

information that determine when to submit a medical device report.

(L) Premarket notification submissions must include the information contained in paragraph (b)(1)(ii)(A) through (K) of this section.

(iii) Manufacturers must submit a log of all complaints. The log must include the following information regarding each complaint, if available: The type of event (*e.g.*, false negative/false nonreactive or false positive/false reactive), lot, date, population, and whether or not the complaint was reported under part 803 of this chapter (Medical Device Reporting). The log must be submitted annually on the anniversary of clearance for 5 years following clearance of a traditional premarket notification.

(2) If the test is intended for Point of Care (PoC) use, the following special controls, in addition to those listed in paragraph (b)(1) of this section, apply:

(i) The PoC labeling must include a statement that the test is intended for PoC use.

(ii) The PoC labeling must include the following information near the statement of the intended use:

(A) That the test is for distribution to clinical laboratories that have an adequate quality assurance program, including planned systematic activities that provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.

(B) That the test is for use only by an agent of a clinical laboratory.

(C) Instructions for individuals to receive the "Subject Information Notice" prior to specimen collection and appropriate information when test results are provided.

(iii) PoC labeling must include instructions to follow current guidelines for informing the individual of the test result and its interpretation.

(iv) The instructions in the labeling must state that reactive results are considered preliminary and should be confirmed following current guidelines.

(v) Device verification and validation for PoC use must include:

(A) Detailed documentation from a well-conducted multisite clinical study conducted at appropriate PoC sites. Performance must be analyzed relative to an FDA cleared or approved comparator. This study must be conducted using patient samples, with appropriate numbers of HIV positive and HIV negative samples in applicable risk categories. Additional subgroup or type claims must be validated using appropriate numbers and types of samples. The samples may be a

combination of fresh and repository samples, sourced from within and outside the United States, as appropriate. If the test is intended solely for PoC use, the test must meet only the performance criteria in paragraphs (b)(2)(v)(A)(1) and (2) of this section and not the criteria in paragraph (b)(1)(ii)(F) of this section:

(1) Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 98 percent.

(2) Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 98 percent.

(B) Premarket notification submissions must include the information contained in paragraph (b)(2)(v)(A) of this section.

(3) If the test is intended for supplemental use in addition to use as an aid in initial diagnosis, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, as appropriate, apply:

(i) The labeling must include a statement that the test is intended for use as an additional test to confirm the presence of HIV viral nucleic acid in specimens found to be repeatedly reactive by a diagnostic screening test.

(ii) Device validation and verification for supplemental use must include a clinical study, including samples that were initially reactive and repeatedly reactive on a diagnostic test but were negative or indeterminate on a confirmatory test. Premarket notification submissions must include this information.

(4) If the test is intended solely as a supplemental test, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, except those in paragraphs (b)(1)(ii)(F) and (b)(2)(v)(A) of this section, as appropriate, apply:

(i) The labeling must include a statement that the test is intended for use as an additional test to confirm the presence of HIV viral nucleic acid in specimens found to be repeatedly reactive by a diagnostic screening test.

(ii) The labeling must clearly state that the test is not for use for initial diagnosis or is not intended as a first-line test.

(iii) Device validation and verification must include a clinical study including samples that were initially reactive and repeatedly reactive on a diagnostic test but were negative or indeterminate on a confirmatory test. Premarket notification submissions must include this information.

(5) If the test is intended to differentiate different HIV types, the

following special controls, in addition to those listed in paragraphs (b)(1) through (4) of this section, as appropriate, apply:

(i) The labeling must include the statement that the test is intended for the confirmation of initial results and differentiation of different HIV types.

(ii) The results interpretation in the labeling must include instructions for the user on how to interpret the results, including un-typeable and co-infection results.

(iii) Device validation and verification must include evaluation of analytical and clinical sensitivity and specificity for each of the types, strains, and subtypes of HIV intended to be differentiated. Premarket notification submissions must include this information.

Dated: May 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-10461 Filed 5-13-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG-2020-0154]

RIN 1625-AA01

Anchorage Regulations; Ten Anchorages on the Mississippi River Mile Markers 12-85 AHP

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: The Coast Guard is amending anchorage regulations for the Lower Mississippi River (LMR) between mile marker (MM) 12 above head of passes (AHP), to MM 85 AHP. This amendment modifies nine anchorage grounds and establishes one new anchorage ground. This regulation increases the available anchorage areas necessary to accommodate vessel traffic, promote navigational safety, provide for the overall safe and efficient flow of vessel traffic and commerce, and bolster the economy through increased anchorage capacity.

