

(2) 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) Performance bench testing in a simulated use model must verify functional aspects of the device design and support device durability during clinical use;

(ii) Dimensional specifications must be verified; and

(iii) Tensile strength testing must be performed for all articulating components.

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

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

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

(6) Training must be provided so that, upon completion of the training program, the user can use the device correctly to approximate tissue to alter the gastric anatomy for the purpose of weight loss with minimal impact to the safety of the patient.

(7) Labeling must include:

(i) A summary of clinical performance testing with the device, including a discussion of adverse events and clinical benefit reported as percent total body weight loss; and

(ii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-10621 Filed 5-27-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2026-0598]

Special Local Regulations; Marine Events Within the Sector Columbia River Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations at various locations in the Sector Columbia River Captain of the Port Zone from May 30, 2026, to August 8, 2026. This action is

necessary to provide for the safety of life and property on these navigable waters during marine events. During the enforcement periods, the operator of any vessel in the regulated area must comply with the directions from the Patrol Commander or any official patrol vessel.

DATES: The regulations in 33 CFR 100.1302 will be enforced for the regulated areas identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander Jesse Wallace, Waterways Management Division, Sector Columbia River, Coast Guard; telephone 503-572-3524, email SCRWWM@USCG.MIL.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.1302 for the following events found in lines 1, 2, and 6 of Table 1 to § 100.1302. The event in line 1, the Rose Fest Dragon Boat Races, will be held from 7:00 a.m. to 4:00 p.m. on June 6, 2026 through June 7, 2026 in Portland, OR. Regulated area includes all waters of the Willamette River shore to shore, bordered on the north by the Hawthorne Bridge, and on the south by the Marquam Bridge.

The event in line 2, Spring Testing Hydroplane races, will be held on May 30, 2026, from 8:00 a.m. to 6:00 p.m. in Kennewick, WA. Regulated area includes all navigable waters within the Columbia River in the vicinity of Columbia Park, commencing at the Interstate 395 Bridge and continuing upriver approximately 2.0 miles and terminating at the northern end of Wade Island.

The event in line 6, Swim the Snake, will be held on August 8, 2026, from 11:00 a.m. to 1:00 p.m. in Perry, WA. Regulated area includes all navigable waters, bank-to-bank of the Snake River, 500 yards upstream and 500 yards downstream from the Washington State Highway 261 Bridge at the approximate position of 46°35'23" N; 118°13'10" W. All coordinates reference Datum NAD 1983.

During the enforcement periods, as reflected in § 100.1302, if you are the operator of a vessel in the regulated area you must comply with the lawful directions from the Patrol Commander or any official patrol vessel. Vessels may not transit the regulated areas without approval from the Patrol Commander. Vessels permitted to transit must operate at a no wake speed, in a manner which will not endanger participants or other crafts in the event. Spectators or other vessels shall not anchor, block,

loiter, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, or dates and times as modified through Local Notice to Mariners, unless authorized by an official patrol vessel. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notification of these enforcement periods via the Local Notice to Mariners and marine information broadcasts.

Dated: May 22, 2026.

Anthony R. Migliorini,

CAPT, U.S. Coast Guard, Captain of the Port Sector Columbia River.

[FR Doc. 2026-10597 Filed 5-27-26; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2026-0096]

RIN 1625-AA08

Special Local Regulation; Sail Grand Prix, Upper Bay, New York City, NY

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) for certain waters of the Upper Bay of New York Harbor. The SLR is needed to provide for the safety of life to mitigate the dangers associated with a high-speed sailboat race. This proposed rulemaking temporarily prohibits persons and vessels from entering, transiting through, blocking, or loitering within the "Event Area", unless authorized by the Captain of the Port New York or a designated representative.

