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Issued in Burlington, Massachusetts, on December 18, 2017.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2017-27778 Filed 12-26-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 732, 734, 738, 740, 746, and 774

[170207157-7157-01]

RIN 0694-AH31

Revisions, Clarifications, and Technical Corrections to the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule; correcting amendments.

SUMMARY: In this final rule, the Bureau of Industry and Security corrects certain provisions in the Export Administration Regulations (EAR) to provide accurate references and fix typographical errors, and amend several Export Control Classification Numbers (ECCNs) to enhance consistency with the other ECCNs on the Commerce Control List (CCL). The corrections are editorial in nature and do not affect license requirements.

DATES: This rule is effective December 27, 2017.

FOR FURTHER INFORMATION CONTACT: Ivan Mogensen, Office of Exporter Services, Bureau of Industry and Security, by telephone: (202) 482-2440 or email: Ivan.Mogensen@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Overview

This final rule updates six parts of the EAR to correct typographical errors, clarify inaccurate or unclear internal references, and correct inconsistencies in certain entries on the Commerce Control List (CCL).

Part 732

Section 732.4(b) discusses steps to be taken when reviewing license exceptions for exports and reexports. In § 732.4(b)(7)(ii), there is a reference to § 740.20(g) listing ECCNs that may be eligible for subsequent export or reexport under license exception STA, following submission of a license application. However, only ECCN 9A610.a is listed in § 732.4(b)(7)(ii), while ECCNs 0A606.a, 8A609.a, 8A620.a, 8A620.b, “spacecraft” in ECCN subparagraphs 9A515.a.1, a.2, a.3, a.4, 9A515.g, and 9E515.b, .d, .e, and .f (which also now appear in § 740.20(g)), are inadvertently omitted. This correction adds the omitted items listed in § 740.20(g) to § 732.4(b)(7)(ii). Additionally, because these items include both commodities and technology, the term “aircraft” in the reference to 9A610.a is replaced with “item.”

This rule also clarifies and corrects the *Export Control Decision Tree* diagram in supplement No. 1 to part 732 that was last revised in a final rule published February 6, 2004 (69 FR 5686 (Feb. 6, 2004)). Several of the decision “blocks” in the flowchart contain references that are unclear or incorrect. This rule provides clarity by changing references to the general prohibitions to citations of specific sections of the EAR, and correcting improper citations to ensure that the citations contained in all decision blocks coincide with the appropriate sections of the EAR. Specifically, the changes are as follows: In the block which begins “Is your item classified under an ECCN on the CCL,” a direct citation to § 736.2(b)(1) through (3) replaces a reference to General Prohibitions 1 through 3, which did not inform the reader where the prohibitions could be found in the EAR; in the block which begins “Is there an ‘X’ in the box,” the EAR citations now directly follow references to the Commerce Country Chart and the CCL, respectively; and, in the block which begins “Use License Exception,” the citation to § 740.1, which is an introduction, is replaced with a reference to the whole of part 740. Additionally, several grammatical errors are addressed, and the section symbol (“§”) is added wherever a section of the EAR is referenced in the decision blocks

for clarity. Finally, this final rule changes the supplement’s name from “*Decision Tree*” to “*Export Control Decision Tree*” to match the title of the diagram, and the duplicative parenthetical in the graphic title reading “(Supp. No. 1 to Part 732)” is deleted.

Part 734

Section 734.18 was created in the rule *Revisions to Definitions in the Export Administration Regulations* (81 FR 35586 (June 3, 2016)) and discusses activities that are not exports, reexports, or transfers. The note following the end of § 734.18(a)(5)(iv) discusses data in transit via the internet, but the note is incorrectly described as the note to paragraph (a)(4)(iv). This rule changes the note to refer to § 734.18(a)(5)(iv).

Part 738

In § 738.2(d)(1), *Composition of an entry*, there is a description of the meaning attached to each alphanumeric character making up an Export Control Classification Number. This paragraph currently explains that the second “digit” in an ECCN indicates the “Reason for Control.” However, in paragraph (d)(1)(i) of this section, the paragraph refers to the Reason for Control as the third “digit.” This final rule amends § 738.2(d)(1)(i) to replace the word “digit” with “alphanumeric character” in order to maintain consistency and prevent confusion.

Additionally, in § 738.2, this final rule makes a correction in § 738.2(d)(2)(iv)(C)(2). The text of this paragraph uses ECCN 2B992 as an example when providing an overview of how to read an ECCN heading on the Commerce Control List (CCL). However, in the latter part of the section, the text erroneously references ECCN 2B999 instead of 2B992. This rule replaces the reference to ECCN 2B999 with 2B992 in this section to correct the ECCN reference.

Part 740

Section 740.20(g)(1) lists 9x515 and “600 series” ECCNs that are eligible for license exception Strategic Trade Authorization. This includes ECCNs 9A515.a.1, .a.2, .a.3, .a.4, and .g, 9A610.a, and technology ECCNs 9E515.b, .d, .e, and .f. In the final rule *Revisions to the Export Administration Regulations (EAR): Control of Spacecraft Systems and Related Items the President Determines No Longer Warrant Control under the United States Munitions List (USML)* (82 FR 2875 (Jan. 10, 2017)), the phrase “that provide space-based logistics, assembly or servicing of any spacecraft (e.g., refueling)” following the list of ECCN

9A515 items paragraphs was intended to be removed since it is only applicable to 9A515.a.4 and not to the other ECCNs. Since the phrase was not removed, this rule removes the phrase to prevent confusion by users.

Part 746

This rule amends § 746.9(a) by removing an outdated reference to § 734.2(b) for the definitions of “deemed export” and “deemed reexport,” as that section is currently reserved, and replacing it with references to §§ 734.13(b) and 734.14(b), because the relevant definitions for deemed “export” and deemed “reexport” has been found in those two sections of the EAR since the publication of the final rule *Revisions to Definitions in the Export Administration Regulations* (81 FR 35586). Additionally, consistent with the guidance in § 774.1(d), the double quotes around deemed export and deemed reexport in § 746.9 are removed as these terms do not appear in § 772.1.

