

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) "For use only on a single patient. Discard the entire device after use."

(B) "Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested."

(b) *Single use only blood lancet without an integral sharps injury prevention feature*—(1) *Identification*. A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification*. Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use.

(iii) The device must be demonstrated to be biocompatible.

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (*e.g.*, blade).

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on preparation (*e.g.*, cleaning, disinfection) of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(1) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) "For use only on a single patient. Discard the entire device after use."

(B) "Warning: Not intended for more than one use. Do not use on more than

one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested."

(c) *Multiple use blood lancet for single patient use only*—(1) *Identification*. A multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification*. Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that:

(A) The lancet blade can be changed with every use, either manually or by triggering a blade storage unit to discard the used blade and reload an unused blade into the reusable base; and

(B) The structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions and allow for validated cleaning and disinfection.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use.

(iii) The device must be demonstrated to be biocompatible.

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (*e.g.*, blade).

(v) Validation testing must demonstrate that the cleaning and disinfection instructions are adequate to ensure that the reusable lancet base can be cleaned and low level disinfected.

(vi) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) The Environmental Protection Agency (EPA) registered disinfectant's contact time for disinfectant use.

(C) Handwashing instructions for the user before and after use of the device.

(D) Instructions on preparation (*e.g.*, cleaning, disinfection) of the skin to be pierced.

(E) Instructions on the cleaning and disinfection of the device.

(F) Instructions for the safe disposal of the device.

(G) Instructions for use must address the safe storage of the reusable blood lancet base between uses to minimize contamination or damage and the safe storage and disposal of the refill lancet blades.

(H) Labeling must be appropriate for the intended use environment.

(1) For those devices intended for health care settings, labeling must address the health care facility use of

these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vii) Labeling must also include the following statements, prominently placed:

(A) "For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use."

(B) "Used lancet blades must be safely discarded after a single use."

(C) "Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient."

(d) *Multiple use blood lancet for multiple patient use*—(1) *Identification*. A multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification*. Class III (premarket approval).

Dated: November 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0077]

RIN 1625-AA11

Regulated Navigation Area; Biscayne Bay Causeway Island Slip, Miami Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a Regulated Navigation Area over certain navigable waters of the Biscayne Bay Causeway Island Slip, immediately west of the Coast Guard Base Miami Beach, Miami Beach, FL. This action is necessary to provide for the safety of life and federal property on

this navigable water. This rulemaking will require all persons and vessels to transit the Regulated Navigation Area at a speed that creates minimum wake, seven miles per hour or less, to safeguard damage to Coast Guard assets, disrupting operations, and/or injuring Coast Guard personnel. Additionally, this rulemaking will prohibit vessels from passing other vessels making way within the regulated area.

DATES: Effective December 22, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2021–0077 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Omar Beceiro, Sector Miami Waterways Management Division, Coast Guard at 305–535–4317 or by email Omar.Beceiro@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

In October 2020, the Fisher Island Ferry Communities Association relocated its ferry terminal to the Biscayne Bay Causeway Island Slip (Slip), west of the Coast Guard Base Miami Beach, Miami Beach, FL. The Slip is the primary terminal for the movement of residents, workers, and goods from Terminal Island to Fisher Island. Prior to October 2020, maritime traffic in the Biscayne Bay Causeway Island Basin (Basin) was limited in scope to occasional private yachts and Coast Guard assets. The addition of ferry traffic at the Slip has resulted in a substantial increase in maritime traffic in the Basin. The Basin has a length of approximately 380 yards and a width of approximately 97 yards. The increase in traffic, particularly of the Fisher Island Ferry, presents a hazard to Coast Guard assets operating in the Basin as the ferries occasionally pass within the Basin, dangerously close to Coast Guard assets. Additionally, and particularly when passing within the Basin, the ferries create a disrupting, and at times dangerous wake, adversely affecting Coast Guard routine operations and personnel. The passing maneuvers and resultant wake also create hazardous

conditions during certain cutter operations, such as unloading and offloading of ammunition or refueling. The Coast Guard’s Seventh District Commander has determined the increased ferry traffic, passing maneuvers, and resultant wake presents a safety and operational concern to Coast Guard personnel and assets moored in the Biscayne Bay Causeway Island Basin.

