

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 744**

[Docket No. 140908761–7999–02]

RIN 0694–AG29

Addition of Certain Entities to the Entity List**AGENCY:** Bureau of Industry and Security, Commerce.**ACTION:** Final rule.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by adding two entities to the Entity List. The two entities being added to the Entity List have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. These two entities will be listed on the Entity List under the destination of Russia.

DATES: This rule is effective December 20, 2017.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: *ERC@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:**Background**

The Entity List (Supplement No. 4 to part 744 of the Export Administration Regulations (EAR)) identifies entities and other persons reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The EAR imposes additional license requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to those listed. The “license review policy” for each listed entity or other person is identified in the License Review Policy column on the Entity List and the impact on the availability of license exceptions is described in the **Federal Register** document adding entities or other persons to the Entity List. BIS places entities and other persons on the Entity List pursuant to sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all

decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes decisions to add an entry to the Entity List by majority vote and decisions to remove or modify an entry by unanimous vote. The Departments represented on the ERC have approved these changes to the Entity List.

ERC Entity List Decisions*Additions to the Entity List*

This rule implements the decision of the ERC to add two entities to the Entity List. These two entities are being added on the basis of § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The two entries added to the Entity List consist of two entities located in Russia.

Under § 744.11(b) (Criteria for revising the Entity List) of the EAR, persons for whom there is reasonable cause to believe, based on specific and articulable facts, that they have been involved, are involved, or pose a significant risk of being or becoming involved in, activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such persons may be added to the Entity List. Paragraphs (b)(1) through (b)(5) of § 744.11 provide an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States.

BIS, pursuant to Section 744.11(b) of the EAR, and in consultation with the Departments of State, Defense, Energy and the Treasury, has designated the two persons, located in the Russian Federation, to be added to the Entity List for actions contrary to the national security or foreign policy interests of the United States. Specifically, these entities produced, for the Russian Federation Ministry of Defense, a ground-launched cruise missile system, and associated transporter-erector-launcher, with a range prohibited by the Intermediate-Range Nuclear Forces Treaty. Both the Russian Federation and the United States are party to the INF Treaty. Therefore, there is reasonable cause to believe, based on specific and articulable facts, that Joint Stock Company Experimental Design Bureau Novator, and Joint Stock Company Federal Scientific and Production Center Titan-Barrikady have been involved in actions contrary to the national security or foreign policy interests of the United States.

The prior review of exports, reexports or transfers (in-country) of all items

subject to the EAR involving these persons, and the possible imposition of license conditions or license denials on shipments to the persons, will enhance BIS’s ability to prevent use of items subject to the EAR contrary to U.S. national security or foreign policy interests.

For the two persons added to the Entity List, BIS imposes a license requirement for all items subject to the EAR, and a license review policy of presumption of denial. The license requirements apply to any transaction in which items are to be exported, reexported, or transferred (in-country) to either of the persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule. The acronym “a.k.a.” (also known as) is used in entries on the Entity List to identify aliases and help exporters, reexporters and transferors to better identify persons on the Entity List.

This final rule adds the following two entities to the Entity List:

Russia

(1) *Joint Stock Company Experimental Design Bureau Novator*, a.k.a., the following two aliases:

—Novator Design Bureau; and
—JSC OKB Novator.

18 Prospekt Kosmonavtov, 620017 Yekaterinburg, Russia; and

(2) *Joint Stock Company Federal Scientific and Production Center Titan-Barrikady*, a.k.a., the following three aliases:

—Federal Research and Production Center Titan Barrikady JSC;
—Titan Design Bureau; and
—JSC FNPTS Titan-Barrikady.

Prospekt Imeni V.I. Lenina, b/n 400071, Volgograd, Russia.

Export Administration Act of 1979

Although the Export Administration Act of 1979 expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 15, 2017, 82 FR 39005 (August 16, 2017), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act of 1979, as appropriate and to the extent permitted by law, pursuant to Executive Order

13222, as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 43.8 minutes for a manual or electronic submission.

Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the

burden, to Jasmeet K. Sehra, Office of Management and Budget (OMB), by email to *Jasmeet_K_Sehra@omb.eop.gov*, or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. For the two persons added to the Entity List in this final rule, the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation and a 30-day delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)). BIS implementation of this rule is necessary to protect U.S. national security or foreign policy interests by preventing items from being exported, reexported, or transferred (in-country) to the persons being added to the Entity List. If this rule were delayed to allow for notice and comment and a delay in effective date, the entities being added to the Entity List by this action would continue to be able to receive items without a license and to conduct activities contrary to the national security or foreign policy interests of the United States. In addition, publishing a proposed rule would give these parties notice of the U.S. Government’s intention to place them on the Entity List, which could create an incentive for these persons to accelerate receiving items subject to the EAR to conduct activities that are contrary to the national security or foreign policy interests of the United States, including taking steps to set up additional aliases, change addresses, and other measures to try to limit the impact of the listing on the Entity List once a final rule is published. Further, no other law requires that a notice of proposed rulemaking and an opportunity for

public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 13, 2017, 82 FR 6165 (January 18, 2017); Notice of August 15, 2017, 82 FR 39005 (August 16, 2017); Notice of September 18, 2017, 82 FR 43825 (September 19, 2017); Notice of November 6, 2017, 82 FR 51971 (November 8, 2017).

■ 2. Supplement No. 4 to part 744 is amended by adding under Russia, two Russian entities.

The additions read as follows:

Supplement No. 4 to Part 744—Entity List

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Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
RUSSIA	*	*	*	*
	Joint Stock Company Experimental Design Bureau Novator, a.k.a., the following two aliases: —Novator Design Bureau; and —JSC OKB Novator. 18 Prospekt Kosmonavtov, 620017 Yekaterinburg, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	82 FR [INSERT FR PAGE NUMBER], December 12/20/17.

Country	Entity	License requirement	License review policy	Federal Register citation
	Joint Stock Company Federal Scientific and Production Center Titan-Barrikady, a.k.a., the following three aliases: —Federal Research and Production Center Titan Barrikady JSC; —Titan Design Bureau; and —JSC FNPTS Titan-Barrikady. Prospekt Imeni V.I. Lenina, b/n 400071, Volgograd, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	82 FR [INSERT FR PAGE NUMBER], 12/20/17.
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Dated: December 15, 2017.
Richard E. Ashooh,
Assistant Secretary for Export Administration.
 [FR Doc. 2017–27388 Filed 12–19–17; 8:45 am]
BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2017–N–6570]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Image Processing Device for Estimation of External Blood Loss

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the image processing device for estimation of external blood loss into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the image processing device for estimation of external blood loss’ classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective December 20, 2017. The classification was applicable on May 9, 2014.

FOR FURTHER INFORMATION CONTACT: Jitendra Virani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G459, Silver Spring,

MD 20993–0002, 301–796–6398, *Jitendra.Virani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the image processing device for estimation of external blood loss as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through “De Novo” classification, a common name for the process

authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining