitting such family members from your entry.

Failure to list all children who are eligible or, listing someone who is not your child, will result in disqualification of the principal applicant and refusal of all visas in the case at the time of the visa interview. See the Frequently Asked Questions for more information about family members.

See the Frequently Asked Questions for more information about completing your Electronic Entry for the DV–2019 Program.

### Selection of Applicants

Based on the allocations of available visas in each region and country, the Department of State will randomly select individuals by computer from among qualified entries. All DV–2020 entrants must go to the *Entrant Status Check* using the unique confirmation number saved from their DV–2020 online entry registration to find out whether their entry has been selected in the DV program. *Entrant Status Check* will be available on the E–DV website at [dvlottery.state.gov](http://dvlottery.state.gov) starting May 7, 2019, through at least September 30, 2020.

If your entry is selected, you will be directed to a confirmation page that will provide further instructions, including information on fees connected with immigration to the United States.

*Entrant Status Check* will be the ONLY means by which the Department of State notifies selectees of their selection for DV–2020. The Department of State will not mail out notification letters or notify selectees by email. U.S. embassies and consulates will not provide a list of selectees. Individuals who have not been selected also will be notified ONLY through *Entrant Status Check*. You are strongly encouraged to access *Entrant Status Check* yourself and not to rely on someone else to check and inform you.

In order to immigrate, DV selectees must be admissible to the United States. The DS–260, Online Immigrant Visa and Alien Registration Application, electronically, and the consular officer, in person will ask you questions about your eligibility to immigrate, and these questions include criminal and security related grounds.

All eligible selectees, including family members, must be issued by September 30, 2020. Under no circumstances can the Department of State issue DVs or approve adjustments after this date, nor can family members obtain DVs to follow-to-join the principal applicant in the United States after this date. See the Frequently Asked Questions for more information about the selection process.

### Submitting a Digital Photograph (Image)

You can take a new digital photograph or scan a recent (taken within the last six months) photograph with a digital scanner, as long as it meets all of the standards below. DV entry photos must be of the same quantity and composition as U.S. visa photos. Do not submit a photograph older than six months or a photograph that does not meet all of the standards described below. Submitting the same photograph that was submitted with a prior year's entry, a photograph that has been manipulated, or a photograph that does not meet the specifications below will result in disqualification.

### Compositional Specifications:

- In color
- In focus
- Sized such that the head is between 1 inch and 1 $\frac{3}{8}$  inches (22 mm and 35 mm) or 50% and 69% of the image's total height from the bottom of the chin to the top of the head. View the Photo Composition Template on [travel.state.gov](http://travel.state.gov) for more size requirement details

- Taken within the last 6 months to reflect your current appearance
- Taken in front of a plain white or off-white background
- Taken in full-face view directly facing the camera
- With a neutral facial expression and both eyes open
- Taken in clothing that you normally wear on a daily basis
- Uniforms should not be worn in your photo, except religious clothing that is worn daily
- Do not wear a hat or head covering that obscures the hair or hairline, unless worn daily for a religious purpose. Your full face must be visible, and the head covering must not cast any shadows on your face
- Headphones, wireless hands-free devices, or similar items are not acceptable in your photo
- Do not wear Eyeglasses
- If you normally wear a hearing device or similar articles, they may be worn in your photo

### Technical Specifications

You must upload your digital image as part of your entry. Your digital image must be:

- In JPEG (.jpg) file format
- Equal to or less than 240 kB (kilobytes) in file size
- In a square aspect ratio (height must equal width)
- 600 x 600 pixels in dimension

Do you want to scan an existing photo? In addition to the digital image requirements, your existing photo must be:

- 2 x 2 inches (51 x 51 mm)
- Scanned at a resolution of 300 pixels per inch (12 pixels per millimeter)

### Frequently Asked Questions (FAQ's)

#### Eligibility

1. What do the terms “NATIVE” and “CHARGEABILITY” mean?

“Native” ordinarily means someone born in a particular country, regardless of the individual's current country of residence or nationality. “Native” can also mean someone who is entitled to be “charged” to a country other than the one in which he/she was born under the provisions of Section 202(b) of the Immigration and Nationality Act.

Because there is a numerical limitation on immigrants who enter from a country or geographic region, each individual is “charged” to a country. Your chargeability” refers to the country towards which limitation you count. Your country of eligibility will normally be the same as your country of birth. However, you may

choose your country of eligibility as the country of birth of your spouse, or the country of birth of either of your parents if you were born in a country in which neither parent was born and in which the parents were not resident at the time of your birth. These are the only three ways to select your country of chargeability.

If you claim alternate chargeability through either of the above, you must provide an explanation on the E-DV Entry Form, in question #6. Listing an incorrect country of eligibility or chargeability (*i.e.*, one to which you cannot establish a valid claim) will disqualify your entry.

2. Can I still apply if I was not born in a qualifying country?

There are two circumstances in which you still might be eligible to apply. First, if your derivative spouse was born in an eligible country, you may claim chargeability to that country. As your eligibility is based on your spouse, you will only be issued a DV-1 immigrant visa if your spouse is also eligible for and issued a DV-2 visa. Both of you must enter the United States together using your DVs. Similarly, your minor dependent child can be "charged" to a parent's country of birth.

Second, you can be "charged" to the country of birth of either of your parents as long as neither of your parents was born in or a resident of your country of birth at the time of your birth. People are not generally considered residents of a country in which they were not born or legally naturalized, if they were only visiting, studying in the country temporarily, or stationed temporarily for business or professional reasons on behalf of a company or government from a different country other than the one in which you were born.

If you claim alternate chargeability through either of the above, you must provide an explanation on the E-DV Entry Form, in question #6. Listing an incorrect country of eligibility or chargeability (*i.e.*, one to which you cannot establish a valid claim) will disqualify your entry.

3. Why do natives of certain countries not qualify for the DV program?

DVs are intended to provide an immigration opportunity for persons who are not from "high admission" countries. The law defines "high admission countries" as those from which a total of 50,000 persons in the Family-Sponsored and Employment-Based visa categories immigrated to the United States during the previous five years. Each year, U.S. Citizenship and Immigration Services (USCIS) counts

the family and employment immigrant admission and adjustment of status numbers for the previous five years to identify the countries that are considered "high admission" and whose natives will therefore be ineligible for the annual diversity visa program. Because USCIS makes this calculation annually, the list of countries whose natives are eligible or not eligible may change from one year to the next.

4. How many DV-2019 visas will go to natives of each region and eligible country?

United States Citizenship and Immigration Services (USCIS) determines the regional DV limits for each year according to a formula specified in Section 203(c) of the Immigration and Nationality Act (INA). The number of visas the Department of State eventually will issue to natives of each country will depend on the regional limits established, how many entrants come from each country, and how many of the selected entrants are found eligible for the visa. No more than seven percent of the total visas available can go to natives of any one country.

5. What are the requirements for education or work experience?

U.S. immigration law and regulations require that every DV entrant must have at least a high school education or its equivalent or have two years of work experience within the past five years in an occupation that requires at least two years of training or experience. A "high school education or equivalent" is defined as successful completion of a 12-year course of elementary and secondary education in the United States OR the successful completion in another country of a formal course of elementary and secondary education comparable to a high school education in the United States. Only formal courses of study meet this requirement; correspondence programs or equivalency certificates (such as the General Equivalency Diploma G.E.D.) are not acceptable. You must present documentary proof of education or work experience to the consular officer at the time of the visa interview.

If you do not meet the requirements for education or work experience, your entry will be disqualified at the time of your visa interview, and no visas will be issued to you or any of your family members.

6. What occupations qualify for the DV program?

The U.S. Department of Labor's (DOL) O\*Net OnLine database will be used to

determine qualifying work experience. The O\*Net Online Database groups job experience into five "job zones." While the DOL website lists many occupations, not all occupations qualify for the DV Program. To qualify for a DV on the basis of your work experience, you must have, within the past five years, two years of experience in an occupation that is classified in a Specific Vocational Preparation (SVP) range of 7.0 or higher.

If you do not meet the requirements for education or work experience, your entry will be disqualified at the time of your visa interview, and no visas will be issued to you or any of your family members.

7. How can I find the qualifying DV occupations in the Department of Labor's O\*Net online database?

When you are in O\*Net OnLine, follow these steps to find out if your occupation qualifies:

1. Under "Find Occupations" select "Job Family" from the pull down;
2. Browse by "Job Family," make your selection, and click "GO;"
3. Click on the link for your specific occupation.
4. Select the tab "Job Zone" to find the designated Job Zone number and Specific Vocational Preparation (SVP) rating range.

As an example, select Aerospace Engineers. At the bottom of the Summary Report for Aerospace Engineers, under the Job Zone section, you will find the designated Job Zone 4, SVP Range, 7.0 to <8.0. Using this example, Aerospace Engineering is a qualifying occupation.

For additional information, see the Diversity Visa—List of Occupations web page ([travel.state.gov/visa/immigrants/types/types\\_1319.html](http://travel.state.gov/visa/immigrants/types/types_1319.html)).

8. Is there a minimum age to apply for the DV program?

There is no minimum age to apply, but the requirement of a high school education or work experience for each principal applicant at the time of application will effectively disqualify most persons who are under age 18.

*Completing Your Electronic Entry for the DV Program*

9. When can I submit my entry?

The DV-2020 entry period will run from 12:00 p.m. (noon), Eastern Daylight Time (EST) (GMT-4), Wednesday, October 3, 2018, until 12:00 p.m. (noon), Eastern Standard Time (EST) (GMT-5), Tuesday, November 6, 2018. Each year, millions of people submit entries. Holding the entry period on these dates

ensures selectees receive notification in a timely manner and gives both the visa applicants and our embassies and consulates time to prepare and complete cases for visa issuance.

