§ 870.1405 Interventional cardiovascular implant simulation software device.

(a) Identification. An interventional cardiovascular implant simulation software device is a prescription device that provides a computer simulation of an interventional cardiovascular implant device inside a patient’s cardiovascular anatomy. It performs computational modeling to predict the interaction of the interventional cardiovascular implant device with the patient-specific anatomical environment.

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

(1) Software verification, validation, and hazard analysis, with identification of appropriate mitigations, must be performed, including a full verification and validation of the software according to the predefined software specifications.

(2) Computational modeling verification and validation activities must be performed to establish the predictive capability of the device for its indications for use.

(3) Performance validation testing must be provided to demonstrate the accuracy and clinical relevance of the modeling methods for the intended implantation simulations, including the following:

(i) Computational modeling results must be compared to clinical data supporting the indications for use to demonstrate accuracy and clinical meaningfulness of the simulations;

(ii) Agreement between computational modeling results and clinical data must be assessed and demonstrated across the full intended operating range (e.g., full range of patient population, implant device sizes and patient anatomic morphologies). Any selection criteria or limitations of the samples must be described and justified;

(iii) Endpoints (e.g., performance goals) and sample sizes established must be justified as to how they were determined and why they are clinically meaningful; and

(iv) Validation must be performed and controls implemented to characterize and ensure consistency (i.e., repeatability and reproducibility) of modeling outputs:

(A) Testing must be performed using multiple qualified operators and using the procedure that will be implemented under anticipated conditions of use; and

(B) The factors (e.g., medical imaging dataset, operator) must be identified regarding which were held constant and which were varied during the evaluation, and a description must be provided for the computations and statistical analyses used to evaluate the data.

(4) Human factors evaluation must be performed to evaluate the ability of the user interface and labeling to allow for intended users to correctly use the device and interpret the provided information.

(5) Device labeling must be provided that describes the following:

(i) Warnings that identify anatomy and image acquisition factors that may impact simulation results and provide cautionary guidance for interpretation of the provided simulation results;

(ii) Device simulation inputs and outputs, and key assumptions made in the simulation and determination of simulated outputs; and

(iii) The computational modeling performance of the device for presented simulation outputs, and the supporting evidence for this performance.

Dated: December 21, 2022.
Lauren K. Roth,
Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY
Office of Foreign Assets Control
31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 8D and 40C

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GLs 8D and 40C, which were previously made available on OFAC’s website.

DATES: GL 8D was issued on November 10, 2022. See SUPPLEMENTARY INFORMATION for additional relevant dates.


SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC’s website: www.treas.gov/ofac.

Background

On November 10, 2022, OFAC issued GL 8D to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR). On November 14, 2022, OFAC issued GL 40C to authorize certain transactions otherwise prohibited by the RuHSR. At the time of issuance, OFAC made GLs 8D and 40C available on its website (www.treas.gov/ofac). The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations: 31 CFR Part 587

GENERAL LICENSE NO. 8D

Authorizing Transactions Related to Energy

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 involving one or more of the following entities that are related to energy are authorized, through 12:01 a.m. eastern daylight time, May 15, 2023:

(1) State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank;

(2) Public Joint Stock Company Bank Financial Corporation Otkritie;

(3) Sovcombank Open Joint Stock Company;

(4) Public Joint Stock Company Sberbank of Russia;

(5) VTB Bank Public Joint Stock Company;

(6) Joint Stock Company Alfa-Bank;

(7) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest; or

(8) the Central Bank of the Russian Federation.

(b) For the purposes of this general license, the term “related to energy” means the extraction, production, refinement, liquefaction, gasification, regasification, conversion, enrichment, fabrication, transport, or purchase of petroleum, including crude oil, lease condensates, unfinished oils, natural gas liquids, petroleum products, natural gas, or other products capable of producing energy, such as coal, wood, or agricultural products used to manufacture biofuels, or uranium in any form, as well as the development, production, generation, transmission, or exchange of power, through any means, including nuclear, thermal, and renewable energy sources.

(c) This general license does not authorize:
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0607]

RIN 1625–AA00

Safety Zone; Chinese Harbor, Santa Cruz Island, California

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The U.S. Coast Guard is establishing a temporary safety zone for the navigable waters in Chinese Harbor of Santa Cruz Island, California. This temporary safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by ongoing oil recovery operations relating to the grounding of a 60-foot fishing vessel in Chinese Harbor. Entry of persons or vessels into this safety zone is prohibited unless specifically authorized by the Captain of the Port Sector Los Angeles—Long Beach (COTP), or his designated representative.

DATES: This rule is effective without actual notice from December 28, 2022 until January 4, 2023. For the purposes of enforcement, actual notice will be used from December 21, 2022 until December 28, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USCG–2022–0607 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LCDR Maria Wiener, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 357–1603, email D11-SMB-SectorLAB-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
LLNR Light List Number
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and