List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.3988 to subpart D to read as follows:

§ 866.3988 Device to detect and identify microorganism nucleic acids and resistance markers from patients with suspected orthopedic infection.

(a) *Identification.* A device to detect and identify microorganism nucleic acids and resistance markers from patients with suspected orthopedic infection is a qualitative in vitro device intended to simultaneously detect and identify microorganism nucleic acids from human clinical specimens collected from patients with suspected orthopedic infection. The device detects specific nucleic acid sequences for microorganism identification as well as markers for antimicrobial resistance. This device is intended to aid in the diagnosis of orthopedic infections when used in conjunction with other clinical signs and symptoms and other laboratory findings. However, the device does not replace traditional methods for culture and susceptibility testing.

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

(1) Any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of specimen types claimed by this device; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) An intended use that includes a detailed description of targets the device detects and measures, the results provided to the user, the clinical indications appropriate for test use, and the specific population(s) for which the device is intended.

(ii) Limiting statements, when applicable, indicating:

(A) The device is intended to be used in conjunction with clinical history, signs and symptoms, and results of other diagnostic tests, including culture and antimicrobial susceptibility testing;

(B) Detection of resistance markers cannot be definitively linked to specific microorganisms and that the source of a detected resistance marker may be an organism not detected by the assay; and

(C) Antimicrobial resistance can occur via multiple mechanisms. A not detected result for the antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Culturing and susceptibility testing of isolates is needed to determine antimicrobial susceptibility.

(iii) A detailed device description, including reagents, instruments, ancillary materials, all control elements, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens.

(iv) Detailed descriptions of the performance characteristics of the device for all claimed specimen types as shown by the analytical and clinical studies required under paragraphs (b)(3)(iii) and (b)(3)(iv) of this section except specimen stability performance characteristics.

(3) Design verification and validation must include:

(i) A detailed device description, including all device parts, control elements incorporated into the test procedure, reagents required but not provided, the principle of device operation and test methodology, and the computational path from collected raw data to reported result (*e.g.,* how collected raw signals are converted into a reported result).

(ii) A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's functions.

(iii) Detailed documentation of analytical studies, including those demonstrating Limit of Detection, inclusivity, cross-reactivity, microbial interference, interfering substances, competitive inhibition, carryover/cross contamination, specimen stability, within lab precision, and reproducibility, as appropriate.

(iv) Detailed documentation and performance results from a clinical study that includes prospective (sequentially collected) samples for each claimed specimen type and, when determined to be appropriate by FDA, additional characterized clinical samples. The study must be performed on a study population consistent with the intended use population and compare the device performance to results obtained using a comparator method that FDA has determined to be appropriate. Detailed documentation must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of all statistical analyses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09335 Filed 5–11–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2026–0531]

Safety Zones; Fireworks Displays in the USCG East District; Philadelphia, PA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display on May 12, 2026, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District identifies the regulated area for this event in Philadelphia, PA. During the enforcement period, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 165.506, for Philadelphia, PA, will be enforced for the location identified in entry 10 of table 1 to paragraph (h)(1) from 8:15 p.m. through 8:30 p.m. on May 12, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, you may call or email Petty Officer Dominick Dobridge, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division, telephone: 206–815–6688, option 3, email: *SecDelBayWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone for the Delaware River, Philadelphia, PA, from 8:15 p.m. to 8:30 p.m. on May 12, 2026. This action is necessary to ensure safety of life on the navigable waters of the United States immediately prior to, during, and immediately after fireworks displays. Our regulation for safety zones

of fireworks displays within the USCG East District, table 1 to paragraph (h)(1) to 33 CFR 165.506, entry 10 specifies the location of the regulated area as all waters of the Delaware River adjacent to Penn's Landing, Philadelphia, PA, within a 500-feet radius of the fireworks barge position. On May 12, 2026, the approximate position will be 39°56′30.39″ N, 75°8′17.55″ W. During the enforcement period, as reflected in § 165.506(d), vessels may not enter, remain in, or transit through the safety zone unless authorized by the Captain of the Port or designated Coast Guard patrol personnel on-scene.

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, marine information broadcasts, and Broadcast Notice to Mariners.

Dated: May 8, 2026.

Kate F. Higgins-Bloom,

Captain, U.S. Coast Guard, Captain of the Port, Sector Delaware Bay.

[FR Doc. 2026–09391 Filed 5–11–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–0496]

RIN 1625–AA00

Safety Zone; Seddon Channel, Tampa, FL

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 Seddon Channel, Tampa Florida. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with airborne and waterborne activities occurring during the Special Operation Forces (SOF) Week Conference 2026. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector St. Petersburg, or their designated representative.

DATES: This rule is effective from May 18, 2026, through May 22, 2026.

ADDRESSES: To view available documents go to *https://www.regulations.gov* and search for USCG–2026–0496.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact Lieutenant Ryan McNaughton, Sector St. Petersburg, Ports & Waterways Branch Chief, U.S. Coast Guard; telephone (813) 918–7270, email *Ryan.A.McNaughton@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
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that SOF Week demonstrations will be occurring in Seddon Channel, in the vicinity of the Tampa Convention Center, Tampa, FL. Hazards from these demonstrations include high speed airborne and waterborne activities. The Captain of the Port (COTP) St. Petersburg has determined that potential hazards associated with these demonstrations are a safety concern for anyone within the event area. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

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 and contrary to the public interest. Additionally, the Coast Guard was notified of this event too late in the planning process to engage in the public comment process, but we must establish this safety zone by May 18, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

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** because delaying the effective date of this rule would risk the safety of the public and marine environment, so it would be contrary to the public interest.

III. Discussion of the Rule

This rule establishes a safety zone daily from 8 a.m. to 5 p.m. on May 18, 2026, through May 22, 2026. The safety zone will cover all navigable waters in the Seddon Channel within the following points: Point 1 at 27°56′14″ N, 082°27′25″ W, thence to Point 2 at 27°56′15″ N, 082°27′19″ W; thence to Point 3 at 27°56′22″ N, 082°27′16″ W, thence to Point 4 at 27°56′25″ N, 082°27′17″ W; thence to Point 5 at 27°56′30″ N, 082°27′29″ W, thence to Point 6 at 27°56′29″ N, 082°27′33″ W, thence to Point 7 at 27°56′25″ N, 082°27′35″ W, thence to Point 8 at 27°56′23″ N, 082°27′33″ W, thence returning to Point 1. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port.

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