We strongly encourage you to enter early during the registration period. Excessive demand at the end of the registration period may slow the system down. We cannot accept entries after noon EST Tuesday, November 6, 2018.

10. I am in the United States. Can I enter the DV program?

Yes, an entrant may apply while in the United States or another country. An entrant may submit an entry from any location.

11. Can I only enter once during the registration period?

Yes, the law allows only one entry by or for each person during each registration period. The Department of State uses sophisticated technology to detect multiple entries. *Individuals with more than one entry will be disqualified.*

12. May my spouse and I each submit a separate entry?

Yes, a husband and a wife may each submit one entry if each meets the eligibility requirements. If either spouse is selected, the other is entitled to apply as a derivative dependent.

13. What family members must I include in my DV entry?

*Spouse:* If you are legally married, you must list your spouse (husband or wife) regardless of whether or not he or she lives with you or intends to immigrate to the United States. You must list your spouse even if you are currently separated from him/her, unless you are legally separated. Legal separation is an arrangement when a couple remain married but live apart, following a court order. If you and your spouse are legally separated, your spouse will not be able to immigrate with you through the Diversity Visa program. You will not be penalized if you choose to enter the name of a spouse from whom you are legally separated. If you are not legally separated by a court order, you must include your spouse even if you plan to be divorced before you apply for the Diversity Visa. Failure to list your eligible spouse, or listing someone who is not your spouse, are grounds for disqualification.

If you are divorced or your spouse is deceased, you do not have to list your former spouse.

The only exception to this requirement is if your spouse is already a U.S. citizen or U.S. Lawful Permanent

Resident. A spouse who is already a U.S. citizen or a Lawful Permanent Resident will not require or be issued a DV. Therefore, if you select “married and my spouse IS a U.S. citizen or U.S. LPR” on your entry, you will not be able to include further information on your spouse.

*Children:* You must list ALL your living children who are unmarried and under 21 years of age at the time of your initial E–DV entry, whether they are your natural children, your stepchildren (even if you are now divorced from that child’s parent), your spouse’s children, or children you have formally adopted in accordance with the applicable laws. List all children under 21 years of age at the time of your electronic entry, even if they no longer reside with you or you do not intend for them to immigrate under the DV program. You are not required to list children who are already U.S. citizens or Lawful Permanent Residents, though you will not be penalized if you do include them.

Parents and siblings of the entrant are ineligible to receive DV visas as dependents, and you should not include them in your entry.

If you list family members on your entry, they are not required to apply for a visa or to immigrate or travel with you. However, if you fail to include an eligible dependent on your original entry or, list someone who is not your eligible dependent, your case will be disqualified at the time of your visa interview and no visas will be issued to you or any of your family members. This only applies to those who were family members at the time the original application was submitted, not those acquired at a later date. Your spouse, if eligible to enter, may still submit a separate entry even though he or she is listed on your entry, as long as both entries include details on all dependents in your family (see FAQ #12 above).

14. Must I submit my own entry, or can someone else do it for me?

We encourage you to prepare and submit your own entry, but you may have someone submit the entry for you. Regardless of whether you submit your own entry, or an attorney, friend, relative, or someone else submits it on your behalf, only one entry may be submitted in your name. You, as the entrant, are responsible for ensuring that information in the entry is correct and complete; entries that are not correct or complete may be disqualified. Entrants should keep their own confirmation number so that they are able to independently check the status of their entry using Entrant Status Check at

[dvlottery.state.gov](http://dvlottery.state.gov). Entrants should keep retain access to the email account used in the E–DV submission.

15. I’m already registered for an immigrant visa in another category. Can I still apply for the DV program?

Yes. Your DV registration will not make you ineligible for another immigrant visa classification.

16. When will E–DV be available online?

You can enter online during the registration period beginning at 12:00 p.m. (noon) Eastern Daylight Time (EDT) (GMT–4) on Wednesday, October 3, 2018, and ending at 12:00 p.m. (noon) Eastern Standard Time (EST) (GMT–5) on Tuesday, November 6, 2018.

17. Can I download and save the E–DV entry form into a word processing program and finish it later?

No, you will not be able to save the form into another program for completion and submission later. The E–DV Entry Form is a Web form only. You must fill in the information and submit it while online.

18. Can I save the form online and finish it later?

No. The E–DV Entry Form is designed to be completed and submitted at one time. You will have 60 minutes starting from when you download the form to complete and submit your entry through the E–DV website. If you exceed the 60-minute limit and have not submitted your complete entry electronically, the system discards any information already entered. The system deletes any partial entries so that they are not accidentally identified as duplicates of a later, complete entry. Read the DV instructions completely before you start to complete the form online, so that you know exactly what information you will need.

19. I don’t have a scanner. Can I send photographs to someone in the United States to scan them, save them, and mail them back to me so I can use them in my entry?

Yes, as long as the photograph meets the requirements in the instructions and is electronically submitted with, and at the same time as, the E–DV online entry. You must already have the scanned photograph file when you submit the entry online; it cannot be submitted separately from the online application. The entire entry (photograph and application together) can be submitted electronically from the United States or from overseas.

20. If the E–DV system rejects my entry, can I resubmit my entry?

Yes, you can resubmit your entry as long as your submission is completed by 12:00 p.m. (noon) Eastern Standard Time (EST) (GMT–5) on Tuesday, November 6, 2018. You will not be penalized for submitting a duplicate entry if the E–DV system rejects your initial entry. Given the unpredictable nature of the internet, you may not receive the rejection notice immediately. You can try to submit an application as many times as is necessary until a complete application is received and the confirmation notice sent. Once you receive a confirmation notice, your entry is complete, and you should NOT submit any additional entries.

21. How soon after I submit my entry will I receive the electronic confirmation notice?

You should receive the confirmation notice immediately, including a confirmation number that you must record and keep. However, the unpredictable nature of the internet can result in delays. You can hit the “Submit” button as many times as is necessary until a complete application is submitted and you receive the confirmation notice. However, once you receive a confirmation notice, do not resubmit your information.

22. I hit the “Submit” button, but did not receive a confirmation number. If I submit another entry, will I be disqualified?

If you did not receive a confirmation number, your entry was not recorded. You must submit another entry. It will not be counted as a duplicate. Once you receive a confirmation number, do not resubmit your information.

#### Selection

23. How do I know if I am selected?

You must use your confirmation number to access the Entrant Status Check available on the E–DV website at [dvlottery.state.gov](http://dvlottery.state.gov) starting May 7, 2019 through September 30, 2020. Entrant Status Check is the sole means by which the Department of State will notify you if you are selected, provided further instructions on your visa application, and notify you of your immigrant visa interview appointment date and time. The only authorized Department of State website for official online entry in the Diversity Visa Program and Entrant Status Check is [dvlottery.state.gov](http://dvlottery.state.gov).

*The Department of State will NOT contact you to tell you that you have been selected (see FAQ #24).*

24. How will I know if I am not selected? Will I be notified?

You may check the status of your DV–2020 entry through the Entrant Status Check on the E–DV website at [dvlottery.state.gov](http://dvlottery.state.gov) starting May 7, 2019, until September 30, 2020. Keep your confirmation number until at least September 30, 2020. (Status information for the previous year’s DV program, DV–2019, is available online from May 15, 2018, through September 30, 2019.) If your entry is not selected, you will not receive any additional instructions.

25. What if I lose my confirmation number?

You must have your confirmation number to access Entrant Status Check. A tool is now available in Entrant Status Check (ESC) on the eDV website that will allow you to retrieve your confirmation number via the email address with which you registered by entering certain personal information to confirm your identity.

U.S. embassies and consulates and the Kentucky Consular Center are unable to check your selection status for you or provide your confirmation number to you directly (other than through the ESC retrieval tool). The Department of State is NOT able to provide a list of those selected to continue the visa process.

26. Will I receive information from the Department of State by email or by postal mail?

The Department of State will not send you a notification letter. The U.S. government has never sent emails to notify individuals that they have been selected, and there are no plans to use email for this purpose for the DV–2020 program. If you are a selectee, you will only receive email communications regarding your visa appointment *after* you have responded to the notification instructions on Entrant Status Check. These emails will not contain information on the actual appointment date and time; they will simply tell you that appointment details are available, and you must then access Entrant Status Check for details. The Department of State may send emails reminding DV lottery applicants to check the ESC for their status. However, such emails will never indicate whether the lottery applicant was or was not selected.

Only internet sites that end with the “.gov” domain suffix are official U.S. government websites. Many other websites (e.g., with the suffixes “.com,” “.org,” or “.net”) provide immigration and visa-related information and services. The Department of State does not endorse, recommend, or sponsor

any information or material on these other websites.

You may receive emails from websites that try to trick you into sending money or providing your personal information. You may be asked to pay for forms and information about immigration procedures, all which are available for free on the Department of State website or through U.S. embassy or consulate websites. Additionally, organizations or websites may try to steal your money by charging fees for DV-related services. If you send money to one of these organizations, you will likely never see it again. Also, do not send personal information to these websites, as it may be used for identity fraud/theft.

These deceptive emails may come from people pretending to be affiliated with the Kentucky Consular Center or the Department of State. Remember, the U.S. government has never sent emails to notify individuals that they have been selected, and will not use email to notify selectees for the DV–2020 program. The Department of State will never ask you to send money by mail or by services such as Western Union.

27. How many individuals will be selected for DV–2020?

For DV–2020, 50,000 DV visas are available. Because it is likely that some of the first 50,000 persons who are selected will not qualify for visas or not pursue their cases to visa issuance, more than 50,000 entries will be selected to ensure that all of the available DV visas are issued. However, this also means that there will not be a sufficient number of visas for all those who are initially selected. To maximize use of all available visas, the Department of State may update Entrant Status Check to include additional selectees at any time before the program ends on September 30, 2020.