Part 774

This rule makes corrections to six ECCNs in supplement No. 1 to part 774, “Commerce Control List,” by correcting misspellings and creating conforming changes. The corrections are as follows:

ECCNs 0A606, 8A609, and 9A610: This final rule amends these ECCNs to correct the title of § 740.20(g) that is referenced in paragraph (1) in the Special Conditions for STA section of the ECCN entries. Currently, these sections refer to § 740.20(g) as *License Exception STA eligibility requests for “600 series” end items*, when the current title for this section is *License Exception STA eligibility requests for 9x515 and “600 series” items*. The title of § 740.20(g) was changed in the rule *Revisions to the Export Administration Regulations (EAR): Control of Spacecraft Systems and Related Items the President Determines No Longer Warrant Control Under the United States Munitions List (USML)*; (79 FR 27417 (May 13, 2014)), but the change was not made to the corresponding ECCNs. This rule amends the title reference in these ECCNs to match the current title of § 740.20(g).

ECCNs 0D606.a and 0E606.a: This final rule amends ECCN subparagraphs 0D606.a and 0E606.a to include references to ECCNs 0B606 and 0C606. The headings of both 0D606 and 0E606 refer to 0B606 and 0C606 but these references do not appear in Items paragraph .a of the List of Items Controlled section. This inconsistency has generated confusion as to whether 0D606.a software “specially designed”

for the “development,” “production,” operation or maintenance of the items controlled under ECCNs 0B606 and 0C606 or 0E606.a technology required for the “development,” “production,” operation or maintenance of the items controlled under ECCNs 0B606 and 0C606 is controlled or not. This edit removes this confusion by clarifying that such software is controlled under ECCN 0D606.a and such technology is controlled under ECCN 0E606.a.

ECCN 2B352: This final rule corrects ECCN 2B352 by revising, in the List of Items Controlled section, Items paragraphs g.1, i.1, i.2 and i.3 and the Technical Notes at the end of the Items paragraphs. The corrections are as follows: The word “dependant” is replaced with the American spelling of the word “dependent” in Items paragraph g.1; double quotes are added around the term “aircraft” in Items paragraphs i.1 and i.2, and in Technical Notes 1 and 3 because “aircraft” is a defined term in the EAR; double quotes are added around the term “laser” in Technical Notes 3.a and .b for the same reason; double quotes are replaced with single quotes around the term ‘VMD’ in Items paragraphs i.1 and i.2 and the term is clarified in Technical Note 3; single quotes are added to the term ‘aerosol generating units’ in Items paragraphs i.2 and i.3 and Technical Note 1.

ECCN 8A609: This final rule revises Related Control paragraph (3) under the List of Items Controlled section in ECCN 8A609 to add a reference to Category VI of the International Traffic in Arms Regulations (ITAR). This is done to indicate that certain diesel engines and electric motors for both EAR surface vessels of war and ITAR surface vessels of war are controlled under ECCN 8A992.g. Additionally, double quotes are added around the term “subject to the EAR” because it is a defined term in the EAR.

Export Administration Act

Since August 21, 2001, the Export Administration Act of 1979, as amended, has been in lapse. However, 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 EAR in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, 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 does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been designated 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. This final rule does not contain information collections subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA). Notwithstanding any other provision of law, no person is required to respond to, nor is 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.

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

4. The Department of Commerce finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act otherwise requiring prior notice and the opportunity for public comment because they are unnecessary. The revisions made by this rule are administrative in nature and do not affect the privileges and obligations of the public. Additionally, it is important that the edits and clarifications are added as soon as possible to prevent improper interpretation of the EAR. The Department also finds that there is good cause under 5 U.S.C. 553(b)(A) to waive the provisions of the Administrative Procedure Act requiring notice and comment because these changes are limited to providing guidance on existing interpretations of current EAR provisions. Because these revisions are not substantive changes to the EAR, the

30-day delay in effectiveness otherwise required by 5 U.S.C. 553(d) is not applicable. No other law requires that a notice of proposed rulemaking and opportunity for public comment be given for this rule. The analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable because no general notice of proposed rulemaking was required for this rule by 5 U.S.C. 553, or by any other law. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects

15 CFR Part 732

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology

15 CFR Part 738

Exports

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Parts 746 and 774

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 732, 734, 738, 740, 746, and 774 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 732—[AMENDED]

- 1. The authority citation for 15 CFR part 732 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

- 2. Section 732.4 is amended by revising paragraph (b)(7)(ii) to read as follows:

§ 732.4 Steps regarding License Exceptions.

* * * * *

(b) * * *

(7) * * *

(ii) If you are going to file a license application with BIS for the export, reexport, or in-country transfer for aircraft or military vessels controlled under ECCNs 0A606.a, 8A609.a, 8A620.a, 8A620.b, certain “spacecraft” controlled under ECCN subparagraphs

9A515.a.1, a.2, a.3, a.4 or 9A515.g, ECCN 9A610.a, or technology under ECCNs 9E515.b, .d, .e, or .f, § 740.20(g) permits you to request in the application that subsequent exports of the type of aircraft, spacecraft, military vessels, or technology at issue be eligible for export under License Exception STA. The types of “items” controlled under ECCNs 0A606.a, 8A609.a, 8A620.a, 8A620.b, certain spacecraft controlled under ECCN subparagraphs 9A515.a.1, a.2, a.3, a.4 or 9A515.g, ECCN 9A610.a, and technology ECCNs 9E515.b, .d, .e, or .f, that have been determined to be eligible for License Exception STA pursuant to § 740.20(g) are identified in the License Exceptions paragraphs of ECCNs 0A606, 8A609, 8A620, 9A610, 9A515, and 9E515. Supplement No. 2 to part 748, paragraph (w) (License Exception STA eligibility requests), contains the instructions for such applications.

