

number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5510 to subpart F to read as follows:

§ 876.5510 Temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia.

(a) *Identification.* A temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia (BPH) is a prescription use device that is inserted transurethally and deployed at the prostate. The implant is designed to increase prostatic urethral patency by increasing prostatic opening. It is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing with the device under anticipated conditions of use must evaluate improvement in urinary outflow symptoms and document the adverse event profile.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following

performance characteristics must be tested:

- (i) Deployment and removal; and
- (ii) Mechanical strength.

(6) Labeling must include:

(i) Instructions for use, including the recommended training for safe use of the device;

(ii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events; and

(iii) A shelf life.

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09640 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0441]

Special Local Regulations; Marine Events Within the Fifth Coast Guard District; Washington, DC Dragon Boat Festival

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for a recurring marine event in the Fifth Coast Guard District. This regulation applies to the Washington, DC Dragon Boat Festival. This action is intended to restrict vessel traffic in a portion of the Upper Potomac River near Washington, DC, in order to provide for the safety of life on navigable waters during the event.

DATES: On May 31, 2025, from 7:30 a.m. until 6:30 p.m., the regulations in 33 CFR 100.501 will be enforced for the location identified in table 2 to 33 CFR 100.501(i)(2) for the event denominated as “Washington, DC Dragon Boat Festival.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email MDNCRMarineEvents@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.501 for the Washington, DC Dragon Boat Festival

regulated area from 7:30 a.m. to 6:30 p.m. on May 31, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. As stated in footnote one to table 2 to paragraph (i)(2), the enforcement dates and times for each of the listed events in the table are subject to change. Due to inclement weather, the Washington, DC Dragon Boat Festival has been rescheduled (for this year only) from the third weekend in May to May 31, 2025, for a one-day event. Our regulation for marine events within the Fifth Coast Guard District, § 100.501, specifies the location of the regulated area for the Washington, DC Dragon Boat Festival, which encompasses portions of the navigable waters of the Upper Potomac River. During the enforcement periods, as reflected in § 100.100(c), the operator of a vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcast.

Dated: May 21, 2025.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2025–09644 Filed 5–28–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0385]

RIN 1625–AA00

Safety Zone; Edgewater Beach, Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of Lake Erie offshore Edgewater Beach in Cleveland, Ohio. This action is necessary to provide for the safety of life on these navigable waters during the US Rowing Beach Sprints Mini Camp. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port,

Sector Eastern Great Lakes, or a designated representative.

DATES: This rule is effective from 6:30 a.m. to 7:30 p.m. on May 31, 2025, and from 1:30 p.m. to 3:30 p.m. on June 1, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0385 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 about this rule, call or email Cody Mayerer at Marine Safety Unit Cleveland’s Waterways Management Division, U.S. Coast Guard; telephone 216–937–0111, email D09-SMB-MSUCLEVELAND-WWM@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

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The sponsor did not notify the Coast Guard of this marine event with adequate time to provide a reasonable comment period and consider those comments before issuing the rule and establishing the safety zone by May 31, 2025.

Also, 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 ensure the safety of participants during the duration of the US Rowing Beach Sprints Mini Camp.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The

Captain of the Port Sector, Eastern Great Lakes (COTP) has determined that a safety zone is required to ensure the safety of participants and the navigable waters before, during, and after the scheduled marine event.

IV. Discussion of the Rule

This rule establishes a safety zone from 6:30 a.m. to 7:30 p.m. on May 31, 2025, and from 1:30 p.m. to 3:30 p.m. on June 1, 2025. The safety zone will cover all navigable waters and tributaries within 250 meters (820 ft) offshore Edgewater Park Beach. There will be 2 parallel lines of 3 buoy’s perpendicular to shore extending 250 meters from water’s edge. The boundaries of the safety zone form a rectangle with the four corners of the polygon located in the following positions: (1) 41°29’22” N, 081°44’20” W; (2) 41°29’29” N, 081°44’25” W; (3) 41°29’25” N, 081°44’34” W; (4) 41°29’18” N, 081°44’29” W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the US Rowing Mini Camp is in session. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

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.

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 section 3(f) of 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 size, location, and duration of rule. This safety zone would restrict navigation for a relatively small area near Edgewater Beach for the course area for 13 hours on one day, and 2 hours on the second day.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The

term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone 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 will 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 safety zone that will restrict navigation through the course area for 13.0 hours one day, and 2.5 hours on the second day. It is 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.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping 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: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T09–0385 to read as follows:

§ 165.T09–0385 Safety Zone; Edgewater Beach, Lake Erie, Cleveland, OH

(a) *Location.* The safety zone covers all navigable waters and tributaries of Lake Erie within Edgewater Park Beach. The boundaries of the safety zone form a rectangle with the corners of the polygon located at the following coordinates: (1) 41°29′22″ N, 081°44′20″ W; (2) 41°29′29″ N, 081°44′25″ W; (3) 41°29′25″ N, 081°44′34″ W; (4) 41°29′18″ N, 081°44′29″ W then return to position (1) above (NAD 83).

(b) *Enforcement Period.* This section will be enforced from 6:30 a.m. to 7:30 p.m. on May 31, 2025, and from 1:30 p.m. to 3:30 p.m. on June 1, 2025.

(c) *Definitions.* *Official Patrol Vessel* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Eastern Great Lakes in the enforcement of the regulations in this section. Participant means all persons and vessels attending the event.

(d) *Regulations.* (1) The Coast Guard may patrol the event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign “PATCOM.”

(2) All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators.

(3) Spectator vessels desiring to transit the safety zone may do so only with prior approval of the Patrol Commander and when so directed by that officer and will be operated at a no wake speed in a manner which will not endanger participants in the event or any other craft.

(4) No spectator shall anchor, block, loiter, or impede the through transit of official patrol vessels in the safety zone during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) The Patrol Commander may forbid and control the movement of all vessels in the safety zone. When hailed or signaled by an official patrol vessel, a

vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(6) Any spectator vessel may anchor outside the regulated areas specified in this chapter, but may not anchor in, block, or loiter in a navigable channel.

(7) The Patrol Commander may terminate the event or the operation of any vessel at any time it is deemed necessary.

(8) The Patrol Commander will terminate enforcement of the safety zone at the conclusion of the event.

Dated: May 13, 2025.

Sean M. Murray

Commander, U.S. Coast Guard, Alternate Captain of the Port Sector Eastern Great Lakes.

[FR Doc. 2025–09590 Filed 5–28–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0364]

RIN 1625–AA00

Safety Zone; Delaware River, Camden, NJ, Battleship New Jersey

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for waters of the Delaware River, in Camden, NJ, for a clay shoot aboard the Battleship New Jersey on June 26, 2025, or on a rain date before July 4, 2025. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the clay shoot. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Delaware Bay (COTP).

DATES: This rule is effective from June 26, 2025, through July 4, 2025. It will only be subject to enforcement, however, on the one day during that time period when the event takes place. Absent postponement, that date will be June 26, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0364 in the search box and click “Search.” Next, in the Document Type