You can check the E–DV website’s Entrant Status Check to see if you have been selected for further processing and your place on the list. Interviews for the DV–2020 program will begin in October 2019 for selectees who have submitted all pre-interview paperwork and other information as requested in the notification instructions. Selectees who provide all required information will be informed of their visa interview appointment through the E–DV website’s Entrant Status Check four to six weeks before the scheduled interviews with U.S. consular officers at overseas posts.

Each month, visas will be issued to those applicants who are eligible for issuance during that month, visa-number availability permitting. Once all of the 50,000 DV visas have been issued,

the program will end. Visa numbers could be finished before September 2020. Selected applicants who wish to apply for visas must be prepared to act promptly on their cases. *Being randomly chosen as a selectee does not guarantee that you will receive a visa. Selection merely means that you are eligible to apply for a Diversity Visa, and if your rank number becomes eligible for final processing, you potentially may be issued a Diversity Visa. Only 50,000 visas will be issued to such applicants.*

28. How will successful entrants be selected?

Official notifications of selection will be made through Entrant Status Check, available starting May 7, 2019, through at least September 30, 2020, on the E-DV website [dvlottery.state.gov](http://dvlottery.state.gov). The Department of State does not send selectee notifications or letters by regular postal mail or by email. Any email notification or mailed letter stating that you have been selected to receive a DV does not come from the Department of State and is not legitimate. Any email communication you receive from the Department of State will direct you to review Entrant Status Check for new information about your application. The Department of State will never ask you to send money by mail or by services such as Western Union.

All entries received from each region are individually numbered, and at the end of the entry period, a computer will randomly select entries from among all the entries received for each geographic region. Within each region, the first entry randomly selected will be the first case registered; the second entry selected will be the second case registered, etc. All entries received within each region during the entry period will have an equal chance of being selected. When an entry has been selected, the entrant will receive notification of his or her selection through the Entrant Status Check available starting May 7, 2019, on the E-DV website [dvlottery.state.gov](http://dvlottery.state.gov). If you are selected and you respond to the instructions provided online via Entrant Status Check, the Department of State's Kentucky Consular Center (KCC) will process your case until you are instructed to appear for a visa interview at a U.S. embassy or consulate or, if you are in the United States, until you apply to adjust status with USCIS in the United States.

29. I am already in the United States. If selected, may I adjust my status with USCIS?

Yes, provided you are otherwise eligible to adjust status under the terms of Section 245 of the Immigration and Nationality Act (INA), you may apply to USCIS for adjustment of status to permanent resident. You must ensure that USCIS can complete action on your case, including processing of any overseas spouse or children under 21 years of age, before September 30, 2020, since on that date your eligibility for the DV-2020 program expires. The Department of State will not approve any visa numbers or adjustments of status for the DV-2020 program after midnight EDT on September 30, 2020, under any circumstances.

30. If I am selected, for how long am I entitled to apply for a diversity visa?

If you are selected in the DV-2020 program, you are entitled to apply for visa issuance only during U.S. government fiscal year 2020, which is from October 1, 2019, through September 30, 2020. We encourage selectees to apply for visas as early as possible, once their lottery rank numbers become eligible for further processing.

*Without exception, all selected and eligible applicants must obtain their visa or adjust status by the end of the fiscal year.* There is no carry-over of DV benefits into the next year for persons who are selected but who do not obtain visas by September 30, 2020 (the end of the fiscal year). Also, spouses and children who derive status from a DV-2020 registration can only obtain visas in the DV category between October 1, 2019 and September 30, 2020. Applicants who apply overseas will receive an appointment notification from the Department through Entrant Status Check on the E-DV website four to six weeks before the scheduled appointment.

31. If a DV selectee dies, what happens to the case?

If a DV selectee dies at any point before he or she has traveled to the United States or adjusted status, the DV case is automatically terminated. Any derivative spouse and/or children of the deceased selectee will no longer be entitled to a DV visa. Any visas that were issued to them will be revoked.

#### Fees

32. How much does it cost to enter the E-DV program?

*There is no fee charged for submitting an electronic entry.* However, if you are

selected and apply for a Diversity Visa, you must pay all required visa application fees at the time of visa application and interview directly to the consular cashier at the U.S. embassy or consulate. If you are a selectee already in the United States and you apply to USCIS to adjust status, you will pay all required application fees directly to USCIS. If you are selected, you will receive details of required DV and immigrant visa application fees with the instructions provided through the E-DV website at [dvlottery.state.gov](http://dvlottery.state.gov).

33. How and where do I pay DV and immigrant visa fees if I am selected?

If you are a randomly selected entrant, you will receive instructions for the DV visa application process through Entrant Status Check at [dvlottery.state.gov](http://dvlottery.state.gov). You will pay all DV and immigrant visa application fees in person only at the U.S. embassy or consulate at the time of the visa application. The consular cashier will immediately give you a U.S. government receipt for payment. Do not send money for DV fees to anyone through the mail, Western Union, or any other delivery service if you are applying for an immigrant visa at a U.S. embassy or consulate.

If you are selected and you are already present in the United States and plan to file for adjustment of status with USCIS, the instructions page accessible through Entrant Status Check at [dvlottery.state.gov](http://dvlottery.state.gov) contains separate instructions on how to mail adjustment of status application fees to a U.S. bank.

34. If I apply for a DV, but don't qualify to receive one, can I get a refund of the visa fees I paid?

No. Visa application fees cannot be refunded. You must meet all qualifications for the visa as detailed in these instructions. If a consular officer determines you do not meet requirements for the visa, or you are otherwise ineligible for the DV under U.S. law, the officer cannot issue a visa and you will forfeit all fees paid.

#### Ineligibilities

35. As a DV applicant, can I receive a waiver of any grounds of visa ineligibility? Does my waiver application receive any special processing?

DV applicants are subject to all grounds of ineligibility for immigrant visas specified in the Immigration and Nationality Act (INA). There are no special provisions for the waiver of any ground of visa ineligibility aside from those ordinarily provided in the INA, nor is there special processing for



waiver requests. Some general waiver provisions for people with close relatives who are U.S. citizens or Lawful Permanent Resident aliens may be available to DV applicants in some cases, but the time constraints in the DV program may make it difficult for applicants to benefit from such provisions.

#### *DV Fraud Warning and Scams*

36. How can I report internet fraud or unsolicited email?

Please visit the *econsumer.gov* website, hosted by the Federal Trade Commission in cooperation with consumer-protection agencies from 17 nations. You may also report fraud to the Federal Bureau of Investigation (FBI) internet Crime Complaint Center. To file a complaint about unsolicited email, use the "Telemarketing and Spam" complaint tool on the *econsumer.gov* website or visit the Department of Justice Unsolicited Commercial Email ("Spam") web page at *www.justice.gov/doj/spam* for additional information and contacts.

#### *DV Statistics*

37. How many visas will be issued in DV-2020?

By law, a maximum of 55,000 visas are available each year to eligible persons. However, in November 1997, the U.S. Congress passed the Nicaraguan Adjustment and Central American Relief Act (NACARA), which stipulates that beginning as early as DV-1999, and for as long as necessary, up to 5,000 of the 55,000 annually-allocated DVs will be made available for use under the NACARA program. The actual reduction of the limit began with DV-2000 and will remain in effect through the DV-2020 program, so 50,000 visas remain for the DV program described in these instructions.

38. If I receive a visa through the DV program, will the U.S. government pay for my airfare to the United States, help me find housing and employment, and/or provide healthcare or any subsidies until I am fully settled?

No. The U.S. government will not provide any of these services to you if you receive a visa through the DV program. If you are selected to apply for a DV, you will need to demonstrate that you will not become a public charge in the United States before being issued a visa. This evidence may be in the form of a combination of your personal assets, an Affidavit of Support (Form I-134) submitted by a relative or friend residing in the United States, an offer of

employment from an employer in the United States, or other evidence.

#### **List of Countries/Areas by Region Whose Natives are Eligible for DV-2020**

The list below shows the countries whose natives are eligible for DV-2020, grouped by geographic region. Dependent areas overseas are included within the region of the governing country. USCIS identified the countries whose natives are not eligible for the DV-2020 program according to the formula in Section 203(c) of the INA. The countries whose natives are not eligible for the DV program (because they are the principal source countries of Family-Sponsored and Employment-Based immigration or "high-admission" countries) are noted after the respective regional lists.

##### *Africa*

Algeria  
Angola  
Benin  
Botswana  
Burkina Faso  
Burundi  
Cameroon  
Cabo Verde  
Central African Republic  
Chad  
Comoros  
Congo  
Congo, Democratic Republic of the  
Cote D'Ivoire (Ivory Coast)  
Djibouti  
Egypt \*  
Equatorial Guinea  
Eritrea  
Ethiopia  
Gabon  
Gambia, The  
Ghana  
Guinea  
Guinea-Bissau  
Kenya  
Lesotho  
Liberia  
Libya  
Madagascar  
Malawi  
Mali  
Mauritania  
Mauritius  
Morocco  
Mozambique  
Namibia  
Niger  
Rwanda  
Sao Tome and Principe  
Senegal  
Seychelles  
Sierra Leone  
Somalia  
South Africa  
South Sudan  
Sudan

Swaziland  
Tanzania  
Togo  
Tunisia  
Uganda  
Zambia  
Zimbabwe

\* Persons born in the areas administered prior to June 1967 by Israel, Jordan, Syria, and Egypt are chargeable, respectively, to Israel, Jordan, Syria, and Egypt. Persons born in the Gaza Strip are chargeable to Egypt; persons born in the West Bank are chargeable to Jordan; persons born in the Golan Heights are chargeable to Syria.

In Africa, natives of Nigeria are not eligible for this year's diversity program.