Note 1 to paragraph (b)(7)(ii): If you intend to use License Exception STA, return to paragraphs (a) and then (b) of this section to review the Steps regarding the use of license exceptions.

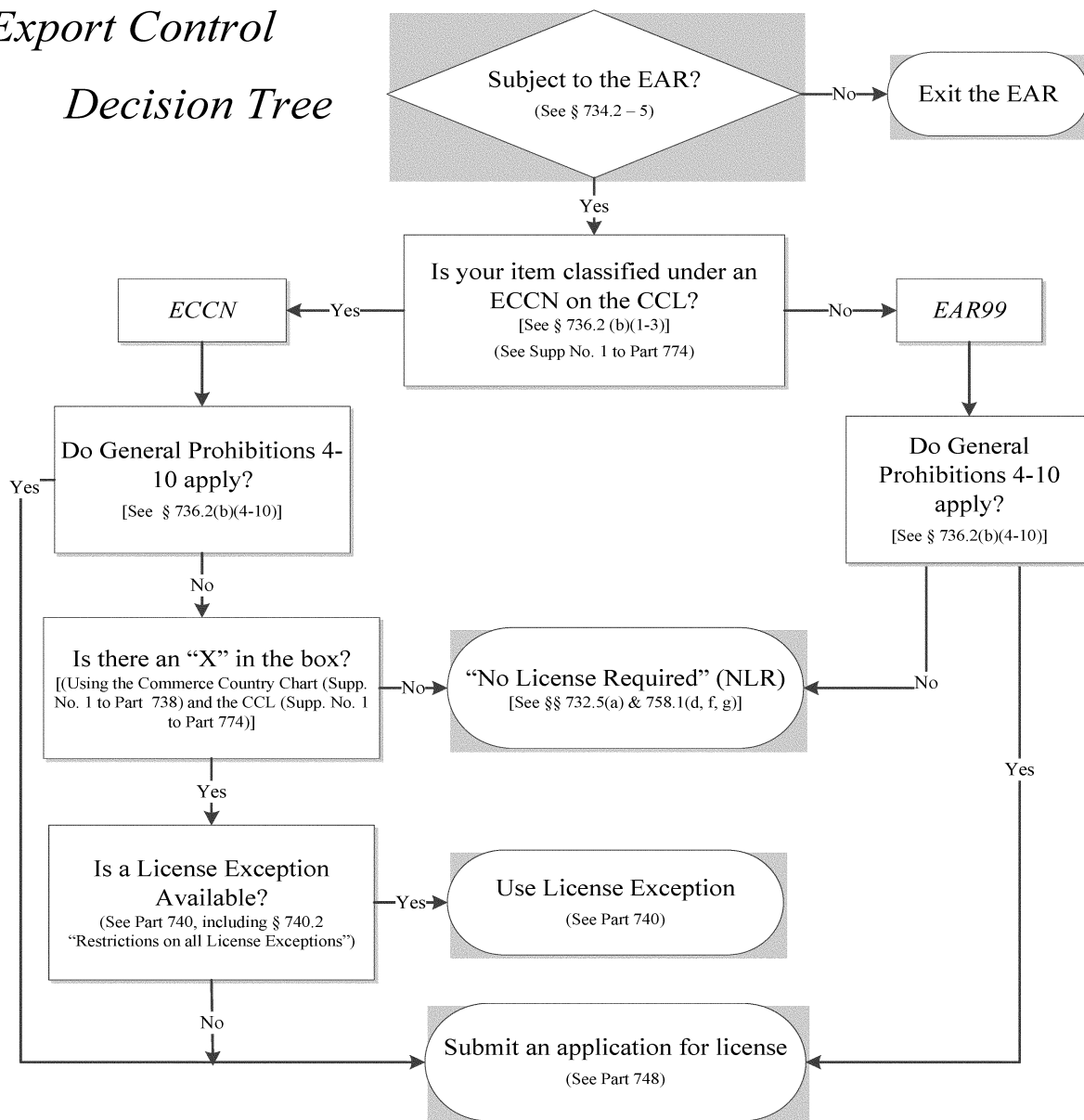
* * * * *

- 3. Supplement No. 1 to part 732 is revised to read as follows:

BILLING CODE 3510-33-P

SUPPLEMENT NO. 1 TO PART 732 – EXPORT CONTROL DECISION TREE

Export Control Decision Tree



BILLING CODE 3510-33-C

PART 734—[AMENDED]

■ 4. The authority citation for 15 CFR part 734 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 8, 2016, 81 FR 79379 (November 10, 2016); Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

§ 734.18 [Amended]

■ 5. Section 734.18 is amended by redesignating the note to paragraph (a)(4)(iv) as note 1 to paragraph (a)(5)(iv).

PART 738—[AMENDED]

■ 6. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR

58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

■ 7. Section 738.2 is amended by revising paragraphs (d)(1)(i) and (d)(2)(iv)(C)(2) to read as follows:

§ 738.2 Commerce Control List (CCL) structure.

* * * * *

(d) * * *

(1) * * *

(i) Since Reasons for Control are not mutually exclusive, numbers are assigned in order of precedence. As an

example, if an item is controlled for both National Security and Missile Technology reasons, the entry's third alphanumeric character will be a "0". If the item is controlled only for Missile Technology the third alphanumeric character will be "1".

(2) * * *

(iv) * * *

(C) * * *

(2) "(See List of Items Controlled)" is in the middle of the ECCN heading. If the phrase "(see List of Items Controlled)" appears in the middle of the ECCN heading, then all portions of the heading that follow the phrase "(see List of Items Controlled)" will list items controlled in addition to the list in the "items" paragraph. An example of such a heading is ECCN 2B992 Non-"numerically controlled" machine tools for generating optical quality surfaces, (see List of Items Controlled) and "specially designed" "parts" and "components" therefor. Under the ECCN 2B992 example, the "items" paragraph must be reviewed to determine whether your item is contained within the first part of the heading ("non-'numerically controlled' machine tools for generating optical quality surfaces") and classified under 2B992. The second part of the ECCN 2B992 heading ("and 'specially designed' 'parts' and 'components' therefor") contains the exclusive list described in the heading. ECCNs 1A006, 3B992, 4A001, 6A006 and 7A001 are other examples where the phrase "(see List of Items Controlled)" appears in the middle of the ECCN heading.

