

(ii) Resistance to dynamic loads (impact testing);

(iii) Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;

(iv) Demonstration of adequate stability of the device on inclined planes (forward, backward, and lateral);

(v) Demonstration of the ability of the device to safely ascend and descend obstacles (i.e., stairs, curb); and

(vi) Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.

(3) The skin-contacting components of the device must be demonstrated to be biocompatible.

(4) Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.

(5) Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(6) Performance testing must demonstrate battery safety and evaluate longevity.

(7) Performance testing must evaluate the flammability of device components.

(8) Patient labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device and the principles of how the device works;

(ii) A clear description of the appropriate use environments/conditions, including prohibited environments;

(iii) Preventive maintenance recommendations;

(iv) Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and

(v) A detailed summary of the device-related adverse events and how to report any complications.

(9) Clinician labeling must include all the information in the Patient labeling noted in paragraph (b)(8) of this section but must also include the following:

(i) Identification of patients who can effectively operate the device; and

(ii) Instructions on how to fit, modify, or calibrate the device.

(10) Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

Dated: April 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2014-0189]

Special Local Regulations; Recurring Marine Events in the Seventh Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Conch Republic Navy Parade and Battle Special Local Regulation in the Gulf of Mexico, from 7:00 p.m. until 8:00 p.m. on April 25, 2014. This action is necessary to ensure the safety of event participants, participant vessels, spectators, and the general public from the hazards associated with this event. During the enforcement period, no person or vessel may enter the regulated area without permission from the Captain of the Port.

DATES: The regulations in 33 CFR 100.701 Table 1 will be enforced from 7:00 p.m. until 8:00 p.m. on April 25, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Marine Science Technician First Class Ian G. Bowes, Sector Key West Prevention Department, U.S. Coast Guard; telephone 305-292-8823, email Ian.G.Bowes@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Conch Republic Navy Parade and Battle Special Local Regulation in the Gulf of Mexico in 33 CFR 100.701 on April 25, 2014. These regulations can be found in the 2013 issue of the **Federal Register** 33 CFR 100.701.

On April 25, 2014, Conch Republic Navy LLC. is hosting the Conch Republic Navy Parade and Battle, a boat parade and simulated naval battle event that will take place approximately 150 yards offshore from Ocean Key Sunset Pier, Mallory Square and the Hilton Pier within the Key West Harbor. The event will be held on the waters of the Gulf of Mexico in Key West. Approximately 10 vessels will participate in the event.

The special local regulations encompass certain waters of the Gulf of

Mexico located offshore from the island of Key West. The special local regulations will be enforced from 7:00 p.m. until 8:00 p.m. on April 25, 2014. The special local regulations area will consist of the following area: An event area, where all persons and vessels, except those persons and vessels participating in the swim event, are prohibited from entering, transiting, anchoring, or remaining. The race area is defined as all waters of the Gulf of Mexico encompassed within the following points: Starting at Point 1 in position 24°33'41" N, 81°48'25" W; thence to Point 2 in position 24°33'43" N, 81°48'34" W; thence to Point 3 in position 24°33'32" N, 81°48'38" W; thence to Point 4 in position 24°33'30" N, 81°48'30" W. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the race area by contacting the Captain of the Port Key West by telephone at 305-292-8727, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the race area is granted by the Captain of the Port Key West, or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Key West or the designated representative. The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.701 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via a Broadcast Notice to Mariners.

Dated: March 31, 2014.

A.S. Young, Sr.,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2014-08368 Filed 4-11-14; 8:45 am]

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