##### *Asia*

Afghanistan  
Bahrain  
Bhutan  
Brunei  
Burma  
Cambodia  
Hong Kong Special Administrative Region \*\*  
Indonesia  
Iran  
Iraq  
Israel \*  
Japan  
Jordan \*  
Kuwait  
Laos  
Lebanon  
Malaysia  
Maldives  
Mongolia  
Nepal  
North Korea  
Oman  
Qatar  
Saudi Arabia  
Singapore  
Sri Lanka  
Syria \*  
Taiwan \*\*  
Thailand  
Timor-Leste  
United Arab Emirates  
Yemen

\* Persons born in the areas administered prior to June 1967 by Israel, Jordan, Syria, and Egypt are chargeable, respectively, to Israel, Jordan, Syria, and Egypt. Persons born in the Gaza Strip are chargeable to Egypt; persons born in the West Bank are chargeable to Jordan; persons born in the Golan Heights are chargeable to Syria.

\*\* For the purposes of the diversity program only, persons born in Macau S.A.R. derive eligibility from Portugal.

Natives of the following Asia Region countries are not eligible for this year's

diversity program: Bangladesh, China (mainland-born), India, Pakistan, South Korea, Philippines, and Vietnam. Hong Kong S.A.R. (Asia region), Macau S.A.R. (Europe region, chargeable to Portugal), and Taiwan (Asia region) do qualify and are listed here.

#### Europe

Albania  
Andorra  
Armenia  
Austria  
Azerbaijan  
Belarus  
Belgium  
Bosnia and Herzegovina  
Bulgaria  
Croatia  
Cyprus  
Czech Republic  
Denmark (including components and dependent areas overseas)  
Estonia  
Finland  
France (including components and areas overseas)  
Georgia  
Germany  
Greece  
Hungary  
Iceland  
Ireland  
Italy  
Kazakhstan  
Kosovo  
Kyrgyzstan  
Latvia  
Liechtenstein  
Lithuania  
Luxembourg  
Macau Special Administrative Region\*\*  
Macedonia  
Malta  
Moldova  
Monaco  
Montenegro  
Netherlands (including components and dependent areas overseas)  
Northern Ireland\*\*  
Norway (including components and dependent areas overseas)  
Poland  
Portugal (including components and dependent areas overseas)  
Romania  
Russia  
San Marino  
Serbia  
Slovakia  
Slovenia  
Spain  
Sweden  
Switzerland  
Tajikistan  
Turkey  
Turkmenistan  
Ukraine  
Uzbekistan

Vatican City

\*\* Macau S.A.R. does qualify and is listed above. For the purposes of the diversity program only, persons born in Macau S.A.R. derive eligibility from Portugal.

Natives of the following European countries are not eligible for this year's DV program: Great Britain (United Kingdom). Great Britain (United Kingdom) includes the following dependent areas: Anguilla, Bermuda, British Virgin Islands, British Indian Ocean Territory, Cayman Islands, Falkland Islands, Gibraltar, Montserrat, Pitcairn, South Georgia and the South Sandwich Islands, St. Helena, and Turks and Caicos Islands. Note that for purposes of the diversity program only, Northern Ireland is treated separately; Northern Ireland does qualify and is listed among the qualifying areas.

#### North America

The Bahamas

In North America, natives of Canada and Mexico are not eligible for this year's diversity program.

#### Oceania

Australia (including components and dependent areas overseas)

Fiji

Kiribati

Marshall Islands

Micronesia, Federated States of

Nauru

New Zealand (including components and dependent areas overseas)

Palau

Papua New Guinea

Samoa

Solomon Islands

Tonga

Tuvalu

Vanuatu

#### South America, Central America, and the Caribbean

Antigua and Barbuda

Argentina

Barbados

Belize

Bolivia

Chile

Costa Rica

Cuba

Dominica

Ecuador

Grenada

Guatemala

Guyana

Honduras

Nicaragua

Panama

Paraguay

Saint Kitts and Nevis

Saint Lucia

Saint Vincent and the Grenadines

Suriname

Trinidad and Tobago

Uruguay

Venezuela

Countries in this region whose natives are not eligible for this year's diversity program: Brazil, Colombia, Dominican Republic, El Salvador, Haiti, Jamaica, Mexico, and Peru.

Dated: September 18, 2018.

**Carl C. Risch,**

*Assistant Secretary, Bureau of Consular Affairs, Department of State.*

[FR Doc. 2018-20796 Filed 9-24-18; 8:45 am]

**BILLING CODE 4710-06-P**

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Fiscal Year 2019 Tariff-Rate Quota Allocations for Refined and Specialty Sugar and Sugar-Containing Products

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice.

**SUMMARY:** The Office of the United States Trade Representative (USTR) is providing notice of the Fiscal Year (FY) 2019 (Oct. 1, 2018 through Sept. 30, 2019) in-quota quantity of the tariff-rate quotas for imports of certain sugars, syrups and molasses (also known as refined sugar), specialty sugar, and sugar-containing products.

**FOR FURTHER INFORMATION CONTACT:** Dylan Daniels, Office of Agricultural Affairs at 202-395-6095 or [Dylan.T.Daniels@ustr.eop.gov](mailto:Dylan.T.Daniels@ustr.eop.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to Additional U.S. Note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains tariff-rate quotas (TRQs) for imports of refined sugar. Pursuant to Additional U.S. Note 8 to Chapter 17 of the HTS, the United States maintains a TRQ for imports of sugar-containing products. Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the U.S. Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On June 29, 2018, the Secretary of Agriculture announced the establishment of the in-quota quantity for the FY 2019 refined sugar TRQ at 192,000 metric tons raw value (MTRV) for which the sucrose content, by weight in the dry state, must have a polarimeter reading of 99.5 degrees or more. This

amount includes the minimum quantity to which the United States is committed under the WTO Agreement—22,000 MTRV, of which 1,656 MTRV is reserved for specialty sugar—and an additional 170,000 MTRV for specialty sugars. The U.S. Trade Representative is allocating 10,300 MTRV of refined sugar to Canada, 2,954 MTRV to Mexico, and 7,090 MTRV of refined sugar to be administered on a first-come, first-served basis.

Imports of all specialty sugar will be administered on a first-come, first-served basis in five tranches. The Secretary has announced that the total in-quota quantity of specialty sugar will be the 1,656 MTRV included in the WTO minimum plus an additional 170,000 MTRV. The first tranche of 1,656 MTRV will open October 1, 2018. All types of specialty sugars are eligible for entry under this tranche. The second tranche of 50,000 MTRV will open on October 10, 2018. The third tranche of 50,000 MTRV each will open on January 23, 2019. The fourth and fifth tranches, both of 35,000 MTRV, will open on April 17, 2019 and July 17, 2019, respectively. The second, third, fourth, and fifth tranches will be reserved for organic sugar and other specialty sugars not currently produced commercially in the United States or reasonably available from domestic sources.

With respect to the in-quota quantity of 64,709 metric tons (conversion factor: 1 metric ton = 1.10231125 short tons) of the TRQ for imports of certain sugar-containing products maintained under Additional U.S. Note 8 to Chapter 17 of the HTS, the U.S. Trade Representative is allocating 59,250 metric tons to Canada. The remainder, 5,459 metric tons, of the in-quota quantity is available for other countries on a first-come, first-served basis.

Refined and specialty sugar and sugar-containing products for FY 2019 TRQs may enter the United States as of October 1, 2018.

**Robert Lighthizer,**

*United States Trade Representative.*

[FR Doc. 2018–20751 Filed 9–24–18; 8:45 am]

**BILLING CODE 3290–F8–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

#### Notice of Funding Opportunity for Consolidated Rail Infrastructure and Safety Improvements; Extension

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice of Funding Opportunity; extension of deadline on solicitation for applications.

**SUMMARY:** Under a notice published in the **Federal Register**, the FRA sought applications from eligible parties for the Fiscal Year 2018 Consolidated Rail Infrastructure and Safety Improvements program that will improve intercity passenger and freight rail transportation systems in terms of safety, efficiency, or reliability. Due to Hurricane Florence, the FRA is extending the application deadline to give applicants additional time to complete the application process and submit applications.

**DATES:** The application deadline for the notice published July 19, 2018 (83 FR 34283), is extended. FRA will accept applications for the Fiscal Year 2018 Consolidated Rail Infrastructure and Safety Improvements program until October 12, 2018 at 5 p.m. EDT. The application deadline was Monday, September 17, 2018 at 5 p.m. EDT.

**ADDRESSES:** Applications must be submitted electronically to <http://www.grants.gov> (“Grants.gov”). *Grants.gov* allows organizations electronically to find and apply for competitive grant opportunities from all Federal grant-making agencies. Any entity wishing to submit an application pursuant to this notice should immediately initiate the process of registering with *Grants.gov* at <http://www.grants.gov>.

**FOR FURTHER INFORMATION CONTACT:** For further project or program-related information in this notice, please contact Ms. Frances Bourne, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–207, Washington, DC 20590; email: [frances.bourne@dot.gov](mailto:frances.bourne@dot.gov); phone 202–493–6366. Grant application submission and processing questions should be addressed to Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590; email: [amy.houser@dot.gov](mailto:amy.houser@dot.gov); phone: 202–493–0303.

**SUPPLEMENTARY INFORMATION:** This notice simply extends the application deadline for the Fiscal Year 2018 Consolidated Rail Infrastructure and Safety Improvements program. The new application deadline is October 12, 2018 at 5 p.m. EDT. Interested applicants should consult the notice published on July 19, 2018 in the **Federal Register** (83 FR 34283) for additional details about the program and the application process.

Issued in Washington, DC.