* * * * *

PART 740—[AMENDED]

■ 8. The authority citation for 15 CFR part 740 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

■ 9. Section 740.20 is amended by revising paragraph (g)(1) to read as follows:

§ 740.20 License Exception Strategic Trade Authorization (STA).

* * * * *

(g) * * *

(1) *Applicability.* Any person may request License Exception STA eligibility for end items described in ECCN 0A606.a, ECCN 8A609.a, ECCNs 8A620.a or .b, "spacecraft" in ECCNs 9A515.a.1, .a.2, .a.3, .a.4, or .g, 9A610.a,

or technology ECCNs 9E515.b, .d, .e, or .f.

* * * * *

PART 746—[AMENDED]

■ 10. The authority citation for 15 CFR part 746 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. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Presidential Determination 2007–7, 72 FR 1899, 3 CFR, 2006 Comp., p. 325; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017); Notice of May 9, 2017, 82 FR 21909 (May 10, 2017).

■ 9. Section 746.9 is amended by revising paragraph (a) to read as follows:

§ 746.9 Syria.

* * * * *

(a) *License requirements.* A license is required for the export or reexport to Syria of all items subject to the EAR, except food and medicine classified as EAR99 (food and medicine are defined in part 772 of the EAR). A license is required for the deemed export and deemed reexport, as described in §§ 734.13(b) and 734.14(b) of the EAR, respectively, of any technology or source code on the Commerce Control List (CCL) to a Syrian foreign national. Deemed exports and deemed reexports to Syrian foreign nationals involving technology or source code subject to the EAR but not listed on the CCL do not require a license.

* * * * *

PART 774—[AMENDED]

■ 11. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

■ 12. In supplement No. 1 to part 774, Category 0, ECCN 0A606 is revised to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

0A606 Ground vehicles and related commodities, as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
NS applies to entire entry, except 0A606.b and .y.	NS Column 1
NS applies to 0A606.b.	NS Column 2
RS applies to entire entry, except 0A606.b and .y.	RS Column 1
RS applies to 0A606.b.	RS Column 2
AT applies to entire entry.	AT Column 1
UN applies to entire entry, except 0A606.y.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: \$1500

GBS: N/A

CIV: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1) of the EAR) may not be used for any item in 0A606.a, unless determined by BIS to be eligible for License Exception STA in accordance with § 740.20(g) (License Exception STA eligibility requests for 9x515 and "600 series" items). (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 0A606.

List of Items Controlled

Related Controls: (1) The ground vehicles, other articles, technical data (including software) and services described in 22 CFR part 121, Category VII are subject to the jurisdiction of the International Traffic in Arms Regulations. (2) See ECCN 0A919 for foreign-made "military commodities" that incorporate more than a de minimis amount of U.S.-origin "600 series" controlled content.

Related Definitions: N/A

Items: a. Ground vehicles, whether manned or unmanned, "specially designed" for a military use and not enumerated or otherwise described in USML Category VII.

Note 1 to paragraph .a: For purposes of paragraph .a, "ground vehicles" include (i) tanks and armored vehicles manufactured prior to 1956 that have not been modified since 1955 and that do not contain a functional weapon or a weapon capable of becoming functional through repair; (ii) military railway trains except those that are armed or are "specially designed" to launch missiles; (iii) unarmored military recovery and other support vehicles; (iv) unarmored, unarmed vehicles with mounts or hard points for firearms of .50 caliber or less; and (v) trailers "specially designed" for use with other ground vehicles enumerated in USML Category VII or ECCN 0A606.a, and not

separately enumerated or otherwise described in USML Category VII. For purposes of this note, the term “modified” does not include incorporation of safety features required by law, cosmetic changes (e.g., different paint or repositioning of bolt holes) or addition of “parts” or “components” available prior to 1956.

Note 2 to paragraph .a: A ground vehicle’s being “specially designed” for military use for purposes of determining controls under paragraph .a. entails a structural, electrical or mechanical feature involving one or more “components” that are “specially designed” for military use. Such “components” include:

- a. Pneumatic tire casings of a kind “specially designed” to be bullet-proof;
- b. Armored protection of vital “parts” (e.g., fuel tanks or vehicle cabs);
- c. Special reinforcements or mountings for weapons;
- d. Black-out lighting.

b. Other ground vehicles, “parts” and “components,” as follows:

b.1. Unarmed vehicles that are derived from civilian vehicles and that have all of the following:

b.1.a. Manufactured or fitted with materials or “components” other than reactive or electromagnetic armor to provide ballistic protection to level III (National Institute of Justice standard 0108.01, September 1985) or better;

b.1.b. A transmission to provide drive to both front and rear wheels simultaneously, including those vehicles having additional wheels for load bearing purposes whether driven or not;

b.1.c. Gross vehicle weight rating (GVWR) greater than 4,500 kg; and

b.1.d. Designed or modified for off-road use.

b.2. “Parts” and “components” having all of the following:

b.2.a. “Specially designed” for vehicles specified in paragraph .b.1 of this entry; and

b.2.b. Providing ballistic protection to level III (National Institute of Justice standard 0108.01, September 1985) or better.

Note 1 to paragraph b: Ground vehicles otherwise controlled by 0A606.b.1 that contain reactive or electromagnetic armor are subject to the controls of USML Category VII.

Note 2 to paragraph b: ECCN 0A606.b.1 does not control civilian vehicles “specially designed” for transporting money or valuables.