DATES: This rule is effective June 15, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2020-0154 in the search box and click

“Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander William Stewart, Sector New Orleans, U.S. Coast Guard; telephone 504-365-2246, email *William.A.Stewart@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AHP	Above Head of Passes
CFR	Code of Federal Regulations
COTP	Captain of the Port Sector New Orleans
CPRA	Coastal Protection and Restoration Authority
CRPPA	Crescent River Port Pilots' Association
DHS	Department of Homeland Security
FR	Federal Register
LDB	Left Descending Bank
LMR	Lower Mississippi River
MM	Mile Marker
MNSA	Maritime Navigation Safety Association
NOI	Notice of Inquiry
NPRM	Notice of proposed rulemaking
RDB	Right Descending Bank
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The legal basis and authorities for this rulemaking are found in 46 U.S.C. 70006, 33 CFR 109.05, 33 CFR 1.05-1, and DHS Delegation No. 0170.1, Revision No. 01.2, which collectively authorize the Coast Guard to propose, establish, and define regulatory anchorage grounds. Under title 33 of the Code of Federal Regulations (CFR) part 109, § 109.05, U.S. Coast Guard District Commanders are delegated the authority to establish anchorage grounds by the Commandant of the U.S. Coast Guard. The Coast Guard established Anchorage Grounds under 33 CFR 110.1(b)(32) FR 17728, Dec. 12, 1967, as amended by 52 FR 33811, Sept. 8, 1987; 63 FR 5526, June 30, 1998).

The project to modify or establish ten anchorage grounds along the LMR was initiated in 2019. From 2019 through 2022, certain port stakeholders, (including Crescent River Port Pilots' Association (CRPPA), Maritime Navigation Safety Association (MNSA), Coastal Protection and Restoration Authority (CPRA) and United States Coast Guard (USCG)) worked to determine if the proposed modifications were necessary and in suitable locations, with consideration given to, among other things, environmental factors.

In 2021, a notice of proposed rulemaking (NPRM) was published on

August 29, 2021 (86 FR 48354), the Coast Guard solicited comments from the maritime stakeholders. At the end of the comment period ending on September 29, 2021, the project received a total of one comment that recommended adding a Note identifying revetments into the text of each of the applicable proposed changes to anchorage grounds.

III. Legal Authority and Need for Rule

The legal basis and authorities for this rulemaking are found in 46 U.S.C. 70006, 33 CFR 109.05, 33 CFR 1.05-1, and DHS Delegation No. 0170.1, Revision No. 01.2, which collectively authorize the Coast Guard to propose, establish, and define regulatory anchorage grounds. Under Title 33 of the Code of Federal Regulation (CFR) part 109.05, U.S. Coast Guard District Commanders are delegated the authority to establish anchorage grounds by the Commandant of the U.S. Coast Guard. The Coast Guard established Anchorage Grounds under title 33 CFR 110.1(b)(32) FR 17728, Dec. 12, 1967, as amended by 52 FR 33811, Sept. 8, 1987; 63 FR 5526, June 30, 1998).

The Commander of Coast Guard District Eight is establishing one new anchorage ground and amending nine existing anchorage grounds along the LMR, ranging from MM 12 to MM 85 AHP. Currently, there are not adequate anchorage grounds along the river system to facilitate the safe anchorage of shallow and deep draft vessels along the LMR. This action would ensure safe navigation of vessels on LMR.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on the NPRM published on August 29, 2021. This comment proposed to include additional text to 6 of the anchorage grounds that would identify revetments located within or adjacent to those specific anchorage grounds. The Coast Guard agrees that, since the NPRM proposed to include notes to Cedar Grove and Lower 12 Mile, which identify revetments located within/adjacent to those specific anchorage grounds, the proposed changes to the anchorage grounds would be beneficial.