**Paul Nissenbaum,**

*Associate Administrator, Office of Railroad Policy and Development.*

[FR Doc. 2018–20833 Filed 9–24–18; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0087]

#### Federal Advisory Committee National Emergency Medical Services Advisory Council (NEMSAC); Notice of Meeting

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

**ACTION:** Meeting notice—National Emergency Medical Services Advisory Council.

**SUMMARY:** The NHTSA announces a meeting of the NEMSAC to be held in the Metropolitan Washington, DC, area. This notice announces the date, time, and location of the meeting, which will be open to the public, as well as opportunities for public input to the NEMSAC. The purpose of NEMSAC, a nationally recognized council of emergency medical services representatives and consumers, is to advise and consult with DOT and the Federal Interagency Committee on Emergency Medical Services (FICEMS) on matters relating to emergency medical services (EMS).

**DATES:** The NEMSAC meeting will be held on October 15, 2018 from 8:30 a.m. to 4:00 p.m. EDT, and on October 16, 2018 from 8:30 a.m. to 12:00 p.m. EDT. A public comment period will take place on October 15, 2018 between 11:15 a.m. and 11:45 a.m. EDT and October 16, 2018 between 10:45 a.m. and 11:15 a.m. EDT. Written comments for the NEMSAC from the public must be received no later than October 8, 2018.

**ADDRESSES:** The meetings will be held at the U.S. Department of Transportation Headquarters, 1200 New Jersey Avenue SE, Washington, DC 20590. Attendees should plan to arrive 10–15 minutes early.

**FOR FURTHER INFORMATION CONTACT:** Gamunu Wijetunge, U.S. Department of Transportation, Office of Emergency Medical Services, 1200 New Jersey Avenue SE, NP4–400, Washington, DC 20590, [Gamunu.Wijetunge@dot.gov](mailto:Gamunu.Wijetunge@dot.gov) or 202–493–2793.

**SUPPLEMENTARY INFORMATION:** Notice of the NEMSAC meeting is given under the

Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.). The NEMSAC is authorized under Section 31108 of the Moving Ahead with Progress in the 21st Century Act of 2012.

### Tentative Agenda of the National EMS Advisory Council Meeting

The tentative NEMSAC agenda includes the following:

*Monday, October 15, 2018 (8:30 a.m. to 4:00 p.m. EDT)*

- (1) Call to Order, Introductions, and Opening Remarks (8:30 a.m. to 9:00 a.m. EDT)
- (2) Swearing in of NEMSAC Members (9:00 a.m. to 9:15 a.m. EDT)
- (3) Disclosure of Conflicts of Interest by NEMSAC Members (9:15 a.m. to 9:30 a.m. EDT)
- (4) Approval of August 14–15, 2017 Meeting Minutes (9:30 a.m. to 9:45 a.m. EDT)
- (5) Federal Liaison Update—Reports and Updates from the Departments of Transportation, Homeland Security, and Health & Human Services (9:45 a.m. to 10:30 a.m. EDT)
- (6) Overview of the FICEMS Strategic Plan (10:30 a.m. to 11:15 a.m. EDT)
- (7) Public Comment Period (11:15 a.m. to 11:45 a.m. EDT)
- (8) Recess for Lunch—(11:45 a.m. to 1:15 p.m. EDT)
- (9) Continue discussion of FICEMS Strategic Plan (1:15 p.m. to 2:15 p.m. EDT)
- (10) Review and Discussion of Previously Approved NEMSAC Recommendations (2:15 p.m. to 3:15 p.m. EDT)
- (11) Review of Ongoing NHTSA Projects (3:15 p.m. to 4:00 p.m. EDT)

*Tuesday, October 16, 2018 (8:30 a.m. to 4:00 p.m. EDT)*

- (1) Reconvene and Introductions (8:30 a.m.–8:45 a.m. EDT)
- (2) Discussion of NEMSAC Focus Areas for 2018–2019 (9:30 a.m.–10:45 a.m. EDT)
- (3) Public Comment Period (10:45 a.m. to 11:15 a.m. EDT)
- (4) Continue Discussion of NEMSAC Focus Areas for 2018–2019 (10:45 a.m.–11:30 a.m. EDT)
- (5) Election of Chair and Vice-Chair (11:30 a.m.–11:45 a.m. EDT)
- (6) NEMSAC Next Steps and Wrap Up, and Adjourn (11:45 a.m.–12 Noon EDT)

*Registration Information:* This meeting will be open to the public; however, pre-registration is requested. Individuals wishing to attend must register online no later than October 8,

2018. For NEMSAC please register at: <https://www.connect.space/nemsac-2018>. For assistance with NEMSAC registration, please contact Gamunu Wijetunge at [Gamunu.Wijetunge@dot.gov](mailto:Gamunu.Wijetunge@dot.gov) or 202-493-2793. There will not be a teleconference option for this meeting.

*Public Comment:* Members of the public are encouraged to comment directly to the NEMSAC during designated public comment periods. In order to allow as many people as possible to speak, speakers are requested to limit their remarks to 5 minutes. Written comments from members of the public will be distributed to NEMSAC at the meeting and should reach the NHTSA Office of EMS no later than October 8, 2018. Written comments may be submitted by either one of the following methods: (1) You may submit comments by email: [nemsac@dot.gov](mailto:nemsac@dot.gov) or (2) you may submit comments by fax: (202) 366-7149.

A final agenda as well as meeting materials will be available to the public online through [www.EMS.gov](http://www.EMS.gov) on or before October 8, 2018.

**Authority:** 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, DC, on September 20, 2018.

**Jeff Michael,**

*Associate Administrator, Research and Program Development.*

[FR Doc. 2018-20817 Filed 9-24-18; 8:45 am]

**BILLING CODE 4910-59-P**

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA 2018-0070]

#### Notice and Request for Comments

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

**ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on August 8, 2017. No comments were received.

**DATES:** Comments must be submitted on or before October 25, 2018.

**ADDRESSES:** Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW, Washington, DC 20503.

#### FOR FURTHER INFORMATION CONTACT:

Alrik L. Svenson, Office of Vehicle Safety Research, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Telephone: 202-366-0436.

Please identify the relevant collection of information by referring to its OMB Control Number.

#### SUPPLEMENTARY INFORMATION:

*Title:* Field Study of Newer Generation Heavy Vehicle Automatic Emergency Braking (AEB) Systems.

*OMB Control Number:* Not assigned.

*Type of Request:* New Information Collection.

*Abstract:* The National Highway Traffic Safety Administration (NHTSA) is assessing the benefits of crash avoidance technologies for heavy trucks that include Automatic Emergency Braking (AEB) to prevent fatalities, injuries, and property damage in crashes involving heavy vehicles. Previous studies have investigated crash problem size, economic cost, and preliminary safety benefits concerning these systems. The underlying methods of these studies have included test track evaluations, objective test procedures, technology field demonstrations, and “naturalistic” studies. As both of the major AEB system suppliers have released new products in the second half of 2017, NHTSA is interested in the real world performance of these new systems, which are designed to address the shortcomings of the previous generation of AEB systems. These systems have been designed to offer improved threat detection and new features such as stationary object braking. Additionally, a new product called Detroit Assurance™ was released in 2016 for Freightliner trucks by Detroit Diesel Corporation. This system shares many features with the OnGuard and Wingman® products including advanced emergency braking (AEB), forward collision warnings (FCW), and adaptive cruise control (ACC).

*Affected Public:* Commercial vehicle drivers who are assigned a single, specific commercial vehicle that is equipped with the eligible technologies. Trucking fleets (approximately 7–10) will be contacted first to see if they have trucks equipped with the technologies and would be willing to have their drivers participate in the study.

*Estimated Number of Respondents:* 175, after compensating for potential drop-outs.

*Frequency:* Twice at the start of participation (demographic and initial CAS technology surveys), once at the

completion of participation approximately 3 months later.

*Number of Responses:* Full participation in the study will include 3 responses for a total of 92 questions

per participant, plus a consent form that will be reviewed prior to participation.

*Estimated Total Annual Burden Hours:* 110 minutes per respondent, including consent (204 hours total).

*Estimated Total Annual Burden Cost:*

TABLE 1—ESTIMATED TOTAL ANNUAL BURDEN COST

Instrument	Number of respondents <sup>1</sup>	Frequency of responses	Number of questions	Estimated individual burden (minutes)	Total estimated burden hours (hours)	Total annualize cost to respondents <sup>2</sup>
Informed Consent Form .....	175	1	N/A	10	29	\$584.64
Demographic questionnaire .....	175	1	14	10	29	584.64
Initial CAS Technology Survey .....	175	1	33	25	73	1471.68
Final CAS Technology Survey .....	150	1	34	25	62.5	1260.00
<b>TOTAL</b> .....					<b>193.5</b>	<b>\$ 3900.96</b>

<sup>1</sup> The number of respondents in this table includes drop-out rates.

<sup>2</sup> Estimated based on the mean hourly rate nationwide for Heavy and Tractor-Trailer Truck Drivers of \$20.16 as reported in the May 2014 Occupational Employment and Wage Estimates, Bureau of Labor Statistics. [http://www.bls.gov/oes/current/oes\\_nat.htm#35-0000](http://www.bls.gov/oes/current/oes_nat.htm#35-0000).

*Public Comments Invited:* You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (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 the use of automated collection techniques or other forms of information technology.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

**Nathaniel Beuse,**

*Associate Administrator, Vehicle Safety Research.*

[FR Doc. 2018-20753 Filed 9-24-18; 8:45 am]

**BILLING CODE 4910-59-P**

**DEPARTMENT OF TRANSPORTATION**

**Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas**

**AGENCY:** Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), U.S. Department of Transportation.

**ACTION:** Notice of limitation on claims for judicial review of actions by TxDOT and Federal agencies.

**SUMMARY:** This notice announces actions taken by TxDOT and Federal agencies that are final. The environmental

review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT and a Memorandum of Understanding dated December 16, 2014, and executed by FHWA and TxDOT. The actions relate to various proposed highway projects in the State of Texas. Those actions grant licenses, permits, and approvals for the projects.