Note 3 to paragraph b: “Unarmed” means not having installed weapons, installed mountings for weapons, or special reinforcements for mounts for weapons.

c. Air-cooled diesel engines and engine blocks for armored vehicles that weigh more than 40 tons.

d. Fully automatic continuously variable transmissions for tracked combat vehicles.

e. Deep water fording kits “specially designed” for ground vehicles controlled by ECCN 0A606.a or USML Category VII.

f. Self-launching bridge “components” not enumerated in USML Category VII(g) “specially designed” for deployment by ground vehicles enumerated in USML Category VII or this ECCN.

g. through w. [RESERVED]

x. “Parts,” “components,” “accessories,” and “attachments” that are “specially designed” for a commodity enumerated or otherwise described in ECCN 0A606 (other than 0A606.b or 0A606.y) or a defense article enumerated in USML Category VII and not elsewhere specified on the USML or in 0A606.y.

Note 1: Forgings, castings, and other unfinished products, such as extrusions and machined bodies, that have reached a stage in manufacture where they are clearly identifiable by mechanical properties, material composition, geometry, or function as commodities controlled by ECCN 0A606.x are controlled by ECCN 0A606.x.

Note 2: “Parts,” “components,” “accessories” and “attachments” enumerated in USML paragraph VII(g) are subject to the controls of that paragraph. “Parts,” “components,” “accessories” and “attachments” described in ECCN 0A606.y are subject to the controls of that paragraph.

y. Specific “parts,” “components,” “accessories,” and “attachments” “specially designed” for a commodity enumerated or otherwise described in this ECCN (other than ECCN 0A606.b) or for a defense article in USML Category VII and not elsewhere specified on the USML or the CCL, as follows, and “parts,” “components,” “accessories,” and “attachments” “specially designed” therefor:

y.1. Brake discs, rotors, drums, calipers, cylinders, pads, shoes, lines, hoses, vacuum boosters, and parts therefor;

y.2. Alternators and generators;

y.3. Axles;

y.4. Batteries;

y.5. Bearings (e.g., ball, roller, wheel);

y.6. Cables, cable assemblies, and connectors;

y.7. Cooling system hoses;

y.8. Hydraulic, fuel, oil, and air filters, other than those controlled by ECCN 1A004;

y.9. Gaskets and o-rings;

y.10. Hydraulic system hoses, fittings, couplings, adapters, and valves;

y.11. Latches and hinges;

y.12. Lighting systems, fuses, and “components;”

y.13. Pneumatic hoses, fittings, adapters, couplings, and valves;

y.14. Seats, seat assemblies, seat supports, and harnesses;

y.15. Tires, except run flat; and

y.16. Windows, except those for armored vehicles.

■ 13. In supplement No. 1 to part 774, Category 0, ECCN 0D606 is revised to read as follows:

0D606 “Software” “specially designed” for the “development,” “production,” operation, or maintenance of ground vehicles and related commodities controlled by 0A606, 0B606, or 0C606 (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

CIV: N/A

TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any “software” in 0D614.

List of Items Controlled

Related Controls: (1) “Software” directly related to articles enumerated in USML Category IX is subject to the control of USML paragraph IX(e). (2) See ECCN 0A919 for foreign made “military commodities” that incorporate more than a de minimis amount of US-origin “600 series” items.

Related Definitions: N/A

Items:

a. “Software” “specially designed” for the “development,” “production,” operation, or maintenance of commodities controlled by ECCNs 0A606 (except for ECCNs 0A606.b or 0A606.y), 0B606, or 0C606.

b. [RESERVED]

■ 14. In supplement No. 1 to part 774, Category 0, ECCN 0E606 is revised to read as follows:

0E606 “Technology” “required” for the “development,” “production,” operation, installation, maintenance, repair, overhaul, or refurbishing of ground vehicles and related commodities in 0A606, 0B606, 0C606, or software in 0D606 (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

CIV: N/A

TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any technology in 0E614.

List of Items Controlled

Related Controls: “Technical data” directly related to articles enumerated in USML Category IX is subject to the control of USML paragraph IX(e).

Related Definitions: N/A

Items:

a. “Technology” “required” for the “development,” “production,” operation, installation, maintenance, repair, overhaul, or refurbishing of commodities enumerated or otherwise described in ECCN 0A606 (except for ECCNs 0A606.b or 0A606.y), 0B606, or 0C606.

b. [RESERVED]

■ 15. In supplement No. 1 to part 774, Category 2, ECCN 2B352 is revised to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738).</i>
CB applies to entire entry.	CB Column 2
AT applies to entire entry.	AT Column 1

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A

GBS: N/A

CIV: N/A

List of Items Controlled

Related Controls: See ECCNs 1A004 and 1A995 for protective equipment that is not covered by this entry. Also see ECCN 9A120 for controls on certain “UAV” systems designed or modified to dispense an aerosol and capable of carrying elements of a payload in the form of a particulate or liquid, other than fuel “parts” or “components” of such vehicles, of a volume greater than 20 liters.

Related Definitions: (1) “Lighter than air vehicles”—balloons and airships that rely on hot air or on lighter-than-air gases, such as helium or hydrogen, for their lift. (2) “UAVs”—Unmanned Aerial Vehicles. (3) “VMD”—Volume Median Diameter.

Items:

a. Containment facilities and related equipment, as follows:

a.1. Complete containment facilities at P3 or P4 containment level.

Technical Note: P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004).

a.2. Equipment designed for fixed installation in containment facilities specified in paragraph a.1 of this ECCN, as follows:

a.2.a. Double-door pass-through decontamination autoclaves;

a.2.b. Breathing air suit decontamination showers;

a.2.c. Mechanical-seal or inflatable-seal walkthrough doors.

b. Fermenters and components as follows:

b.1. Fermenters capable of cultivation of micro-organisms or of live cells for the production of viruses or toxins, without the propagation of aerosols, having a capacity of 20 liters or greater.

b.2. Components designed for such fermenters, as follows:

b.2.a. Cultivation chambers designed to be sterilized or disinfected in situ;

b.2.b. Cultivation chamber holding devices;

or

b.2.c. Process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (e.g., temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Technical Note: Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:

c.1. One or more sealing joints within the steam containment area;

c.2. A flow rate greater than 100 liters per hour;

c.3. “Parts” or “components” of polished stainless steel or titanium; and

c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note: Centrifugal separators include decanters.

d. Cross (tangential) flow filtration equipment and “accessories,” as follows:

d.1. Cross (tangential) flow filtration equipment capable of separation of microorganisms, viruses, toxins or cell cultures having all of the following characteristics:

d.1.a. A total filtration area equal to or greater than 1 square meter (1 m²); and

d.1.b. Having any of the following characteristics:

d.1.b.1. Capable of being sterilized or disinfected in-situ; or

d.1.b.2. Using disposable or single-use filtration “parts” or “components”.

