

(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.*

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## 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](mailto: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.*

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## 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](mailto:SectorNYWWM@uscg.mil).