**DATES:** By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of TxDOT and Federal agency actions on the highway project will be barred unless the claim is filed on or before February 25, 2019. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

**FOR FURTHER INFORMATION CONTACT:** Carlos Swonke, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416-2734; email: [carlos.swonke@txdot.gov](mailto:carlos.swonke@txdot.gov). TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE) or Environmental Assessment (EA) issued in connection with the projects and in

other key project documents. The CE or EA, and other key documents for the listed projects are available by contacting TxDOT at the address provided above.

This notice applies to all TxDOT and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act, 42 U.S.C. 7401–7671(q).

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [54 U.S.C. 312501 *et seq.*]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF), 16 U.S.C. 4601–4604; Safe Drinking Water Act (SDWA), 42 U.S.C. 300(f)–300(j)(6); Rivers and Harbors Act of 1899, 33 U.S.C. 401–406; Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287; Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931; TEA–21 Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(11); Flood Disaster Protection Act, 42 U.S.C. 4001–4128.

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

The projects subject to this notice are:

1. I–10 Connect, from Yandell Drive to Loop 375 (Cesar Chavez Border Highway) in El Paso County. This project will construct or modify six direct connectors between I–10 and various other highways and one direct connector from U.S. 54 to I–110, and would reconfigure the I–110/U.S. 62 (Paisano Drive) interchange. The six I–10 direct connectors are Eastbound I–10 to Southbound U.S. 54 Direct Connector, Eastbound Loop 375 (Cesar Chavez Border Highway) to Eastbound I–10 Direct Connector, Westbound I–10 to Southbound U.S. 54 Direct Connector, Southbound U.S. 54 to Westbound I–110 Direct Connector, Eastbound I–10 to Westbound I–110 Direct Connector, Westbound I–10 to Westbound I–110 Direct Connector. Along with these improvements, the proposed project would also include reconfiguring some of the merging lanes along I–110 and U.S. 54. The proposed improvements would require 0.14 acre of additional right-of-way and approximately 0.81 acre of temporary construction easements. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on August 23, 2018, the Finding of No Significant Impact (FONSI) issued on August 28, 2018, and other documents in the TxDOT project

file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT El Paso District, 13301 Gateway West, El Paso, Texas 79928; telephone (915) 790–4340. The Final EA and FONSI can also be viewed and downloaded from the following website: <https://www.txdot.gov/inside-tydot/projects/studies/el-paso/i10-connect.html>.

2. Zaragoza Port-of-Entry, Pan American Drive & Winn Road Build Improvements, TxDOT El Paso District with Camino Real Regional Mobility Authority and the City of El Paso, El Paso County. The proposed project would consist of widening the existing Winn Road between Pan American Drive and Southside Road to a 90-foot-wide four-lane divided facility with concrete pavement, raised medians, sidewalks, illumination, and drainage improvements. The proposed project would also involve construction of a new location roadway extension heading west and then north from Southside Road to connect the existing Winn Road to Rio Del Norte Drive. Proposed improvements to Pan American Drive would entail adding raised medians where none exist, adding illumination, landscaping, resurfacing the existing pavement, and restriping to four lanes. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on August 15, 2018, the Finding of No Significant Impact (FONSI) issued on August 15, 2018, and EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT El Paso District Office, 13301 Gateway Blvd. West, El Paso, Texas 79928; telephone 915–790–4340. The Final EA and FONSI can also be viewed and downloaded from the following website: <https://www.elpasotexas.gov/capital-improvement>.

3. Amistad Acres Road, Val Verde County. The project would replace an existing 2.6 mile unpaved road (known as Holman Road) by constructing an approximately 2.0 mile paved roadway consisting of two 10-foot wide travel lanes and two 4-foot wide shoulders (28 feet total pavement width) from Box Canyon Road to the Amistad Acres Subdivision near the Amistad Reservoir, northwest of Del Rio, in Val Verde County, Texas. The proposed roadway would include a portion of the current access roadway for approximately 0.7 miles, and a section of new location roadway for approximately 1.3 miles.

The actions by the TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on June 9, 2015, in the Finding of No Significant Impact (FONSI) issued on June 12, 2015, and in documents in the TxDOT administrative record. The EA, FONSI, and other documents in the TxDOT administrative record are available by contacting TxDOT at the addresses provided above or the TxDOT Laredo District Office, 1817 Bob Bullock Loop, Laredo, TX 78043; telephone (956) 712–7400.

4. I–35 Northeast Expansion Project in Bexar, Comal and Guadalupe Counties. The project includes the construction of four elevated managed lanes (two in each direction) generally between the existing I–35 main lanes and frontage roads along I–35 from I–410 South in San Antonio to FM 1103 in Schertz. Direct connectors at the I–35/I–410 South, I–35/I–410 West and I–35/Loop 1604 interchanges and operational improvements at the FM 2252, Old Wiederstein Road, and FM 1103 intersections are also included. The project is approximately 15.4 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on July 2, 2015, the Finding of No Significant Impact (FONSI) issued on July 2, 2015 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office, 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

5. FM 1626 from RM 967 to FM 2770, Hays County. The build alternative consists of four 12-foot-wide travel lanes (two in each direction), a 14-foot-wide center left turn lane, and outside shoulders of varying widths. The project also includes improvements to the bridges at Onion Creek and Mustang Branch. The project is approximately 3.3 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on July 1, 2015, the Finding of No Significant Impact (FONSI) issued on July 1, 2015, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office, 7901 North I–35, Austin, TX 78753; telephone (512) 832–7000.

6. FM 1626 from Brodie Lane to Manchaca Road (FM 2304), Travis

County. The build alternative consists of four 12-foot-wide travel lanes (two in each direction) separated by a continuous left turn lane. The continuous left turn lane would range in width from 14 feet (usual) to 23.5 feet at the intersection with Brodie Lane. The project is approximately 1.3 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on February 24, 2016, the Finding of No Significant Impact (FONSI) issued on February 24, 2016, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office, 7901 North I-35, Austin, TX 78753; telephone (512) 832-7000.

7. US 183 from US 290 to SH 71, Travis County. The project would include six tolled main lanes and four to six non-tolled access road lanes. Direct connections to SH 71 west of US 183 would be tolled and would provide two lanes of travel in each direction. Throughout the corridor, a shared use path, bike lanes and sidewalks are included. The project is approximately 8 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on March 6, 2015, the Finding of No Significant Impact (FONSI) issued on March 6, 2015, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office, 7901 North I-35, Austin, TX 78753; telephone (512) 832-7000.

8. Callaghan Road from IH 410 to Spur 421 (Bandera Road) in Bexar County. The project includes widening Callaghan Road to a four-lane roadway with a continuous left center turn lane, including the installation of curbs, sidewalks and a shared-use path. The project is approximately 1.1 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on July 1, 2015, the Finding of No Significant Impact (FONSI) issued on July 1, 2015 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office, 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615-5839.

9. FM 1560 from SH 16 to Loop 1604 in Bexar County. The project would widen this section of FM 1560 from two to four lanes, including a center turn lane, raised medians at the approaches to SH 16 and Loop 1604, bike lanes, and sidewalks. The project is approximately 2 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on July 2, 2015, the Finding of No Significant Impact (FONSI) issued on July 2, 2015 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office, 4615 NW Loop 410, San Antonio, TX 78229; (210) 615-5839.

10. FM 1516 from FM 78 to FM 1976 in Bexar County. The project includes reconstructing existing FM 1516 to four main lanes with bike lanes, a continuous center turn lane, adding sidewalks, constructing a storm sewer system between FM 78 and Gibbs Sprawl Road/FM 3502, and extending FM 1516 from the Gibbs Sprawl Road/FM 3502 intersection to FM 1976 at Hilltop Avenue. The project is approximately 0.76 mile in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on February 17, 2015, the Finding of No Significant Impact (FONSI) issued on February 17, 2015 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office, 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615-5839.

11. FM 664 from Westmoreland Road to IH 35E in Ellis County, Texas. The proposed improvements would include the expansion of the existing facility from a two-lane rural roadway to a six-lane urban, divided roadway. The project also includes bicycle and pedestrian accommodations. The length of the proposed project is approximately 3.13 miles. The purpose of the proposed project is to improve mobility and safety and manage congestion. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on June 10, 2015, Finding of No Significant Impact (FONSI) issued on June 10, 2015, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT

at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

12. FM 3549 from IH 30 to North of SH 66 in Rockwall County, Texas. The proposed improvements would include widening the existing two-lane rural roadway to a four-lane urban section. The project would consist of a four-lane urban divided section with selected left-turn lanes. The proposed typical section provides one additional 12-foot travel lane, one 14-foot multipurpose lane for bicycle use, and 2-foot offset to a concrete curb. A raised median is also provided to control ingress and egress. The length of the proposed project is approximately 1.3 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on March 8, 2016, Finding of No Significant Impact (FONSI) issued on March 8, 2016, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E. Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

13. IH 20 from SH 161/Lake Ridge Parkway to FM 1382/Belt Line Road in Dallas County, Texas. The proposed improvements would include the construction of new frontage roads and ramps; reconstruction and reconfiguration of the intersections at Robinson Road and Carrier Parkway; reconstruction and reconfiguration of a section of Westchase Drive south of IH 20; construction of U-turns at Carrier Parkway and Belt Line Road; and other improvements along IH 20. The length of the proposed project is approximately 2.318 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on November 2, 2015, Finding of No Significant Impact (FONSI) issued on November 2, 2015, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