N.B.: 2B352.d.1 does not control reverse osmosis and hemodialysis equipment, as specified by the manufacturer.

d.2. Cross (tangential) flow filtration “parts” or “components” (e.g., modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m²) for each component and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

TECHNICAL NOTE: In this ECCN, “sterilized” denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. “Disinfected” denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. “Disinfection” and “sterilization” are distinct from “sanitization”, the latter referring to cleaning procedures designed to lower the microbial content of equipment

without necessarily achieving elimination of all microbial infectivity or viability.

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

f. Spray-drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:

f.1. A water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h;

f.2. The ability to generate a typical mean product particle size of ≤ 10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; and

f.3. Capable of being sterilized or disinfected in situ.

g. Protective and containment equipment, as follows:

g.1. Protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure;

Technical Note: This entry does not control suits designed to be worn with self-contained breathing apparatus.

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; and

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 does not control isolators “specially designed” for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater.

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

i. Spraying or fogging systems and “parts” and “components” therefor, as follows:

i.1. Complete spraying or fogging systems, “specially designed” or modified for fitting to “aircraft,” “lighter than air vehicles,” or “UAVs,” capable of delivering, from a liquid suspension, an initial droplet ‘VMD’ of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.2. Spray booms or arrays of ‘aerosol generating units’, “specially designed” or

modified for fitting to “aircraft,” “lighter than air vehicles,” or “UAVs,” capable of delivering, from a liquid suspension, an initial droplet ‘VMD’ of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.3. ‘Aerosol generating units’ “specially designed” for fitting to the systems specified in paragraphs i.1 or i.2 of this ECCN.

Technical Notes:

1. ‘Aerosol generating units’ are devices “specially designed” or modified for fitting to “aircraft” and include nozzles, rotary drum atomizers and similar devices.

2. This ECCN does not control spraying or fogging systems, “parts” and “components,” as specified in 2B352.i, that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

3. Volume Median Diameter ‘VMD’ for droplets produced by spray equipment or nozzles “specially designed” for use on “aircraft” or “UAVs” should be measured using either of the following methods (pending the adoption of internationally accepted standards):

- a. Doppler “laser” method,
- b. Forward “laser” diffraction method.

■ 16. In supplement No. 1 to part 774, Category 8, ECCN 8A609 is revised to read as follows:

8A609 Surface vessels of war and related commodities (see List of Items Controlled)

License Requirements

Reason for Control: NS, RS, AT, UN

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
NS applies to entire entry, except 8A609.y.	NS Column 1
RS applies to entire entry, except 8A609.y.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry, except 8A609.y.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: \$1500
GBS: N/A
CIV: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1) of the EAR) may not be used for any item in 8A609.a, unless determined by BIS to be eligible for License Exception STA in accordance with § 740.20(g) (License Exception STA eligibility requests for 9x515 and “600 series” items).

List of Items Controlled

Related Controls: (1) Surface vessels of war and special naval equipment, and technical data (including software), and services directly related thereto, described in 22 CFR part 121, Category VI, Surface Vessels of War and Special Naval Equipment, are

subject to the jurisdiction of the International Traffic in Arms Regulations. (2) See ECCN 0A919 for foreign-made “military commodities” that incorporate more than a de minimis amount of U.S.-origin “600 series” controlled content. (3) For controls on diesel engines and electric motors that are “subject to the EAR” for surface vessels of war “subject to the EAR” or “subject to the ITAR,” see ECCN 8A992.g. For diesel engines and electric motors for surface vessels of war “subject to the ITAR,” see 22 CFR part 121, Category VI(c) for parts, components, accessories, and attachments, “specially designed” for developmental vessels funded by the Department of Defense via contract or other funding authorization. (4) For controls on military gas turbine engines and related items for vessels of war, see ECCN 9A619.

Related Definitions: N/A
Items:
a. Surface vessels of war “specially designed” for a military use and not enumerated or otherwise described in the USML.

Note 1: 8A609.a includes: (i) Underway replenishment ships; (ii) surface vessel and submarine tender and repair ships, except vessels that are “specially designed” to support naval nuclear propulsion plants; (iii) non-submersible submarine rescue ships; (iv) other auxiliaries (e.g., AGDS, AGF, AGM, AGOR, AGOS, AH, AP, ARL, AVB, AVM, and AVT); (v) amphibious warfare craft, except those that are armed; and (vi) unarmored and unarmed coastal, patrol, roadstead, and Coast Guard and other patrol craft with mounts or hard points for firearms of .50 caliber or less.

Note 2: For purposes of paragraph .a, surface vessels of war includes vessels “specially designed” for military use that are not identified in paragraph (a) of ITAR § 121.15, including any demilitarized vessels, regardless of origin or designation, manufactured prior to 1950 and that have not been modified since 1949. For purposes of this note, the term modified does not include incorporation of safety features required by law, cosmetic changes (e.g., different paint), or the addition of “parts” or “components” available prior to 1950.

b. Non-magnetic diesel engines with a power output of 50 hp or more and either of the following:
b.1. Non-magnetic content exceeding 25% of total weight; or
b.2. Non-magnetic parts other than crankcase, block, head, pistons, covers, end plates, valve facings, gaskets, and fuel, lubrication and other supply lines.
c. through w. [RESERVED]
x. “Parts,” “components,” “accessories” and “attachments” that are “specially designed” for a commodity enumerated or otherwise described in ECCN 8A609 (except for 8A609.y) or a defense article enumerated or otherwise described in USML Category VI and not specified elsewhere on the USML, in 8A609.y or 3A611.y.

b. Non-magnetic diesel engines with a power output of 50 hp or more and either of the following:

b.1. Non-magnetic content exceeding 25% of total weight; or

b.2. Non-magnetic parts other than crankcase, block, head, pistons, covers, end plates, valve facings, gaskets, and fuel, lubrication and other supply lines.

c. through w. [RESERVED]

x. “Parts,” “components,” “accessories” and “attachments” that are “specially designed” for a commodity enumerated or otherwise described in ECCN 8A609 (except for 8A609.y) or a defense article enumerated or otherwise described in USML Category VI and not specified elsewhere on the USML, in 8A609.y or 3A611.y.

