

List of Subjects in 21 CFR Part 888

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 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

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

■ 2. Add § 888.3695 to subpart D to read as follows:

§ 888.3695 Shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis is a device using a replacement humeral head made of ceramic materials such, as pyrolytic carbon, and a stem made of alloys, such as cobalt-chromium-molybdenum. It is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed with or without bone cement (§ 888.3027). This device is not intended for use in total shoulder arthroplasty.

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

(1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Evaluation of improvement of shoulder function and reduction of symptoms, including pain and function, for the indications for use; and

(ii) Evaluation of adverse events, including pain, unanticipated adverse device effects, subsequent surgical interventions, wear of the native bone, osteolysis, loosening and migration, and revision, including revision due to device wear, component dissociation, or device brittle fracture.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Evaluation of the mechanical function (mechanical fatigue strength including evaluation of fretting and corrosion, static mechanical strength, modular component disassembly strength, and wear analysis) and durability of the implant; and

(ii) Evaluation of worst-case device range of motion.

(3) All patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.

(5) Performance data must validate the reprocessing instructions for the reusable components of the device.

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

(7) Labeling must include the following:

(i) Validated methods and instructions for reprocessing of any reusable components; and

(ii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-11306 Filed 6-4-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket Number USCG-2026-0291]

RIN 1625-AA08

Special Local Regulation; Genesee River, Rochester, 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 navigable waters of the Genesee River. The SLR is needed to protect personnel and vessels from potential hazards created by the Rochester, NY Harborfest Water Ski Show on June 20, 2026. This regulation prohibits persons and vessels from being in the regulated area unless specifically authorized by the Captain of the Port, Sector Eastern Great Lakes or their designated representative.

DATES: This rule is effective from 11:45 a.m. until 5:30 p.m. on June 20, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG-2026-0291.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST1 Ori Martinez, Sector Eastern Great Lakes Waterways Management Division, U.S. Coast

Guard; telephone 716-818-7693, or email D09-SMB-SECBuffalo-WWM@uscg.mil.

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

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

II. Background and Authority

An organization notified the Coast Guard that they will be holding two water ski shows on the Genesee River near Rochester, NY, on June 20, 2026. Hazards from water ski shows include watercraft and water skiers performing high speed maneuvers and multiple waterway obstructions used to enhance and protect the show.

The Captain of the Port Sector Eastern Great Lakes (COTP) is issuing this Special Local Regulation (SLR) under the authority in 46 U.S.C. 70041. The COTP has determined that potential hazards associated with the show are a safety concern for anyone within the regulated area. The purpose of this rulemaking is to protect event participants, non-participants, and transiting vessels before, during, and after the scheduled event.

Because of these potential hazards, 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. We must establish this SLR by June 20, 2026, to protect personnel and vessels. Therefore, we do 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

This rule establishes a temporary SLR from 11:45 a.m. until 5:30 p.m. on June 20, 2026. The regulated area would cover all navigable waters encompassing the show event area and require vessels transiting around the special regulated area to operate at a no wake speed. No vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP or their designated representative.

IV. 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. 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

We have analyzed this rule under Executive Order 13132, Federalism, and have 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

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 *et seq.*), 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 is a special regulated area. It is categorically excluded from further review under paragraph L61.

List of Subjects in 33 CFR Part 100

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 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.T999–0291 to read as follows:

§ 100.T999–0291 Special Local Regulation; Genesee River, Rochester, NY.

(a) *Location.* This special local regulation applies to the following regulated area: All waters of Genesee River, from surface to bottom, encompassed by a line connecting the following points beginning at 43°15'24.98" N, 077°36'18.94" W, thence to 43°15'23.07" N, 077°36'15.72" W, thence to 43°15'17.30" N, 077°36'22.72" W, thence to 43°15'18.80" N, 077°36'26.08" W, and along the shoreline back to the beginning point. Vessels transiting around the special regulated area must operate at a no wake speed, in a manner that will not endanger participants or other crafts in the event. These coordinates are based on the North American Datum 83 (NAD 83).

(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 Captain of the Port Eastern Great Lakes (COTP) in the enforcement of the regulated area. *Participant* means all persons and vessels registered with the event sponsor as a participant in the race.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the COTP or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone at (888) 230–4703. 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) *Enforcement period.* This section will be enforced from 11:45 a.m. to 5:30 p.m. on June 20, 2026.

Matthew J. Walter,

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

[FR Doc. 2026–11311 Filed 6–4–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2026–0548]

RIN 1625–AA08

Special Local Regulation; Marine Events Within the USCG East District

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its special local regulations (SLR) for marine events within the USCG East District by adding SLRs for three recurring events located in the Virginia Captain of the Port Zone. This Final Rule will provide for the safety of life on the navigable waters of the York River, the East River, and the Elizabeth River Western Branch during high speed boat races which are typically held on each of those rivers annually.

DATES: This rule is effective June 8, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2026–0548.