14. Medical District Drive from IH 35 to Harry Hines Boulevard in Dallas County, Texas. The proposed improvements would include the reconstruction and widening of the current Medical District Drive from a four-lane section to a six-lane divided

thoroughfare with turn lanes. The project also proposes to relocate a driveway providing access to the Trinity Railway Express station and to construct right and left-turn lanes from Medical District Drive. The length of the proposed project is approximately 1,380 feet. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on April 2, 2015, Finding of No Significant Impact (FONSI) issued on April 2, 2015, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

15. SH 276 from SH 205 to East of FM 549 in Rockwall County, Texas. The proposed improvements would include widening SH 276 from a two-lane rural roadway to a four-lane divided urban arterial that would ultimately accommodate a six-lane divided with urban minor arterial. The limits of the widening begin at the intersection of the realignment with the existing alignment at Wildrose Drive and continues east to approximately FM 549. SH 276 would be realigned between SH 205 and Wildrose Drive through an existing reserved roadway corridor. The existing SH 205/SH 276 intersection would be relocated to Sids Road, approximately 0.5 miles south of its current location. SH 276 would accommodate one 11-foot travel lane and one 14-foot shared use lane in each direction, a 40-foot median, and five-foot sidewalks with two-foot buffers on each side of the roadway. The proposed section would also accommodate an ultimate six-lane facility. The length of the proposed project is approximately 1.96 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on February 24, 2016, Finding of No Significant Impact (FONSI) issued on February 24, 2016, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E. Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

16. U.S. 80 from Interstate IH 635 to Galloway Avenue and IH 635 from South of Gross Road to Eastbound U.S. 80 Frontage Road in Dallas County, Texas. The proposed U.S. 80 improvements would include

reconstruction of the eastbound frontage road and relocation of the North Galloway Avenue exit ramp; and the improvements to IH 635 would include the addition of a new northbound frontage road and the widening of the exit ramp at Gross Road. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on December 28, 2015, Finding of No Significant Impact (FONSI) issued on December 28, 2015, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

17. U.S. 287 from SH 34 to IH 45 in Ellis County, Texas. The proposed improvements would include the reconstruction and widening of U.S. 287 to accommodate the addition of mainlanes, ramps, and frontage road lanes throughout the project limits. The proposed project would also include the addition of grade-separated intersections as well as entrance and exit ramps along the existing facility. The length of the proposed project is approximately 4.51 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on July 8, 2015, Finding of No Significant Impact (FONSI) issued on July 8, 2015, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

18. U.S. 377 from Henrietta Creek Road to SH 114 in Denton County, Texas. The proposed improvements would include the reconstruction and widening of U.S. 377 from a two-lane rural section to a four-lane divided urban section with a raised median between Henrietta Creek Road and James Street. The project would also construct left-turn bays at Crockett, Denton, and Main Streets. The length of the proposed project is approximately one mile. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on August 6, 2015, Finding of No Significant Impact (FONSI) issued on August 6, 2015, and other documents in the TxDOT project

file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

19. Max Road from FM 518 to Hughes Ranch Road, Brazoria County. This project would widen Max Road from a two-lane undivided roadway with open ditches to a four-lane divided boulevard facility with curb and gutter. A portion of the project would be on new location to connect Max Road to the current terminus of Reid Boulevard, just north of FM 518. A cul-de-sac is proposed on existing Max Road approximately 875 feet north of FM 518. Included in the project is construction of a shared-use hike and bike trail along the west side of the roadway, new twin bridge structures at Hickory Slough, improved drainage including a detention pond, and a traffic signal at Hughes Ranch Road. The project length is approximately 4,500 feet. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on July 16, 2015, the Finding of No Significant Impact (FONSI) issued on July 16, 2015, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office, 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802-5000.

20. Hurricane Lane/Lake Olympia Parkway from Fort Bend Parkway to Trammel-Fresno Road, Fort Bend County. This project would construct Hurricane Lane from its present terminus as a two-lane, undivided urban section from Trammel-Fresno Road to a point along Lake Olympia Parkway approximately 685 feet east of Fort Bend Parkway. Construction of two linear detention ponds is included. The typical cross-sections incorporate two 11-foot travel lanes with 1-foot curb offsets on Hurricane Lane and Lake Olympia Parkway. The intersections of Hurricane Lane at Trammel-Fresno Road and of Lake Olympia Parkway at Fort Bend Parkway would each consist of a four-lane divided roadway containing 11- to 12-foot lanes and a 0- to 24-foot raised landscaped median. A 10-foot wide shared use path is proposed along the west side of Hurricane Lane and along the southern side of Lake Olympia Parkway. A 5-foot wide sidewalk segment is proposed on the east side of Hurricane Lane at its



southern terminus at Trammel-Fresno Road and along the north side of Lake Olympia Parkway's transitional section to four lanes. The project length is approximately 1.5 mile. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on August 24, 2015, the Finding of No Significant Impact (FONSI) issued on August 24, 2015, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802-5000.

21. FM 2978, from FM 1488 to Conroe-Huffsmith Road, Montgomery County. This project involves widening the existing two-lane undivided roadway to a four-lane roadway with an intermittent two-way turn lane. The proposed facility consists of four travel lanes (two 11-foot lanes in each direction), five-foot outside shoulders which would accommodate bicycles, and a four-foot sidewalk in various locations on the east side of FM 2978. The project includes the construction of four detention ponds. The project is approximately 6.5 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on December 1, 2015, the Finding of No Significant Impact (FONSI) issued on December 1, 2015, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office, 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802-5000.

22. FM 528 from SH 35B (Gordon Street) to SH 6, Brazoria County. This project extends FM 528 from SH 35B (Gordon Street) to SH 6. The proposed undivided, curb and gutter facility would include two 14-foot lanes (one 12-foot lane in each direction), accommodations for bicycle traffic and a five-foot sidewalk on the north side of FM 528. The proposed facility would also include a grade separation at the Burlington Northern Santa Fe (BNSF) Railway, new signalized intersections at SH 35B (Gordon Street) and SH 6, and left turn lanes at SH 35B (Gordon Street). The project is approximately 0.9 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken

are described in the Final Environmental Assessment (EA) approved on February 5, 2016, the Finding of No Significant Impact (FONSI) issued on February 5, 2016, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office, 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802-5000.

23. IH 10 Exit 365 EB Ramp Relocation, from 0.25 miles west of Rio Grande Street to SH 163, in Crockett County. The project is designed to relocate the IH10 eastbound exit ramp 365 approximately 0.8 miles west of the existing location, construct new frontage roadway to tie into the new exit ramp, and includes the construction of a new bridge over Johnson Draw. The project will convert the traffic on the existing frontage road from two-way traffic to one-way traffic. Total project length is approximately 1 mile. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination approved on June 15, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Angelo District Office, 4502 Knickerbocker Road, San Angelo, Texas 76904; telephone (325) 947-9205.

24. U.S. 380 from State Loop (SL) 288 to West of County Road (CR) 26 in Denton County, Texas. The proposed improvements would include reconstruction and widening of existing U.S. 380 from a four-lane undivided rural to a six-lane divided urban roadway consisting of two 11- to 12-foot wide inside travel lanes and 14-foot wide outside shared-use lanes (for bicycle accommodation), with raised medians and curb and gutter in each direction. The proposed roadway would also include intersection improvements and left and right turn lanes at designated locations. In addition, interchange improvements are proposed including five new grade separations. A minimum of five-foot sidewalks would be located along the outer lanes of the roadway. The length of the proposed project is approximately 14.2 miles. The purpose of the proposed project is to improve mobility by increasing capacity and reducing traffic congestion, and to meet current design standards. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final

Environmental Assessment (EA) approved on June 29, 2018, Finding of No Significant Impact (FONSI) issued on June 29, 2018, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-6100.

25. FM 179 from 800 feet north of SH 114 to Donald Preston Drive in Lubbock County. TxDOT, Lubbock District, proposes to widen approximately 4.1 miles of the existing FM 179 in Lubbock, Texas. Interim improvements would consist of a five lane suburban section with four 11-foot wide lanes, two eight-foot wide shoulders, and a 14-foot wide center left turn lane. The ultimate seven lane section would include an additional travel lane in each direction, sidewalks, shoulders and curb-and-gutter drainage. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on February 24, 2016 the Finding of No Significant Impact (FONSI) issued on February 24, 2016 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Lubbock District Office, 135 Slaton Road, Lubbock, Texas 79404; telephone (806) 745-4411.

26. Erskine Street from Texas Tech Parkway to Indiana Avenue in Lubbock County. TxDOT, Lubbock District, proposes to widen and improve Erskine Street with new right of way to be added at various locations on both sides of the roadway. Improvements would consist of a five-lane suburban section with two 11-foot wide lanes, two 13.5-foot wide lanes, and a 14-foot wide center left turn lane. An additional 11-foot wide right turn lane would be located at the northwest corner of the project area leading up to the terminus at Texas Tech Boulevard. Additional sidewalks would be added on the north side of the project at the locations where sidewalks are not present. The project length is approximately 1 mile in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on April 7, 2016 the Finding of No Significant Impact (FONSI) issued on April 7, 2016 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by

contacting TxDOT at the address provided above or the TxDOT Lubbock District Office, 135 Slaton Road, Lubbock, Texas 79404; telephone (806) 745-4411.

27. SL 88 from 0.5 miles north of U.S. 62/82 to 0.5 miles east of U.S. 87 in Lubbock County. TxDOT, Lubbock District, proposes to construct a segment (segment three) of a new loop around Lubbock along a portion of the existing Farm-to-Market Road (FM) 1585. The project length is approximately 12.4 miles in length. The proposed improvements would convert the existing two-lane rural FM 1585 roadway section to an access-controlled, four-lane divided freeway section with frontage roads and ramps. The improved roadway has been designated as SL 88. Multiple interchanges are proposed at the crossroad locations. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on February 27, 2018, the Finding of No Significant Impact (FONSI) issued on February 27, 2018 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Lubbock District Office, 135 Slaton Road, Lubbock, Texas 79404; telephone (806) 745-4411.