Note 1: Forgings, castings, and other unfinished products, such as extrusions and machined bodies, that have reached a stage

in manufacturing where they are clearly identifiable by mechanical properties, material composition, geometry, or function as commodities controlled by ECCN 8A609.x are controlled by ECCN 8A609.x.

Note 2: “Parts,” “components,” “accessories” and “attachments” specified in USML subcategory VI(f) are subject to the controls of that paragraph. “Parts,” “components,” “accessories,” and “attachments” specified in ECCN 8A609.y are subject to the controls of that paragraph.

y. Specific “parts,” “components,” “accessories” and “attachments” “specially designed” for a commodity subject to control in this ECCN or for a defense article in USML Category VI and not elsewhere specified in the USML, as follows, and “parts,” “components,” “accessories,” and “attachments” “specially designed” therefor:

- y.1. Public address (PA) systems;
- y.2. Filters and filter assemblies, hoses, lines, fittings, couplings, and brackets for pneumatic, hydraulic, oil and fuel systems;
- y.3. Galleys;
- y.4. Lavatories;
- y.5. Magnetic compass, magnetic azimuth detector;
- y.6. Medical facilities;
- y.7. Potable water tanks, filters, valves, hoses, lines, fittings, couplings, and brackets;
- y.8. Panel knobs, indicators, switches, buttons, and dials whether unfiltered or filtered for use with night vision imaging systems;
- y.9. Emergency lighting;
- y.10. Gauges and indicators;
- y.11. Audio selector panels.

■ 17. In supplement No. 1 to part 774, Category 9, ECCN 9A610 is revised to read as follows.

9A610 Military aircraft and related commodities, other than those enumerated in 9A991.a (see List of Items Controlled)

License Requirements

Reason for Control: NS, RS, MT, AT, UN

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
NS applies to entire entry except: 9A610.b; parts and components controlled in 9A610.x if being exported or reexported for use in an aircraft controlled in 9A610.b; and 9A610.y.	NS Column 1
RS applies to entire entry except: 9A610.b; parts and components controlled in 9A610.x if being exported or reexported for use in an aircraft controlled in 9A610.b; and 9A610.y.	RS Column 1

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
MT applies to 9A610.t, .u, .v, and .w.	MT Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry except 9A610.y.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: \$1500

GBS: N/A

CIV: N/A

Special Conditions For STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1) of the EAR) may not be used for any item in 9A610.a (i.e., “end item” military aircraft), unless determined by BIS to be eligible for License Exception STA in accordance with § 740.20(g) (License Exception STA eligibility requests for 9x515 and “600 series” items). (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 9A610.

List of Items Controlled

Related Controls: (1) Military aircraft and related articles that are enumerated in USML Category VIII, and technical data (including software) directly related thereto, are subject to the ITAR. (2) See ECCN 0A919 for controls on foreign-made “military commodities” that incorporate more than a de minimis amount of U.S.-origin “600 series” controlled content. (3) See USML Category XIX and ECCN 9A619 for controls on military aircraft gas turbine engines and related items.

Related Definitions: In paragraph .y of this entry, the term ‘fluid’ includes liquids and gases.

Items:

a. ‘Military Aircraft’ “specially designed” for a military use that are not enumerated in USML paragraph VIII(a).

Note 1: For purposes of paragraph .a the term ‘military aircraft’ means the LM–100J aircraft and any aircraft “specially designed” for a military use that are not enumerated in USML paragraph VIII(a). The term includes: Trainer aircraft; cargo aircraft; utility fixed wing aircraft; military helicopters; observation aircraft; military non-expansive balloons and other lighter than air aircraft; and unarmed military aircraft, regardless of origin or designation. Aircraft with modifications made to incorporate safety of flight features or other FAA or NTSB modifications such as transponders and air data recorders are “unmodified” for the purposes of this paragraph .a.

Note 2: 9A610.a does not control ‘military aircraft’ that:

- a. Were first manufactured before 1946;
- b. Do not incorporate defense articles enumerated or otherwise described on the U.S. Munitions List, unless the items are required to meet safety or airworthiness

standards of a Wassenaar Arrangement Participating State; and

c. Do not incorporate weapons enumerated or otherwise described on the U.S. Munitions List, unless inoperable and incapable of being returned to operation.

b. L–100 aircraft manufactured prior to 2013.

c.–d. [Reserved]

e. Mobile aircraft arresting and engagement runway systems for aircraft controlled by either USML Category VIII(a) or ECCN 9A610.a.

f. Pressure refueling equipment and equipment that facilitates operations in confined areas, “specially designed” for aircraft controlled by either USML paragraph VIII(a) or ECCN 9A610.a.

g. Aircrew life support equipment, aircrew safety equipment and other devices for emergency escape from aircraft controlled by either USML paragraph VIII(a) or ECCN 9A610.a.

h. Parachutes, paragliders, complete parachute canopies, harnesses, platforms, electronic release mechanisms, “specially designed” for use with aircraft controlled by either USML paragraph VIII(a) or ECCN 9A610.a, and “equipment” “specially designed” for military high altitude parachutists, such as suits, special helmets, breathing systems, and navigation equipment.

i. Controlled opening equipment or automatic piloting systems, designed for parachuted loads.

j. Ground effect machines (GEMS), including surface effect machines and air cushion vehicles, “specially designed” for use by a military.

k. through s. [Reserved]

t. Composite structures, laminates, and manufactures thereof “specially designed” for unmanned aerial vehicles controlled under USML Category VIII(a) with a range equal to or greater than 300 km.