The changes in the regulatory text of this rule from the rule in the NPRM are discussed below. The specific anchorage boundaries are described in detail in the regulatory text at the end of the document. In general, this rule will have the following effects:

1. Increase the length of the Boothville Anchorage from 5.5 miles to 6.45 miles and

add a note to the text of the Boothville Anchorage (33 CFR 110.195(a)(4)).

2. Increase the length of the Magnolia Anchorage from 2.1 miles to 2.2 miles and add a note to the text of the Magnolia Anchorage (33 CFR 110.195(a)(7)).

3. Increase the length of the Davant Anchorage from 1.1 miles to 1.4 miles (33 CFR 110.195(a)(9)).

4. Decrease the width of the Wills Point Anchorage from 600 feet to 500 feet (33 CFR 110.195(a)(11)).

5. Add a note to the text of the Cedar Grove Anchorage (33 CFR 110.195(a)(12)).

6. Increase the length of the Belle Chasse Anchorage from 2.1 miles to 2.15 miles, decrease the width from 575 feet to 500 feet and add a note to the text of the Belle Chasse Anchorage ((33 CFR 110.195(a)(13)).

7. Add a Note to the text of the Lower 12 Mile Point Anchorage (33 CFR 110.195(a)(14)).

8. Increase the length of the Lower 9 Mile Point Anchorage from 2.3 miles to 2.4 miles add a note to the text of the Lower 9 Mile Anchorage (33 CFR 110.195(a)(15)).

9. Increase the length of the Point Michel Anchorage from 1.4 miles to 2.2 miles and add a note to the text of the Point Michel Anchorage (33 CFR 110.195(a)(35)).

10. Add a new anchorage, the Phoenix Anchorage, to include the area, 0.6 miles in length, along the left descending bank of the river extending from mile 57.82 to mile 58.42 Above Head of Passes. The width of the anchorage is 400 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 400 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 800 feet from the water's edge into the river as measured from the LWRP. Add a note to the text of the Phoenix Anchorage.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on minimal impact to routine navigation. The anchorage areas do not restrict traffic as they are located well outside the established navigation channel. Vessels maneuver in, around and through the anchorages.

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 will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the anchorage grounds 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.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct

effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of one new anchorage grounds and the modification of nine existing anchorage grounds along the LMR. It is categorically excluded from further review under paragraph Land L59 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters.

Protesters are asked to call or email 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 110

Anchorage Regulations.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C 2071, 46 U.S.C. 70006, 70034; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1, Revision No. 01.2

- 2. Amend § 110.195 by:
 - a. Revising paragraphs (a)(4), (7), (9), and (11) through (15);
 - b. Revising the headings for the notes following paragraphs (a)(16), (18), and (22);
 - c. Revising paragraph (a)(35);
 - d. Adding paragraph (a)(37); and
 - e. Revising the heading for the note following paragraph (c)(6).

The revisions and addition to read as follows:

§ 110.195 Mississippi River below Baton Rouge, LA, including South and Southwest Passes.

(a) * * *

(4) *Boothville Anchorage.* An area, 6.45 miles in length, along the right descending bank of the river extending from mile 12.05 to mile 18.5 Above Head of Passes. The width of the anchorage is 750 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 250 feet from the water’s edge into the river as measured from the Low Water Reference Plane (LWRP). The outer boundary of the anchorage is a line parallel to the nearest bank 1,000 feet from the water’s edge into the river as measured from the LWRP.

Note 1 to paragraph (a)(4): Venice Revetment extends/runs adjacent to this anchorage. Mariners are urged to use caution in this anchorage.

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(7) *Magnolia Anchorage.* An area, 2.2 miles in length, along the right descending bank of the river extending from mile 45.4 to mile 47.6 Above Head of Passes. The width of the anchorage is 700 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 400 feet from the water’s

edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 1,100 feet from the water's edge into the river as measured from the LWRP.

Note 2 to paragraph (a)(7): Point Michel and Diamond Revetments extend/run adjacent to this anchorage. Mariners are urged to use caution in this anchorage.

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(9) *Davang Anchorage.* An area, 1.4 miles in length, along the left descending bank of the river extending from mile 52.5 to mile 53.9 Above Head of Passes. The width of the anchorage is 800 feet.