28. U.S. 59 from 3.0 miles south of U.S. 287 to 3.4 miles north of U.S. 287 in Polk County. TxDOT, Lufkin District, proposes to build a new location controlled access relief route west of U.S. 59 in the town of Corrigan, Texas. The proposed relief route would provide a four lane controlled access freeway section, ramps, and grade separations on the north and south ends at the Union Pacific Railroad and U.S. 287. Additional bridges would be construction over several creek crossings and Union Springs Road. The proposed project is approximately 6.4 miles in length. The purpose of the project is to bring U.S. 59 in the Corrigan area up to current interstate design standards by making U.S. 59 a controlled access roadway within the project limits and reduce congestion and increase mobility. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on January 28, 2018, the Finding of No Significant Impact (FONSI) issued on March 8, 2018, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are

available by contacting TxDOT at the address provided above or the TxDOT Lufkin District Office, 1805 North Timberland Drive, Lufkin, Texas 75901; telephone (936) 634-4433.

29. Farm-To-Market (FM) 1570 from State Highway (SH) 66 to United States Highway (US) 380 in Hunt County. The proposed action is the construction of a two-lane roadway from the terminus of Farm-to-Market Road (FM) 1570 at State Highway (SH) 66 north for a distance of 1.9 miles to U.S. 380. The project is located in Hunt County at the west edge of the city of Greenville. The proposed project would provide two 12-foot wide travel lanes with ten-foot outside paved shoulders within an approximate 264-foot wide right-of-way (ROW). The project end points at SH 66 and U.S. 380, as well as intersections with intervening roadways, would be at-grade. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final "Assessment (EA) approved on June 17, 2015, the Finding of No Significant Impact (FONSI) issued on June 24, 2015, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Paris District Office, 1365 North Main Street, Paris, Texas 75460; telephone (903) 737-9300.

30. Spur 248 from 1.75 Miles West of FM 848 (Old Omen Road), East to SH 64, Smith County. The proposed project would widen Spur 248 to a 4-lane facility with a flush median between Old Omen Road and SH 64. The proposed design would consist of a curb and gutter section with two 12-foot travel lanes, two 12-foot outside lanes with a 5-foot outside bike lane, and a 14-foot flush median within a ROW that would vary 140 to 230 feet in width. The length of the project is 2.17 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on January 28, 2015, the Finding of No Significant Impact (FONSI) issued on January 30, 2015, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Tyler District Office, 2709 W Front Street, Tyler, Texas 75702; telephone (903) 510-9267.

31. FM 2206 from SH 42 to SL 281, Gregg County. The proposed project is a roadway widening and improvement project. Proposed improvements would

widen approximately 3.7 miles of FM 2206 from an existing two-lane road to a four-lane divided highway corridor. However, the curve located between Cox Road and Jordan Valley Drive would be straightened and the road would be in a new alignment in this section. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on December 12, 2016, the Finding of No Significant Impact (FONSI) issued on December 20, 2016, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Tyler District Office, 2709 W Front Street, Tyler, Texas 75702; (903) 510-9267.

32. FM 2493 from FM 2813 in Gresham, south to FM 346 in Flint, Smith County. FM 2493 would be widened from its existing 2-lane highway configuration to a 4-lane highway divided by a flush median (continuous two-way, left-turn lane) in the center. It includes four 12-ft. vehicle lanes (two in each direction), two 4-ft. striped bicycle lanes (one in each direction) plus 2-ft. curb-and-gutter offsets, and a 16-ft. wide flush median. The length of the project is 2.5 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on July 20, 2015, the Finding of No Significant Impact (FONSI) issued on July 31, 2015, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Tyler District Office, 2709 W Front Street, Tyler, Texas 75702; telephone (903) 510-9267.

33. U.S. 59 from FM 2919 to FM 710 in Wharton County. TxDOT, Yoakum District, proposes to upgrade U.S. 59 through Wharton County to Interstate Highway (IH) standards. The proposed project would consist of a four-lane divided freeway facility (two 12-foot lanes in each direction) with 12-foot inside shoulders and 12-foot outside shoulders divided by a concrete traffic barrier. The freeway facility would have continuous frontage roads (two 12-foot lanes in each direction) with 10-foot outside shoulders and 4-foot inside shoulders. Within the proposed construction limits, the intersections along existing U.S. 59 would be given access to frontage roads or in some areas overpasses would be built. The

proposed construction area is approximately 39.5 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on May 25, 2017, the Finding of No Significant Impact (FONSI) issued on May 25, 2017 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office, 403 Huck Street, Yoakum, Texas 77995; telephone (361) 293-4300.

34. U.S. 59 from Business 59 south of El Campo to SH 71 in Wharton County. TxDOT, Yoakum District, proposes to provide frontage roads and convert the existing lanes of U.S. 59 in El Campo to a controlled access facility that meets Interstate standards. Interchanges and/or slip ramps would be included to provide necessary access to and around the facility. The proposed project length is 2.6 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on June 2, 2015, the Finding of No Significant Impact (FONSI) issued on June 2, 2015 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office, 403 Huck Street, Yoakum, Texas 77995; telephone (361) 293-4300.

35. U.S. 59 from SH 71 to Business 59 north of El Campo in Wharton County. TxDOT, Yoakum District, proposes to provide frontage roads and convert the existing lanes of U.S. 59 in El Campo to a controlled access facility that meets Interstate standards. Interchanges and/or slip ramps would be included to provide necessary access to and around the facility. The proposed project length is 3.1 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on February 19, 2016, the Finding of No Significant Impact (FONSI) issued on February 19, 2016 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office, 403 Huck Street, Yoakum, Texas 77995; telephone (361) 293-4300.

36. FM 457 at the Gulf Intracoastal Waterway (GIWW) in Matagorda County. TxDOT, Yoakum District, proposes to replace the FM 457 swing bridge that crosses the GIWW near Sargent, Texas. The proposed project would replace the existing, at-grade, pontoon barge swing span and approach spans with a new fixed-span, high-clearance structure with spiral approaches. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on March 1, 2016 the Finding of No Significant Impact (FONSI) issued on March 1,

2016 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office, 403 Huck Street, Yoakum, Texas 77995; telephone (361) 293-4300.

37. State Highway 31 Relief Route from 3.2 Miles West of FM 2555 to 3.7 Miles East of Interstate Highway 45 in Corsicana, Navarro County. TxDOT, Dallas District, proposes to construct a four-lane divided relief route on new location. The proposed roadway would be a grade-separated facility with frontage roads. The length of the preferred alignment is 14 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on December 18, 2014 the Finding of No Significant Impact (FONSI) issued on December 18, 2014 and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office, 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320-4480.

**Authority:** 23 U.S.C. 139(l)(1).

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**Michael T. Leary,**

*Director, Planning and Program Development,  
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# FEDERAL REGISTER

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Part II

The President

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Proclamation 9789—National POW/MIA Recognition Day, 2018



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# Presidential Documents

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Title 3—

Proclamation 9789 of September 20, 2018

The President

National POW/MIA Recognition Day, 2018

**By the President of the United States of America****A Proclamation**

Throughout American history, the men and women of our Armed Forces have selflessly served our country, making tremendous sacrifices to defend our liberty. On National POW/MIA Recognition Day, we honor all American prisoners of war and express our deep gratitude for the courage and determination they exemplified while enduring terrible hardships. We also pay tribute to those who never returned from the battlefield and to their families, who live each day with uncertainty about the fate of their loved ones. These families are entitled to the knowledge that their loved ones still missing and unaccounted for will never be forgotten.

As a Nation, it is our solemn obligation to account for the remains of our fallen American service members and civilians and to bring them home whenever possible. We owe an incalculable debt of gratitude to these patriots who gave their last full measure of devotion for our country. For this reason, I have pledged my Administration's best efforts to account for our country's missing heroes. We continue to work to account for the missing personnel from the Vietnam War. American and partner nation search teams are also working tirelessly in South Korea, Europe, the South Pacific, and elsewhere around the world to recover and identify those who served in World War II, the Korean War, the Cold War, and other past conflicts.

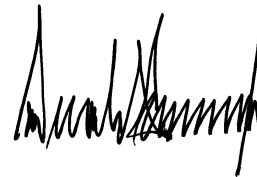
During my meeting with Chairman Kim Jong Un of the Democratic People's Republic of Korea in June, I raised my concern for the thousands of grieving American families whose loved ones remain missing from the Korean War uncertainty. As a result, I secured a commitment from Chairman Kim to recover and repatriate the remains of those Americans who were prisoners of war or killed in action. Last month, we repatriated the remains of some of those courageous service members to American soil. As a result of this homecoming, two of our missing fallen have already been identified, renewing our hope for the fullest possible accounting of the Americans who have yet to be recovered from the Korean War. These recovery efforts are vital to fulfilling our Nation's promise to leave no fellow American behind.

On September 21, 2018, the stark black and white banner symbolizing America's Missing in Action and Prisoners of War will again be flown over the White House; the United States Capitol; the Departments of State, Defense, and Veterans Affairs; the Selective Service System Headquarters; the World War II Memorial; the Korean War Veterans Memorial; the Vietnam Veterans Memorial; United States post offices; national cemeteries; and other locations across the country. We do this, each year, to recognize those who have suffered the horrors of enemy captivity, those who have still not returned from war, and the families who have yet to lay their loved ones to rest with the honor and dignity they deserve.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 21, 2018, as National POW/MIA Recognition Day. I call upon the people of the United States to join me in saluting all American POWs and those missing in action who valiantly served our country. I call upon Federal, State, and

local government officials and private organizations to observe this day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twentieth day of September, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.

A handwritten signature in black ink, appearing to be the name of Donald Trump, written in a stylized, cursive script.

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