

(1) The intended use of the device must specify:

(i) The Red Blood Cell components that can be processed and stored including acceptable anticoagulants and additive solutions;

(ii) The hold time after Red Blood Cell component collection;

(iii) The processing capacity (volume) of the device; and

(iv) The storage temperature and dating period of processed Red Blood Cell components.

(2) Studies must demonstrate that the device is biocompatible and include detailed documentation of the biocompatibility evaluation.

(3) Performance testing and nonclinical studies must include a detailed study of leached materials extracted under conditions similar to clinical usage of the device, and a toxicologic risk assessment of those extracted or leached materials.

(4) Performance testing must support sterility of the device and include sterilization validation, endotoxin testing, and container closure integrity evaluation.

(5) Nonclinical and clinical studies must include evaluation of red blood cell quality throughout the duration of storage based on in vitro and in vivo studies, including hemolysis and red blood cell survival and recovery.

(6) Performance studies must include:

(i) Detailed documentation of functional and mechanical testing, including evaluation of oxygen and, if applicable, carbon dioxide levels during Red Blood Cell components storage; and

(ii) Detailed documentation of device shelf-life testing demonstrating continued sterility, package integrity, and functionality over the identified shelf life.

(7) The labeling must include a contraindication against processing Red Blood Cell components collected from donors with hemoglobin S.

Dated: November 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-24717 Filed 11-8-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2023-0783]

Special Local Regulations; OPA World Championships; Gulf of Mexico; Englewood, FL

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the OPA World Championships to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District identifies the regulated area for this event in Englewood Beach, FL. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any designated representative.

DATES: The regulations in 33 CFR 100.703 will be enforced daily from 8 a.m. until 6 p.m. on November 18, 2023, through November 19, 2023, for the location identified in Item 8 in table 1 to § 100.703.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Marine Science Technician First Class Mara Brown, Sector St. Petersburg Prevention Department, Coast Guard; telephone 813-228-2191, email maraj.brown@uscg.mil.

SUPPLEMENTARY INFORMATION: *The Coast Guard will enforce the special local regulations in 33 CFR 100.703 for the OPA World Championships identified in Table 1 to § 100.703, Item No. 8, from 8 a.m. until 6 p.m., on November 18, 2023, through November 19, 2023. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for recurring marine events, Sector St. Petersburg, § 100.703, Table 1 to § 100.703, Item No. 8, specifies the locations of the regulated area for the OPA World Championships which encompasses portions of the Gulf of Mexico near Englewood, FL. During the enforcement periods, as reflected in § 100.703(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any designated representative.*

In addition to this notice 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, or both.

Dated: November 2, 2023.

Michael P. Kahle,

Captain, U.S. Coast Guard, Captain of the Port St. Petersburg.

[FR Doc. 2023-24787 Filed 11-8-23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2023-0883]

Safety Zone; Military Ocean Terminal Concord Safety Zone, Suisun Bay, Military Ocean Terminal Concord, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone in the navigable waters of Suisun Bay, off Concord, CA, in support of explosive on-loading to Military Ocean Terminal Concord (MOTCO) on November 13, 2023, through November 20, 2023. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential explosion within the explosive arc. The safety zone is open to all persons and vessels for transitory use, but vessel operators desiring to anchor or otherwise loiter within the safety zone must obtain the permission of the Captain of the Port San Francisco or a designated representative. All persons and vessels operating within the safety zone must comply with all directions given to them by the Captain of the Port San Francisco or a designated representative.

