

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

■ 2. Add § 870.1405 to subpart B to read as follows:

§ 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.

[FR Doc. 2022-28173 Filed 12-27-22; 8:45 am]

BILLING CODE 4164-01-P

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.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202-622-2480; Assistant Director for Regulatory Affairs, 202-622-4855; or

Assistant Director for Sanctions Compliance & Evaluation, 202-622-2490.

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:

(1) Any transactions prohibited by Directive 1A under E.O. 14024, *Prohibitions Related to Certain Sovereign Debt of the Russian Federation*;

(2) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions*;

(3) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation; or

(4) Any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

(d) Effective November 10, 2022, General License No. 8C, dated June 14, 2022, is replaced and superseded in its entirety by this General License No. 8D.

Note to General License No. 8D. This authorization is valid until May 15, 2023 unless renewed.

Bradley T. Smith
Deputy Director, Office of Foreign Assets Control.

Dated: November 10, 2022.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations; 31 CFR Part 587

GENERAL LICENSE NO. 40C

Civil Aviation Safety

(a) Except as provided in paragraph (b), all transactions ordinarily incident and necessary to the provision, exportation, or reexportation of goods, technology, or services to ensure the safety of civil aviation involving one or more of the blocked entities listed in the Annex to this general license and that are prohibited by Executive Order (E.O.) 14024 are authorized, provided that:

(1) The aircraft is registered in a jurisdiction solely outside of the Russian Federation; and

(2) The goods, technology, or services that are provided, exported, or reexported are for use on aircraft operated solely for civil aviation purposes.

(b) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions*;

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation*; or

(3) Any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving

any person blocked pursuant to the RuHSR other than the blocked entities listed in the Annex to this general license, unless separately authorized.

(c) Effective November 14, 2022, General License No. 40B, dated August 3, 2022, is replaced and superseded in its entirety by this General License No. 40C.

Note to General License 40C. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies, including export, reexport, and transfer (in-country) licensing requirements maintained by the Department of Commerce's Bureau of Industry and Security under the Export Administration Regulations, 15 CFR parts 730–774.

Andrea M. Gacki
Director, Office of Foreign Assets Control.

Dated: November 14, 2022.

Annex—Blocked Entities Described in Paragraph (a) of General License 40C

List of blocked entities described in paragraph (a) of General License 40C:

- (a) Public Joint Stock Company United Aircraft Corporation;
- (b) Irkut Corporation Joint Stock Company;
- (c) Energotsentr Irkut;
- (d) Irkut-Avtotrans;
- (e) Irkut-Remstroi;
- (f) Irkut-Stanko Service;
- (g) Rapart Servisez;
- (h) Sportivno-Oz dorovitelyi Tsentr Irkut Zenit;
- (i) Tipografiya Irkut;
- (j) Joint Stock Company Ilyushin Finance Company;
- (k) Open Joint Stock Company Ilyushin Aviation Complex;
- (l) Public Joint Stock Company Taganrog Aviation Scientific-Technical Complex N.A. G.M. Beriev;
- (m) Joint Stock Company Flight Research Institute N.A. M.M. Gromov;
- (n) Tupolev Public Joint Stock Company;
- (o) Limited Liability Company Kapo-Avtotrans;
- (p) Limited Liability Company Kapo-Zhilbitservis;
- (q) Limited Liability Company Networking Company Irkut;
- (r) Joint Stock Company State Transportation Leasing Company;
- (s) Emperor Aviation LTD; or
- (t) 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.

Andrea M. Gacki
Director, Office of Foreign Assets Control.

[FR Doc. 2022-28240 Filed 12-27-22; 8:45 am]

BILLING CODE 4810-AL-P

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 SMB-SectorLALB-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
U.S.C.	United States Code

II. Background Information and Regulatory History

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