DATES: This rule is effective from noon on May 30, 2026, through 6:30 p.m. on May 31, 2026. The rule will only be enforced, however, from noon until 6:30 p.m. on Saturday May 30, 2026, and from noon until 6:30 p.m. on Sunday, May 31, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG-2026-0096.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MSTC Sean Fitzgerald, Sector New York Waterways Management Division, U.S. Coast Guard; telephone 718-801-2932, or email SectorNYWWM@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
 COTP Captain of the Port, New York
 DHS Department of Homeland Security
 FR Federal Register
 NPRM Notice of proposed rulemaking
 Sail GP Sail Grand Prix
 § Section
 SLR Special Local Regulation
 U.S.C. United States Code

II. Background and Authority

On January 15, 2026, the Coast Guard received an application for a marine event permit under 33 CFR 100.15 to conduct Sail Grand Prix (Sail GP) 2026 in the Upper Bay of New York Harbor. The event will be held from noon until 6:30 p.m. on Saturday, May 30, 2026, and again, from noon until 6:30 p.m. on Sunday, May 31, 2026. The race features 12 high-speed F50 catamaran teams racing at speeds of up to 60 mph, hundreds of spectator vessels, and thousands of spectators.

The Captain of the Port, New York (COTP) has determined that due to the high-profile nature of this event, the presence of spectator vessels, event support vessels, and race participants operating in close proximity to each other at high speeds, there is an increased potential of collision and allision hazards. The hazards associated with the race itself and the race location are a safety concern for anyone within the “Race Area” and adjacent navigable waters. To mitigate those dangers, and having issued a marine event permit, the COTP is issuing this Special Local Regulation (SLR) under the authority in 46 U.S.C. 70041.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), 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 Coast Guard does not have enough time to solicit and respond to comments.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

The Coast Guard is establishing a Special Local Regulation (SLR) in the Upper Bay of New York Harbor from noon on Saturday, May 30, 2026, through 6:30 p.m. on Sunday, May 31, 2026.

In the event that weather conditions prevent or delay a safe race start, the public will be notified of changes to the enforcement period through marine

broadcasts, local notices to mariners, or by on-scene designated representatives. The areas regulated by this SLR lie between Governors Island, Ellis Island, and Liberty Island and cover all navigable waters, from surface to bottom, as more specifically defined in the regulatory text below. The Sail GP Sponsor will mark the regulated areas via colored visual markers. The regulated area will include a “Transit Only Area” and an “Event Area”. No vessel or person will be permitted to enter the “Event Area” without obtaining permission from the COTP or their designated representative.

Within the “Event Area”, the event sponsor will establish a smaller, dynamic “Race Area” based on prevailing weather conditions. The location and boundaries of the “Race Area” are subject to change and will be demarcated by on-scene assets, colored markers, and announced by the event sponsor. The “Race Area” is restricted to registered race participants and official safety and support personnel. All other persons and vessels are prohibited from entering, transiting, or remaining in the “Race Area”. All waters within the “Event Area” not designated as the “Race Area” will be considered the “Spectator Area”. Spectators and their vessels must remain in the “Spectator Area” and are responsible for maneuvering to avoid the changing “Race Area”.

IV. Regulatory Analyses

The Coast Guard developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below is a summary of the Coast Guard’s analyses based on a number of these statutes and Executive Orders.

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act’s flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman

and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

The Coast Guard has analyzed this rule under Executive Order 13132, Federalism, and has determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

The Coast Guard has 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 has 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 is a Special Local Regulation. It is categorically excluded from further review under paragraph L61 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.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T0199–0096 to read as follows:

§ 100.T0199–0096 Special Local Regulation; Upper Bay, New York City, NY.

(a) *Regulated areas.* (1) “*Event Area*”—*Location.* This special local regulation applies to the following area: all waters of the Upper Bay of New York Harbor, from surface to bottom, encompassed by a line connecting the following points beginning at 40°41′49.68″ N 74°02′2.28″ W; thence to 40°41′49.74″ N 74°01′23.64″ W; thence to 40°41′43.140″ N 74°1′9.00″ W; thence to 40°41′43.140″ N, 074°01′08.996″ W; thence to 40°41′35.616″ N, 074°01′10.011″ W; thence along the shore to 40°41′02.594″ N, 074°01′24.182″ W; thence to 40°40′47.760″ N 74°1′43.200″ W thence to 40°40′38.460″ N 74°2′0.420″ W; thence to 40°40′38.940″ N 74°2′45.000″ W; thence to 40°41′2.040″ N 74°2′24.720″ W; thence to 40°41′13.080″ N 74°2′24.360″ W; thence to 40°41′35.820″ N 74°2′15.600″ W and thence back to the point of origin. Positions provided are expressed in Degrees (°) Minutes (′) Seconds (″) (DMS) based on North American Datum 1983 (NAD 83).