DATES: The regulations in 33 CFR 165.1198 will be enforced from 12:01 a.m. on November 13, 2023, until 11:59 p.m. on November 20, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call, or email LT Abby Hamann, U.S. Coast Guard Sector San Francisco, Waterways Management Division, at 415-399-3585, SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.1198 for the Military Ocean Terminal Concord, CA (MOTCO) regulated area from 12:01 a.m. on November 13, 2023, until 11:59 p.m. on

November 20, 2023, or as announced via marine local broadcasts. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential explosion within the explosive arc. The regulation for this safety zone, § 165.1198, specifies the location of the safety zone which encompasses the navigable waters in the area between 500 yards of MOTCO Pier in position 38°03'30" N, 122°01'14" W and 3,000 yards of the pier. During the enforcement periods, as reflected in § 165.1198(d), if you are the operator of a vessel in the regulated area you must comply with the instructions of the COTP or the designated on-scene patrol personnel. Vessel operators desiring to anchor or otherwise loiter within the safety zone must contact Sector San Francisco Vessel Traffic Service at 415-556-2760 or VHF Channel 14 to obtain permission.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via marine information broadcasts.

Dated: November 4, 2023.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2023-24845 Filed 11-8-23; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2023-0861]

RIN 1625-AA87

Security Zones; San Francisco Bay, San Francisco, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary security zones in the navigable waters of the San Francisco Bay, and the Pacific Ocean within the San Francisco Captain of the Port (COTP) zone. The security zones are along San Francisco Pier 15/17, approximately 1,000 yards from shore, and the Legion of Honor, approximately 450 yards from shore. The security zones are necessary to protect the harbors, ports, and waterfront facilities during a visit from high-ranking government officials and members of the official party. Entry of vessels or persons into these zones is prohibited

unless specifically authorized by the Captain of the Port San Francisco or a designated representative.

DATES: This rule is effective from November 15, 2023, through November 18, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2023-0861 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 LT William Harris, U.S. Coast Guard Sector San Francisco, Waterways Management Division; telephone 415-399-7443, email SFWaterways@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 without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This 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." Under 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. The Coast Guard was not notified with ample time to allow for public comment. The visit by high-ranking government officials and members of their official party will conclude prior to the publication and completion of a comment period. Additionally, it is impracticable to publish a NPRM because the visit is scheduled to occur from November 15 through November 16, 2023, and we must establish these security zones by those dates. We lack sufficient time to solicit comments and review prior to issuing a final action.

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 would be impracticable because action is needed starting November 15, 2023, to provide for the protection of high-ranking government officials, members of their official party, and the security of harbors, ports, and waterfront facilities, and the mitigation of subversive acts.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70051 and 70124. The Captain of the Port San Francisco (COTP) has determined that high-ranking government officials and members of their official party plan to visit the San Francisco area and will be in the areas of San Francisco Pier 15/17, and the Legion of Honor. These are located adjacent to U.S. navigable waters in the San Francisco COTP Zone. This rule is needed to ensure the safety of the high-ranking government officials and members of their official party.

IV. Discussion of the Rule

This rule establishes two security zones on November 15 and November 16, 2023. These security zones will cover all navigable waters of the San Francisco Bay and Pacific Ocean, from surface to bottom, and be for the areas and times described below or as otherwise noted by Marine Information Broadcast, and will be referred to as Zones A, and B.

Zone A is a security zone along San Francisco Pier 15/17, approximately 1,000 yards from shore. Zone A will be within the area formed by connecting the following latitude and longitude points in the following order: 37°48'29.13" N, 122°24'10.27" W; thence to 37°48'34.68" N, 122°24'3.44" W; thence to 37°48'39.4" N, 122°23'47.2" W; thence to 37°48'28.4" N, 122°23'19.04" W; thence to 37°48'9.85" N, 122°23'10.34" W; thence to 37°47'47.89" N, 122°23'41.35" W; thence along the shore and piers to the point of beginning. This zone will be in effect from 6 a.m. through 11:59 p.m. on November 15, 2023.

Zone B is a security zone along the Legion of Honor in the San Francisco Bay, approximately 450 yards from shore. Zone B will be within the area formed by connecting the following latitude and longitude points in the following order: 37°47'17.72" N, 122°30'21.74" W; thence to 37°47'30.86" N, 122°30'13.6" W; thence to 37°47'30.87" N, 122°29'54.91" W; thence to 37°47'14.68" N, 122°29'45.43" W; thence along the shore to the point of beginning. This zone will be in effect