

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

(1) Clinical performance data must demonstrate the device performs as intended under anticipated conditions of use and evaluate the following:

(i) Radiation dose to adjacent organs at risk;

(ii) Device stability;

(iii) Ability to deploy, expand, and remove the device; and

(iv) Patient comfort.

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

(i) Testing to evaluate the effect of therapeutic radiation levels on device integrity;

(ii) Bioburden testing to demonstrate the device does not pose an infection risk, if the device is not provided sterile; and

(iii) Structural integrity testing of the container, including tensile strength, container leakage, and burst strength.

(3) Performance testing must demonstrate space creation and maintenance for the duration of a radiation treatment fraction.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the sterility of patient-contacting components of the device that are provided sterile.

(6) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the labeled shelf life.

(7) Labeling must include:

(i) Warnings that:

(A) A three-dimensional imaging method is needed to ensure the device is placed correctly; and

(B) Failure to perform the standard imaging position verification protocol may cause the device to not perform as intended.

(ii) Instructions on how to proceed if the device fails to perform as intended;

(iii) A summary of clinical data relevant to the device, including device-related complications; and

(iv) An expiration date or shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-18427 Filed 9-9-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions and Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; stay of effectiveness.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is indefinitely suspending three general licenses and one licensing policy issued pursuant to the Iranian Transactions and Sanctions Regulations to align with changes in the foreign policy of the United States towards Iran.

DATES: Effective September 8, 2026, 31 CFR 560.522, 560.528, and 560.529 are stayed indefinitely.

As of September 8, 2026, the effectiveness of Iran General License J-1, which is available on OFAC's website (<https://ofac.treasury.gov>), is stayed indefinitely.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Regulatory Affairs, 202-622-4855; or <https://ofac.treasury.gov/contact-ofac>.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: <https://ofac.treasury.gov>.

Background

On October 22, 2012, OFAC issued a final rule that amended the former Iranian Transactions Regulations, 31 CFR part 560 (ITR), and reissued them in their entirety as the Iranian Transactions and Sanctions Regulations (ITSR or "the Regulations") (77 FR 64664, October 22, 2012). Since then, OFAC has amended the Regulations on several occasions.

On December 15, 2016, OFAC published on its website General License J-1, which was issued pursuant to the Regulations. This general license is available on OFAC's website (www.treasury.gov/ofac).

Rules To Be Stayed

In response to Iran's continued disruptions to global energy markets, attacks on partners and allies in the Middle East, reconstitution of its conventional and nuclear weapons programs, efforts to monetize the Strait of Hormuz, and continued support to terrorist proxies, OFAC is indefinitely

suspending the general licenses and licensing policy contained at 31 CFR 560.522, 560.528, and 560.529. These general licenses and licensing policy authorize, respectively, certain payments for overflights of Iranian airspace; the issuance of specific licenses for certain transactions related to aircraft safety; and bunkering and emergency repairs. As a result of this suspension, any such transactions are no longer authorized by OFAC as of September 8, 2026.

In addition, OFAC is suspending indefinitely Iran General License J-1, published on OFAC's website on December 15, 2016. Iran General License J-1 authorizes the reexportation of certain civil aircraft to Iran on temporary sojourn, as well as related transactions. As a result of this suspension, any such transactions are no longer authorized by OFAC as of September 8, 2026.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of E.O. 14192 of January 31, 2025, "Unleashing Prosperity Through Deregulation" (90 FR 9065, February 6, 2025) and E.O. 14219 of February 19, 2025, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative" (90 FR 10583, February 25, 2025), are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601-612) does not apply.

Executive Order 14294

Section 5 of E.O. 14294 of May 9, 2025, "Fighting Overcriminalization in Federal Regulations" (90 FR 20367, May 14, 2025), directs that all future notices of proposed rulemaking (NPRMs) and final rules published in the **Federal Register**, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense and the authorizing statute. E.O. 14294 directs agencies to draft this statement in consultation with the Department of Justice.

E.O. 14294 further directs that the regulatory text of all NPRMs and final rules with criminal consequences

published in the **Federal Register** after May 9, 2025 should explicitly state a mens rea requirement for each element of a criminal regulatory offense, accompanied by citations to the relevant provisions of the authorizing statute.

Willful violations of the regulations set forth in this final rule may be subject to criminal penalties pursuant to 50 U.S.C. 1705 and regulations promulgated thereunder. The statutory authority for criminal liability requires a mens rea of willfulness as an element pursuant to 50 U.S.C. 1705(c). In drafting this statement, OFAC has consulted with the Department of Justice.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not impose information collection requirements that would require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects in 31 CFR Part 560

Administrative practice and procedure, Banks, Banking, Blocking of assets, Credit, Foreign trade, Iran, Sanctions, Services.

For the reasons set forth in the preamble, OFAC amends 31 CFR part 560 as follows:

PART 560—IRANIAN TRANSACTIONS AND SANCTIONS REGULATIONS

■ 1. The authority citation for part 560 continues to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa–9, 7201–7211, 8501–8551, 8701–8795; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217; E.O. 13599, 77 FR 6659, 3 CFR, 2012 Comp., p. 215; E.O. 13846, 83 FR 38939, 3 CFR, 2018 Comp., p. 854.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§§ 560.522, 560.528, and 560.529 [Stayed]

■ 2. Sections 560.522, 560.528, and 560.529 are stayed indefinitely.

Bradley T. Smith,

*Director, Office of Foreign Assets Control,
Department of the Treasury.*

[FR Doc. 2026–18461 Filed 9–8–26; 4:15 pm]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2026–0998]

Special Local Regulation; Southern California Annual Marine Events for the San Diego Captain of the Port Zone, San Diego TriRock Triathlon

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the San Diego TriRock Triathlon special local regulation on the waters of San Diego Bay, California on September 12, 2026. This special local regulation is 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 regulation in 33 CFR 100.1101, Table 1 to § 100.1101, Item No. 8, will be enforced from 6:30 a.m. until 9 a.m. on September 12, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Skye Eastman, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email D11MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.1101, Table 1 to § 100.1101, Item No. 8, for the San Diego TriRock Triathlon race regulated area daily from 6:30 a.m. until 9 a.m. on September 12, 2026. This action is being taken to provide for the safety of life on navigable waterways during this event. The Southern California Annual Marine Events for the San Diego Captain of the Port Zone, § 100.1101, Table 1 to § 100.1101, Item No. 8, specifies the location of the regulated area for the San Diego TriRock Triathlon which encompasses the waters of San Diego Bay to include Spanish Landing. Under the provisions of § 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 notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and Marine Safety Information Broadcasting.

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 Safety Marine Information Broadcast or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

R.C. Tucker,

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

[FR Doc. 2026–18492 Filed 9–9–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2026–1156]

Special Local Regulations; Marine Events Within the USCG East District—Ocean City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Ocean City Airshow on September 20, 2026, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District identifies the regulated area for this event in Ocean City, NJ. During the enforcement period, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.501 will be enforced for the special local regulations listed in Table 1 to Paragraph (i)(1) of § 100.501 for the Ocean City Airshow from 11:30 a.m. through 3:30 p.m. on September 20, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Petty Officer Dominick J. Dobridge, Waterways Management