

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 892 continues to read as follows:

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

■ 2. Add § 892.6510 to subpart G to read as follows:

§ 892.6510 Cream for x-ray attenuation.

(a) *Identification.* A cream for x-ray attenuation is a sterile cream intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. Cream for x-ray attenuation is intended to be used during medical procedures in which hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 kVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures. Cream for x-ray attenuation is not intended to be used in or adjacent to the primary x-ray beam or the transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in radiography for those studies requiring the physician's hand or forearm be in the direct path of the primary x-ray beam.

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

(1) Design verification and validation must include documentation of results from safety and effectiveness testing. The results from safety and effectiveness testing must include:

(i) Biocompatibility data consistent with the intended use for the device;

(ii) Sterilization, packaging, and expiration date testing; and

(iii) Nonclinical and/or clinical performance testing representative of "as use" conditions demonstrating:

(A) Compatibility to the type(s) of surgical glove (e.g., latex, nitrile, vinyl) to be used with the device;

(B) Attenuation performance; and

(C) Proper application of the device.

(2) Labeling must include:

(i) A statement that the device is sterile and an expiration date.

(ii) A boxed warning statement prominently placed in all labeling material for these devices. That boxed warning statement must read: "The device is not intended to be used in or adjacent to the primary X-ray beam or transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in

radiography for those studies requiring the physician's hand or forearm be in the direct path of the primary X-ray beam."

(iii) The methods and results from nonclinical and/or clinical performance testing representative of "as use" conditions demonstrating the amount of attenuation the device provides to the end user at 60, 80, 100, and 120 kVp.

(iv) Validated instructions for use for device application and a statement of how often the device must be removed and reapplied for effective shielding.

(v) Identification of the type(s) of surgical glove (e.g., latex, nitrile, vinyl) that is compatible for use with the device.

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket No. USCG-2025-0428]

RIN 1625-AA08

Special Local Regulation; Marine Events; Annual Bayview Mackinac Race, Lake Huron, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the annual Bayview Yacht Club Port Huron to Mackinac Race. This action is necessary to safely control vessel movements in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. During this enforcement period, no person or vessel may enter the regulated area without the permission of the Coast Guard Patrol Commander (PATCOM).

DATES: The regulation in 33 CFR 100.902 will be enforced from 10 a.m. through 3 p.m. on July 12, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Tracy Girard, Waterway Management Division, U.S. Coast Guard Sector Detroit, 110 Mt. Elliott Street, Detroit, MI at (313) 568-9564 or Tracy.M.Girard@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local

regulation in 33 CFR 100.902 for the Annual Bayview Mackinac Race from 10 a.m. through 3 p.m. on July 12, 2025. This action is being taken to provide for the safe control vessel movements in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. Our regulation for marine events within the Captain of the Port Detroit zone in § 100.902(a) specifies the location of the regulated area for the Annual Bayview Mackinac Race. During the enforcement period, no vessel may enter the regulated area without prior approval from the Coast Guard's designated Patrol Commander (PATCOM). The PATCOM may restrict vessel operation within the regulated area to vessels having particular operating characteristics. Vessels desiring to transit the regulated area may do so only with prior approval of the PATCOM and when so directed by that officer. The PATCOM may be contacted on Channel 16 (156.8 MHz) by the call sign "Coast Guard Patrol Commander." Vessels permitted to transit the regulated area will operate at no wake speed and in a manner which will not endanger participants in the event or any other craft.

If the District Commander, Captain of the Port, or PATCOM determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: June 11, 2025.

Richard P. Armstrong,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG-2025-0270]

RIN 1625-AA00

Safety Zone; Milwaukee Air and Water Show, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending a published safety zone for certain waters of Lake Michigan encompassing the Milwaukee Air and Water Show to include an additional day. This action is necessary to provide for the safety of life on these navigable waters in the vicinity