FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order. FDA supports the principles of the ''3Rs,'' to replace, reduce, and/or refine animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for phase-changing fiducial markers for radiation therapy. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

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

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

■ 2. Add § 892.5727 to subpart F to read as follows:

§ 892.5727 Phase-changing fiducial marker for radiation therapy.

(a) *Identification.* A phase-changing fiducial marker for radiation therapy is a single-use, sterile liquid material that changes phase in situ when injected in tissue for the purposes of aiding radiation therapy treatment. The device is intended to be visualized using one or more radiologic imaging modalities.

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

(1) Clinical performance data under anticipated conditions of use must evaluate:

(i) Risk of marker migration in tissue during the course of radiation therapy through post-treatment follow-up;

(ii) The ability to visualize the marker to allow for adequate localization during the course of radiation therapy through post-treatment follow-up;

(iii) Risk of device interference with tumor response assessment post-treatment; and

(iv) All adverse events.

(2) Animal performance data under anticipated conditions of use must evaluate device toxicity and the risk of marker migration.

(3) Non-clinical performance data under anticipated conditions of use must evaluate:

(i) Maintenance of physical form throughout the course of therapy and post-treatment follow-up;

(ii) Device visibility on one or more radiologic imaging modalities; and

(iii) Device interference with radiation dose delivery.

(4) Performance testing must demonstrate the patient-contacting components of the device are biocompatible.

(5) Performance testing must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(6) Performance testing must demonstrate device sterility and non-pyrogenicity.

(7) Usability testing must demonstrate that the device can be positioned as indicated based solely on reading the directions for use.

(8) The labeling must include:

(i) A detailed description of the device including materials and composition, chemical and physical properties, a description of the mechanism of the change of phase, and timeframe for achieving final state;

(ii) Summary of all reported device-related adverse events from clinical testing;

(iii) Information describing the injection procedure, including any use of image guidance, and the range of compatible injection needle gauges; and

(iv) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15303 Filed 7–28–26; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

Correction

In rule document 2026–13124, appearing on pages 39463–39465 in the issue of Tuesday, June 30, 2026, make the following corrections:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

§ 4044.54 [Corrected].

■ 1. On page 39464, the table, the heading titled ''TABLE 1 TO PARAGRAPH—SPREADS'' should read ''TABLE 1 TO PARAGRAPH(e)—SPREADS''

■ 2. On page 39465, in the table, the heading titled ''TABLE 1 TO PARAGRAPH—SPREADS—Continued'' should read ''TABLE 1 TO

PARAGRAPH(e)—SPREADS—Continued''

[FR Doc. C1–2026–13124 Filed 7–28–26; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–0861]

RIN 1625–AA00

Safety Zone; Lake Ontario, Olcott, NY

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on Lake Ontario, Olcott, NY. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with an over water fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Eastern Great Lakes, or their designated representative.

DATES: This rule is effective on August 8, 2026, from 8:45 p.m. through 10:15 p.m. local time.

ADDRESSES: To view available documents go to *https://www.regulations.gov* and search for USCG–2026–0861.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST1 Alexander Leatherman, Sector Eastern Great Lakes Waterways Management Division, U.S. Coast Guard; telephone 716–931–4680, or email *D09-SMB-SECBuffalo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from a point on land over Lake Ontario, in Olcott, NY. The Captain of the Port (COTP) Eastern Great Lakes has determined that potential hazards associated with fireworks are a safety concern for anyone within a 280-foot radius of the fireworks launch site. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of this event on June 22, 2026, but we must establish this safety zone by August 8, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone from 8:45 p.m. to 10:15 p.m. on August 8, 2026. The safety zone will cover all navigable waters in Lake Ontario within a 280-foot radius of the launch position at 43° 20′26.2″ N, 78° 43′06.8″ W. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port.

IV. 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. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

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

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of $100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. 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 *et seq.*), 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 is a safety zone. 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