

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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BILLING CODE 4164-01-P

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.

[FR Doc. 2025-11802 Filed 6-25-25; 8:45 am]

BILLING CODE 9110-04-P

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

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

of McKinley Park and Bradford Beach, during this recurring event on the third weekend in July. This rulemaking prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Lake Michigan or a designated representative.

DATES: This rule is effective July 28, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2025-0270 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 LCDR Jessica Anderson, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414-747-7182, email jessica.P.Anderson@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 Milwaukee Air and Water Show is a long-standing event that has occurred for 14 years. During that time, there have been numerous requests to establish a safety zone for four days in duration, rather than the three days currently enforced. The Captain of the Port (COTP) Sector Lake Michigan determined that, due to the repetitive requests, it was pertinent to revise the current safety zone in 33 CFR 165.929, table 4 to § 165.929, line No. 29 for the Milwaukee Air and Water Show to add a fourth day for the event.

In response, on April, 8, 2025, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Milwaukee Air and Water Show, Milwaukee, WI.¹ There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended May 8, 2025, we received 4 comments, all in support of the additional day for enhanced safety.

¹ 90 FR 15127.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034. The COTP Sector Lake Michigan determined that potential hazards were associated with the previously established safety zone in 33 CFR 165.929, table 4 to § 165.929, line No. 29 for the Milwaukee Air and Water Show that could be addressed through an additional day. The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within an area approximately 5,000-yards by 1,500-yards before, during, and after the scheduled event, which required expanding the enforcement period to include four days.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received 4 comments on our NPRM published April 8, 2025. All comments were in support of the proposed amendment. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule amended an established safety zone in 33 CFR 165.929, table 4 to § 165.929, line No. 29 for the Milwaukee Air and Water Show by adding a fourth day to the event. The Milwaukee Air and Water Show event is a recurring event held on the third weekend in July from 8:00 a.m. to 5 p.m. The safety zone covers all navigable waters of Lake Michigan in the vicinity of McKinley Park and Bradford Beach located within an area that is approximately 5,000 yards by 1,500 yards. The expanded duration of the zone ensures the safety of vessels and these navigable waters before, during, and after the scheduled Milwaukee Air and Water Show. No vessel or person is be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs

and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 14192 (Unleashing Prosperity Through Deregulation) directs agencies to significantly reduce the private expenditures required to comply with Federal regulations and provides that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations."

The Office of Management and Budget (OMB) has not designated this rule a "significant regulatory action," under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it.

This rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866. See OMB Memorandum M-25-20, "Guidance Implementing Section 3 of Executive Order 14192, titled 'Unleashing Prosperity Through Deregulation'" (Mar. 26, 2025).

This regulatory action determination is based on the size, location, duration and time of day of the regulated area. This regulatory action determination is based on the previous rulemaking and the additional day not substantially altering the previous regulation. Additionally, prior events have included temporary final rules to encompass the four-day timeframe.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This regulatory action determination is based on the size, location, and duration of the safety zone. The regulation will be in effect only during the event listed in this regulation for which the COTP has determined pose risks to the safety of life and property for the maritime public and event participants. The size, location, and duration of the regulation will be limited to the extent necessary to minimize these risks. Moreover, the COTP will make advance notice of the

enforcement of the regulation through the Local Notice to Mariners and/or Broadcast Notice to Mariners. This regulation also provides a means for anyone needing to transit through or within the safety zone to seek permission from the COTP.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have

analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have

determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves expanding a long-standing safety zone from three days to four days. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

- 2. In § 165.929, amend table 4, by revising item 29 to read as follows:

§ 165.929 Safety Zones; annual events requiring safety zones in the Captain of the Port Lake Michigan Zone.

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TABLE 4 TO § 165.929—SAFETY ZONES IN THE STATE OF WISCONSIN

Event	Location ¹	Enforcement date ²
*	*	*
(29) Milwaukee Air And Water Showe.	Milwaukee, WI. All waters of Lake Michigan in the vicinity of McKinley Park and Bradford Beach located within an area that is approximately 5,000 yards by 1,500 yards. The area will be bounded by the points beginning at 43°02.455' N, 087°52.880' W; then southeast to 43°02.230' N, 087°52.061' W; then northeast to 43°04.451' N, 087°50.503' W; then northwest to 43°04.738' N, 087°51.445' W; then southwest to 43°02.848' N, 087°52.772' W; then returning to the point of origin.	4 days—Third weekend in July; 8 a.m. to 5 p.m.

¹ All coordinates listed in Table 4 of this section reference Datum NAD 1983.

² As noted in paragraph (a)(3) of this section, the enforcement dates and times for each of the listed safety zones are subject to change.

Dated: June 10, 2025.

