

(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.

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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 mara.j.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