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(11) *Wills Point Anchorage.* An area, 1.1 miles in length, along the left descending bank of the river extending from mile 66.5 to mile 67.6 Above Head of Passes. The width of the anchorage is 500 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 200 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 700 feet from the water's edge into the river as measured from the LWRP.

(12) *Cedar Grove Anchorage.* An area, 1.34 miles in length, along the right descending bank of the river extending from mile 69.56 to mile 70.9 Above Head of Passes. The width of the anchorage is 500 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 200 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 700 feet from the water's edge into the river as measured from the LWRP.

Note 3 to paragraph (a)(12): Jesuit Bend Revetment extends/runs adjacent to the lower portion of this anchorage. Mariners are urged to use caution in this anchorage.

(13) *Belle Chasse Anchorage.* An area, 2.15 miles in length, along the right descending bank of the river extending from mile 73.05 to mile 75.2 Above Head of Passes. The width of the anchorage is 500 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 375 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 875 feet from the water's edge into the river as measured from the LWRP.

Note 4 to paragraph (a)(13): Oak Point Revetment extends/runs adjacent to the lower portion of this anchorage. Mariners are urged to use caution in this anchorage.

(14) *Lower 12 Mile Point Anchorage.* An area, 2.2 miles in length, along the right descending bank of the river extending from mile 78.6 to mile 80.8 Above Head of Passes. The width of the anchorage is 500 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 300 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 800 feet from the water's edge into the river as measured from the LWRP.

Note 5 to paragraph (a)(14): English Turn Revetment extends/runs adjacent to the lower portion of this anchorage. Mariners are urged to use caution in this anchorage.

(15) *Lower 9 Mile Anchorage.* An area, 2.4 miles in length, along the right descending bank of the river extending from mile 82.6 to mile 85.0 Above Head of Passes. The width of the anchorage is 500 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 300 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 800 feet from the water's edge into the river as measured from the LWRP.

Note 6 to paragraph (a)(15): Twelve Mile Point Revetment extends/runs adjacent to the lower portion of this anchorage. Mariners are urged to use caution in this anchorage.

Caution: A wreck is located within the boundaries of this anchorage. Mariners are urged to use caution in this anchorage.

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Note 7 to paragraph (a)(16): * * *

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Note 8 to paragraph (a)(18): * * *

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Note 9 to paragraph (a)(22): * * *

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(35) *Point Michel Anchorage.* An area, 2.2 miles in length, along the right descending bank of the river extending from mile 40.0 to mile 42.2 Above Head of Passes. The width of the anchorage is 500 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 325 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 825 feet from the water's edge into the river as measured from the LWRP.

Note 10 to paragraph (a)(35): Point Michel Revetment extends/runs adjacent to this anchorage. Mariners are urged to use caution in this anchorage.

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(37) *Phoenix Anchorage.* An area, 0.6 miles in length, along the left

descending bank of the river extending from mile 57.82 to mile 58.42 Above Head of Passes. The width of the anchorage is 400 feet. The inner boundary of the anchorage is a line parallel to the nearest bank 400 feet from the water's edge into the river as measured from the LWRP. The outer boundary of the anchorage is a line parallel to the nearest bank 800 feet from the water's edge into the river as measured from the LWRP.

Note 11 to paragraph (a)(37): Myrtle Grove Revetment extends/runs adjacent to this anchorage. Mariners are urged to use caution in this anchorage.

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(c) * * *

(6) * * *

Note 12 to paragraph (c)(6): * * *

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Dated: 2 May 2022.

John W. Reed,

Captain, U.S. Coast Guard, Acting Commander, Eighth Coast Guard District.

[FR Doc. 2022-10356 Filed 5-13-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 13

RIN 2900-AR11

Fiduciary Bond

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulations that govern fiduciary activities. More specifically, the amendments revise specific procedures to exempt a VA-appointed fiduciary who is also serving as a court-appointed fiduciary from posting multiple bonds and to also exempt a VA-appointed fiduciary that is also a State agency with existing, State-mandated liability insurance or a blanket bond from having to obtain an additional bond payable to the Secretary of Veterans Affairs (Secretary).

DATES: This rule is effective June 15, 2022.

FOR FURTHER INFORMATION CONTACT:

Kevin Baresich, Program Analyst, Pension and Fiduciary Service (21PF), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632-8863. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In a document published in the **Federal**