Joseph B. Parker,

Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

[FR Doc. 2025-11839 Filed 6-25-25; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED-2024-OSERS-0131]

Innovative Rehabilitation Training Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final priority and requirements.

SUMMARY: The U.S. Department of Education (Department) announces the final priority and requirements under the Innovative Rehabilitation Training program, Assistance Listing Number 84.263G. The Department may use the priority and requirements for competitions in fiscal year (FY) 2025 and later years. We take this action to promote the development of innovative and improved methods of training on promising vocational rehabilitation (VR) counseling, engagement, and service delivery strategies and practices to State VR agency personnel or other public or non-profit rehabilitation professionals and paraprofessionals (including those enrolled in master's or bachelor's level rehabilitation programs) to provide quality VR and supported employment services that lead to quality employment outcomes for individuals with disabilities.

DATES: The priority and requirements are effective July 28, 2025.

FOR FURTHER INFORMATION CONTACT: Felipe Lulli, U.S. Department of Education, 400 Maryland Avenue SW, Room 4A10, Washington, DC 20202. Telephone: (202) 987-0128. Email: 84.263G@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7-1-1.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The Innovative Rehabilitation Training program is designed to develop: (a) new types of training programs for rehabilitation personnel and to demonstrate the effectiveness of these new types of training programs for rehabilitation personnel in providing rehabilitation services to individuals with disabilities; (b) new and improved methods of training rehabilitation personnel so that

there may be a more effective delivery of rehabilitation services to individuals with disabilities by designated State rehabilitation agencies and designated State rehabilitation units or other public or non-profit rehabilitation service agencies or organizations; and (c) new innovative training programs for VR professionals and paraprofessionals to have a 21st-century understanding of the evolving labor force and the needs of individuals with disabilities so they can more effectively provide VR services to individuals with disabilities.

Assistance Listing Number: 84.263G

Program Authority: 29 U.S.C. 709(c) and 772.

Applicable Program Regulations: 34 CFR parts 385 and 387.

We published a notice of proposed priority and requirements (NPP) for this program in the **Federal Register** on December 18, 2024 (89 FR 102841). That notice contained background information and the Department's reasons for proposing the priority and requirements.

Public Comment: In response to our invitation in the NPP, 18 parties submitted comments on the proposed priority and requirements.

Generally, we do not address technical and other minor changes or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raised concerns not directly related to the proposed priority or requirements.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priority and requirements since publication of the NPP follows.

Comment: Several commenters suggested that Topic Area 2 (Career Assessment Addressing Emerging Career and Employment Trends) should focus on improving the quality and availability of career assessment and vocational evaluation services through the development of formal, graduate-level training programs. A few commenters specifically noted that the discontinuation of formal, graduate-level training programs in recent years appears to have contributed to a shortage of qualified evaluators and VR professionals trained in using career assessment data. A few commenters also specified that, given these shortages, there are long waitlists for critical career assessment and vocational evaluation services. A few commenters specifically noted considerations for the ways that artificial intelligence (AI) can be part of career assessment.

Discussion: The Department acknowledges the value of career assessment and VR professionals with career assessment expertise. It is also clear that career assessment and VR professionals should be exposed to additional learning options (coursework, practicums, internships, etc.). As a general matter, the Department notes that Topic Area 2 already affords potential applicants flexibility in their proposed approaches, which may include AI.

Changes: Topic Area 2 has been revised to clarify that proposed projects under this topic area must focus on strengthening the capacity of career assessment and vocational evaluation professionals to serve VR participants under this priority. The topic area has also been revised to clarify that an applicant may propose various approaches to strengthen the capacity of career assessment and vocational evaluation professionals. Application Requirement C has also been revised to remove the specific reference to VR counselors in the training plan given that other VR professionals may also be part of such plan.

Comment: One commenter provided support for the importance of Topic Area 2 but noted that the other topic areas in the NPP were overly prescriptive, noting a general burden on data collection and entry requirements and caseload sizes.

Discussion: The Department contends that the commenter's concerns about prescriptiveness do not seem to pertain to other topic areas under this proposed priority and are rather general issues in the field of vocational rehabilitation. However, as a general matter, the Department notes that the priority already affords potential applicants flexibility in their proposed approaches, activities, and objectives in response to the topic area(s) within the priority.

Changes: None.

Comment: One commenter recommended adding language to Topic Area 2 requiring career development professionals working under this priority to hold one or more specified professional certifications and to maintain records showing that they have received 30 hours of continuing education every three years.

Discussion: We do not believe that the recommendation to require or verify specific standards or credentials is within the scope of purpose of the Innovative Rehabilitation Training Program, as defined in the program regulations at 34 CFR part 387. Moreover, we believe that this level of specificity is not necessary and that individual projects are best positioned