In response, on April 14, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) titled, “Regulated Navigation Area: Biscayne Bay Causeway Island Slip, Miami Beach, FL” (86 FR 19599). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this Regulated Navigation Area. During the comment period that ended May 14, 2021, we received 0 comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Coast Guard’s Seventh District Commander has determined that potential hazards associated with the increased maritime traffic in the Biscayne Bay Causeway Island Basin (Basin), where ferries occasionally pass within the Basin dangerously close to Coast Guard assets, is a safety and operational concern. The purpose of this regulation is to ensure navigational safety, protection of Coast Guard assets and personnel, and to facilitate safe execution of Coast Guard statutory missions.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on the NPRM published April 14, 2021. We are making one change in the regulatory text. We discovered that the section number in the CFR, 33 CFR 165.789 is already in use. Section 165.789 contains a safety zone regulation. Therefore, we are revising the section number for this Regulated Navigation Area in the final rule regulatory text. We are deleting “165.789,” and replacing it with “165.790.”

This rule establishes a permanent Regulated Navigation Area that will require all persons and vessels to transit the regulated area at a speed that creates minimum wake, seven miles per hour or less, to safeguard damage to Coast Guard assets, disrupting operations, and/or injuring Coast Guard personnel. Additionally, this rule will prohibit vessels from passing other vessels making way within the regulated area. This Regulated Navigation Area covers

all navigable waters within the Biscayne Bay Causeway Island Slip, immediately west of the Coast Guard Base Miami Beach, Miami Beach, FL.

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 the size, and location of the Regulated Navigation area. The Regulated Navigation Area will only affect vessels entering, and passing within, the Biscayne Bay Causeway Island Slip in Miami Beach, Miami Beach, FL. Vessels will continue to operate within the Biscayne Bay Causeway Island Slip with the only restriction being the requirement to operate at speeds below seven miles per hour and avoid passing other vessels making way within the regulated area. Moreover, upon activating the Regulated Navigation Area, the Coast Guard will notify the local maritime community through various means including, Local Notice to Mariners and Broadcast Notice to Mariners issued on VHF–FM marine radio channel 16.

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 0 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 Regulated Navigation Area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please 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 a Regulated Navigation Area requiring all persons and vessels to transit the regulated area at a speed that creates minimum wake, seven miles or less, and to avoid passing other vessels making way within the regulated area. 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. 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 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 AREA; BISCAYNE BAY CAUSEWAY ISLAND SLIP, MIAMI BEACH, FL

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.790 to read as follows:

§ 165.790 Regulated Navigation Area; Biscayne Bay Causeway Island Slip, Miami Beach, FL.

(a) *Regulated area.* The following area is a Regulated Navigation Area: All waters of Biscayne Bay Causeway Island Slip within the following points: Beginning at Point 1 in position 25°46'18" N, 080°08'50" W; thence east to Point 2 in position 25°46'19" N, 080°08'47" W; thence southeast to Point 3 in position 25°46'10" N, 080°08'41" W; thence west to Point 4 in position 25°46'10" N, 080°08'45" W; thence back to origin at Point 1.

(b) *Applicability.* This section applies to all vessels operating within the RNA, except vessels that are engaged in law enforcement or search and rescue operations.

(c) *Regulations.* (1) The general regulations governing Regulated Navigation Areas found in 33 CFR 165.10, 165.11, and 165.13, including the Regulated Navigation Area described in paragraph (a) of this section and the following regulations, apply.

(2) All persons and vessels are required to transit the Regulated Navigation Area at a speed that creates minimum wake, seven miles per hour or less, to prevent damage to Coast Guard assets, disrupting operations, and/or injuring Coast Guard personnel.

(3) All persons and vessels are required to avoid passing other vessels making way within the Regulated Navigation Area.

(d) *Enforcement.* The Coast Guard may be assisted in the patrol and enforcement of the Regulated Navigation Area by other Federal, State, and local agencies.

Dated: November 8, 2021.

B.C. McPherson,

Rear Admiral, U.S. Coast Guard, District Commander.

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