Note to paragraph .t: Composite structures, laminates, and manufactures thereof “specially designed” for unmanned aerial vehicles controlled under USML Category VII(a) with a maximum range less than 300 km are controlled in paragraph .x of this entry.

u. Apparatus and devices “specially designed” for the handling, control, activation and non-ship-based launching of UAVs or drones controlled by either USML paragraph VIII(a) or ECCN 9A610.a, and capable of a range equal to or greater than 300 km.

Note to paragraph .u: Apparatus and devices “specially designed” for the handling, control, activation and non-ship-based launching of UAVs or drones controlled by either USML paragraph VIII(a) or ECCN 9A610.a with a maximum range less than 300 km are controlled in paragraph .x of this entry.

v. Radar altimeters designed or modified for use in UAVs or drones controlled by either USML paragraph VIII(a) or ECCN 9A610.a, and capable of delivering at least 500 kilograms payload to a range of at least 300 km.

Note to paragraph .v: Radar altimeters designed or modified for use in UAVs or

drones controlled by either USML paragraph VIII(a) or ECCN 9A610.a. that are not capable of delivering at least 500 kilograms payload to a range of at least 300 km are controlled in paragraph .x of this entry.

w. Pneumatic hydraulic, mechanical, electro-optical, or electromechanical flight control systems (including fly-by-wire and fly-by-light systems) and attitude control equipment designed or modified for UAVs or drones controlled by either USML paragraph VIII(a) or ECCN 9A610.a, and capable of delivering at least 500 kilograms payload to a range of at least 300 km.

Note to paragraph .w: Pneumatic, hydraulic, mechanical, electro-optical, or electromechanical flight control systems (including fly-by-wire and fly-by-light systems) and attitude control equipment designed or modified for UAVs or drones controlled by either USML paragraph VIII(a) or ECCN 9A610.a., not capable of delivering at least 500 kilograms payload to a range of at least 300 km are controlled in paragraph .x of this entry.

x. “Parts,” “components,” “accessories,” and “attachments” that are “specially designed” for a commodity enumerated or otherwise described in ECCN 9A610 (except for 9A610.y) or a defense article enumerated or otherwise described in USML Category VIII and not elsewhere specified on the USML or in 9A610.y, 9A619.y, or 3A611.y.

y. Specific “parts,” “components,” “accessories,” and “attachments” “specially designed” for a commodity subject to control in this entry, ECCN 9A619, or for a defense article in USML Categories VIII or XIX and not elsewhere specified in the USML or the CCL, and other aircraft commodities “specially designed” for a military use, as follows, and “parts,” “components,” “accessories,” and “attachments” “specially designed” therefor:

- y.1. Aircraft tires;
- y.2. Analog gauges and indicators;
- y.3. Audio selector panels;
- y.4. Check valves for hydraulic and pneumatic systems;
- y.5. Crew rest equipment;
- y.6. Ejection seat mounted survival aids;
- y.7. Energy dissipating pads for cargo (for pads made from paper or cardboard);
- y.8. Fluid filters and filter assemblies;
- y.9. Galleys;
- y.10. Fluid hoses, straight and unbent lines (for a commodity subject to control in this entry or defense article in USML Category VIII), and fittings, couplings, clamps (for a commodity subject to control in this entry or defense article in USML Category VIII) and brackets therefor;
- y.11. Lavatories;
- y.12. Life rafts;
- y.13. Magnetic compass, magnetic azimuth detector;
- y.14. Medical litter provisions;
- y.15. Cockpit or cabin mirrors;
- y.16. Passenger seats including palletized seats;
- y.17. Potable water storage systems;
- y.18. Public address (PA) systems;
- y.19. Steel brake wear pads (does not include sintered mix or carbon/carbon materials);
- y.20. Underwater locator beacons;

- y.21. Urine collection bags/pads/cups/pumps;
- y.22. Windshield washer and wiper systems;
- y.23. Filtered and unfiltered panel knobs, indicators, switches, buttons, and dials;
- y.24. Lead-acid and Nickel-Cadmium batteries;
- y.25. Propellers, propeller systems, and propeller blades used with reciprocating engines;
- y.26. Fire extinguishers;
- y.27. Flame and smoke/CO2 detectors;
- y.28. Map cases;
- y.29. 'Military Aircraft' that were first manufactured from 1946 to 1955 that do not incorporate defense articles enumerated or otherwise described on the U.S. Munitions List, unless the items are required to meet safety or airworthiness standards of a Wassenaar Arrangement Participating State; and do not incorporate weapons enumerated or otherwise described on the U.S. Munitions List, unless inoperable and incapable of being returned to operation;
- y.30. "Parts," "components," "accessories," and "attachments," other than electronic items or navigation equipment, for use in or with a commodity controlled by ECCN 9A610.h;
- y.31. Identification plates and nameplates; and
- y.32. Fluid manifolds.

Dated: December 18, 2017.

Richard E. Ashooh,
Assistant Secretary for Export
Administration.

[FR Doc. 2017-27616 Filed 12-26-17; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA-2017-N-6593]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Reagents for Molecular Diagnostic Instrument Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the reagents for molecular diagnostic instrument test systems into class I (general controls). We are taking this action because we have determined that classifying the device into class I (general 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 27, 2017. The classification was applicable on November 19, 2013.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993-0002, 301-796-5866, steven.tjoe@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the reagents for molecular diagnostic instrument test systems as class I (general 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 (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

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 is required to 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 in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 4, 2013, Illumina, Inc., submitted a request for De Novo classification of the MiSeqDx Universal Kit 1.0. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(A)). After review of the information submitted in the request, we determined that the device can be classified into class I. FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.