

(ii) A statement in the labeling that the safety and effectiveness of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;

(iii) Identification of compatible devices;

(iv) The list of surgical procedures for which the device has been determined to be safe with clinical justification;

(v) Reprocessing instructions for reusable components;

(vi) A shelf life for any sterile components;

(vii) A description of the device-specific use training program;

(viii) A statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and

(ix) A detailed summary of the post-market surveillance data collected under paragraph (b)(3) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (b)(3) of this section.

(6) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

(7) Human factors validation testing must be performed and must demonstrate that the user interfaces of the system support safe use in an operating room environment.

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

(i) Device motion accuracy and precision;

(ii) System testing;

(iii) Instrument reliability;

(iv) Thermal effects on tissue;

(v) Human-device interface;

(vi) Mounting hardware testing;

(vii) Workspace access testing; and

(viii) Performance testing with

compatible devices.

(9) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(10) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(11) Performance data must demonstrate the sterility of all patient-contacting device components.

(12) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

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

(14) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(15) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2022-0227]

Special Local Regulation; Crystal Pier Outrigger Race, San Diego, CA

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Crystal Pier Outrigger Race special local regulations on the waters of Mission Bay, California, on May 7, 2022. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 7 a.m. through 5 p.m. on May 7, 2022, for the locations described in Item No. 14 in Table 1 to § 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA;

telephone 619-278-7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the Crystal Pier Outrigger Race in Mission Bay, CA in 33 CFR 100.1101, for the locations described in Item No. 14 in Table 1 to that section from 7 a.m. until 5 p.m. on May 7, 2022. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities and area for this event. Under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: May 2, 2022.

T.J. Barelli,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0190]

RIN 1625-AA00

Safety Zone; Sabine River, Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Sabine