(2) “*Transit Only Area*”—*Location.* All navigable waters of the Upper Bay of New York Harbor, from surface to bottom, encompassed by a line connecting the following points beginning at 40°41′49.68″ N 74°02′11.21″ W; thence 40°41′49.68″ N 74°02′02.28″ W; thence to 40°41′35.28″ N 74°02′15.6″ W; thence to 40°41′13.08″ N 74°02′24.36″ W; thence to 40°41′02.04″ N 74°02′24.72″ W; thence to 40°40′38.94″ N 74°02′45.00″ W; thence to 40°40′38.94″ N 74°02′54.18″ W; thence to 40°41′02.04″ N 74°02′33.83″ W; thence to 40°41′13.08″ N 74°02′33.48″ W; thence to 40°41′35.82″ N 74°02′24.68″ W; thence back to the point of origin.

(3) “*Race Area*”—*Location.* All navigable waters of the Upper Bay of New York Harbor, from surface to

bottom, which will be demarcated by visual markers and on scene race control vessels within the “*Event Area*” designated in paragraph (a)(1) of this section.

(4) “*Spectator Area*”—*Location.* All navigable waters of the Upper Bay of New York Harbor, from surface to bottom, within the “*Event Area*” as described in paragraph (a)(1) of this section outside of the “*Race Area*”.

(b) *Definitions.* As used in this section:

Designated representative 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 COTP in the enforcement of the special local regulation.

Participant means all persons and vessels registered with the event sponsor as a participant in the race.

Spectator means any person or vessel, which is not designated by the sponsor as a support vessel or participant, in the vicinity of the event with the primary purpose of witnessing the event. Spectator vessels can observe the marine event from the designated “*Spectator Area*”.

(c) *Regulations.* (1) No vessel shall enter the “*Event Area*” described in paragraph (a)(1) of this section unless authorized by the COTP or their designated representative.

(2) No vessels within the “*Event Area*”, except participants and official safety and support personnel, shall enter the “*Race Area*” as described in paragraph (a)(3) of this section unless authorized by the COTP or their designated representative. The event sponsor will demarcate the exterior perimeter of the “*Race Area*” by colored markers and on scene assets. The COTP or their designated representative may restrict the number of vessels allowed within the “*Spectator Area*” to prevent overcrowding and ensure safe navigation. Once the COTP or their designated representative determines that the “*Spectator Area*” has reached a safe capacity, no additional vessels will be allowed to enter unless specifically authorized by the COTP or their designated representative.

(3) No vessels may stop, loiter, remain, or anchor in the “*Transit Only Area*” described in paragraph (a)(2) of this section during the period of enforcement.

(4) To seek permission to enter the “*Event Area*”, contact the COTP or the COTP’s representative on VHF–FM channel 16. Those in the regulated area must comply with all lawful orders or

directions given to them by the COTP or the COTP’s designated representative.

(d) *Effective and enforcement periods.*

(1) This section is effective from noon on May 30, 2026, through 6:30 p.m. on May 31, 2026. The rule will only be enforced, however, from noon until 6:30 p.m. on Saturday, May 30, 2026, and from noon until 6:30 p.m. on Sunday, May 31, 2026.

(2) In the event that weather conditions prohibit a safe race start or causing delays, the public will be notified of changes to the enforcement period as described in paragraph (d)(1) of this section through marine broadcasts, local notices to mariners, or by on-scene designated representatives.

Jonathan A. Andrechik,

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

[FR Doc. 2026–10612 Filed 5–27–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG–2026–0418]

RIN 1625–AA00

Safety Zone; Atlantic Ocean, Atlantic City, NJ

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Atlantic Ocean, near Atlantic City, NJ. This action is necessary to provide for the safety of life on these navigable waters during an offshore airshow on May 29, 2026, through May 31, 2026. This regulation prohibits persons and vessels from entering the regulated area unless specifically authorized by the Captain of the Port, Sector Delaware Bay, or their designated representative.

DATES: This rule is effective from 11:30 a.m. on May 29, 2026, through 3:30 p.m. on May 31, 2026. It will, however, only be subject to enforcement between 11:30 a.m. and 3:30 p.m. on each of those days.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2026–0418.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST2 Dominick Dobridge,