Authority and Issuance

Accordingly, 12 CFR part 1005 is corrected by making the following correcting amendments:

PART 1005—ELECTRONIC FUND TRANSFERS (REGULATION E)

§ 1005.36—Transfers Scheduled in Advance and paragraph 1 underlined said heading are removed.

§ 1005.36—Transfers Scheduled before the Date of Transfer, paragraph 1 is added.

The revisions and additions read as follows:

Supplement I to Part 1005—Official Interpretations

Section 1005.33—Procedures for Resolving Errors

33(a) Definition of Error

9. Account number or recipient institution identifier. For purposes of the exception in §1005.33(a)(1)(iv)(D), the terms account number and recipient institution identifier refer to alphanumerical account or institution identifiers other than names or addresses, such as account numbers, routing numbers, Canadian transit numbers, International Bank Account Numbers (IBANs), Business Identifier Codes (BICs) and other similar account or institution identifiers used to route a transaction. In addition and for purposes of this exception, the term designated recipient’s account in §1005.33(a)(1)(iv)(D) refers to an asset account, regardless of whether it is a consumer asset account, established for any purpose and held by a bank, savings association, credit union, or equivalent institution. A designated recipient’s account does not, however, include a credit card, prepaid card, or a virtual account held by an Internet-based or mobile telephone company that is not a bank, savings association, credit union or equivalent institution.

33(g) Error Resolution Standards and Recordkeeping Requirements

1. Record retention requirements. As noted in §1005.33(g)(2), remittance transfer providers are subject to the record retention requirements under §1005.13. Therefore, remittance transfer providers must retain documentation, including documentation related to error investigations, for a period of not less than two years from the date a notice of error was submitted to the provider or action was required to be taken by the provider. A remittance transfer provider need not maintain records of individual disclosures that it has provided to each sender; it need only retain evidence demonstrating that its procedures reasonably ensure the sender’s receipt of required disclosures and documentation.

\[\text{§1005.31(g) and related commentary continue to apply to disclosures provided in accordance with §1005.36(a)(2).}\]


Richard Cordray,
Director, Bureau of Consumer Financial Protection.

[FR Doc. 2016–24506 Filed 10–11–16; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 740, 742, 744, 772, and 774

[Docket No. 140221170–6403–03]

RIN 0694–AF75

Revisions to the Export Administration Regulations (EAR): Control of Fire Control, Laser, Imaging, and Guidance Equipment the President Determines No Longer Warrant Control Under the United States Munitions List (USML)

AGENCY: Bureau of Industry and Technology, Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule describes how articles the President determines no longer warrant control under Category XII (Fire Control, Laser, Imaging, and Guidance Equipment) of the United States Munitions List (USML) of the International Traffic in Arms Regulations (ITAR) will be controlled under the Commerce Control List (CCL) of the Export Administration Regulations (EAR) by amending Export Control Classification Number (ECCN) 7A611 and creating new “600 series” ECCNs 7B611, 7D611, and 7E611. In addition, for certain dual-use infrared detection items, this final rule expands controls for certain software and technology, eliminates the use of some license exceptions, revises licensing policy, and expands license requirements for certain transactions involving military end users or foreign military commodities. This final rule also harmonizes provisions within the EAR by revising controls related to certain quartz rate sensors.

DATES: This rule is effective December 31, 2016.

FOR FURTHER INFORMATION CONTACT: For questions regarding the ECCNs included in this rule, contact Dennis Krepp, Office of National Security and Technology Transfer Controls, Bureau of Industry and Technology, Telephone: 202–482–1309, Email:
Warrant Control Under the United
President Determines No Longer
Guidance and Control Equipment the
Regulations (EAR): Control of Fire
''Revisions to the Export Administration
Reform'' (78 FR 22660, April 16, 2013),
Initial Implementation of Export Control
Export Administration Regulations:
Export Administration Regulations (EAR):
Control of Fire Control, Laser,
Imaging, and Guidance and Control
Equipment the President Determines No
Longer Warrant Control Under the
United States Munitions List (USML)”
(81 FR 8421) (“February 2016 rule”).
This second proposed rule was also
published in conjunction with a second
proposed rule published by DDTC to
propose new controls for USML
Category XII.
In response to the February 2016 rule,
BIS received twenty public comments.
Eleven commenters believed that the
February 2016 rule was an improvement
over the May 2015 rule, while no
commenters believed that the February
2016 rule was worse than the May 2015
rule. The commenters supported the
efforts, including the greater use of
“specially designed,” to reduce
controlling items in normal commercial
use in USML Category XII or the
corresponding 600 series entries in the
CCL. Further, many commenters noted
that the revisions in the February 2016
rule created a more transparent and
predictable structure and reduced
collision and complexity associated
with terminology proposed in the May
2015 rule. With the changes made in the
February 2016 rule, many commenters
believed that the proposals would better
balance national security concerns
while reflecting technological
advancement and the increasing
commercial market demand for many
items in the laser, photonics, optics,
infrared detection, and related
industries. Consequently, some
commenters stated that the February
2016 rule would help reduce current
and future competitive disadvantages
for U.S. industry and reduce the
incentive to offshore production and
research activities.
Some commenters also expressed
general concerns regarding the February
2016 rule. Many commenters believed
that the increased controls proposed for
infrared detection items were still too
strict, overly complicated, and not
reflective of foreign availability and
licensing policies of Wassenaar-member
countries and non-Wassenaar countries.
To address some of these concerns, BIS
is amending some of the proposed
controls, as described further herein.
Additionally, to address concerns on
complexity and increased costs of
compliance, especially for small
businesses, BIS will continue to conduct
extensive outreach to assist
organizations in their compliance
efforts. A summary of the public
comments and changes made to the
proposed rule are addressed below.
In this final rule, all references to the
USML are to the list of defense articles
that are controlled for the purpose of
export or temporary import pursuant to
the ITAR, and not to the defense articles
on the USML that are controlled by the
Bureau of Alcohol, Tobacco, Firearms
and Explosives (ATF) for the purpose of
permanent import under its regulations
(see 27 CFR part 447). Pursuant to
§ 38(a)(1) of the AECA, all defense
articles controlled for export or import
are part of the USML under the AECA.
For the sake of clarity, the list of defense
articles controlled by ATF for the
purpose of permanent import is the
United States Munitions Import List
(USMIL). The transfer of defense articles
from the ITAR’s USML to the EAR’s
CCL for the purpose of export controls
does not affect the list of defense articles
controlled on the USMIL under the
AECA for the purpose of permanent
import.
Revisions To Further Harmonize
and Simplify the EAR
The February 2016 rule included two
proposed changes to harmonize
provisions in the EAR—removing
controls related to certain QRS–11
sensors and revising license
requirements related to certain uncooled
thermal imaging cameras. This final rule
adopts the proposed changes for QRS–
11 sensors but does not adopt the
proposed changes for license
requirements related to uncooled
thermal imaging cameras.
Removal of Controls Specific to QRS–11
Sensors
As described in the February 2016
rule, BIS published a final rule in 2007
to control certain QRS–11 sensors that
were previously subject to the ITAR.
These sensors were originally designed
for military application but began to be
used in civil aircraft, which would have
required State Department authorization
for exports and reexports, as the ITAR
does not contain a de minimis level or a
general exception for controlled
content embedded within uncontrolled
systems. Since ECR accounts for the
movement of items from control on the
ITAR to control on the EAR, BIS
proposed to remove special controls
related to such QRS–11 sensors,
including removing the RS Column 1
control and references to such sensors

Dennis.Krepp@bis.doc.gov. For general
questions regarding the regulatory
changes, contact Steven Emme, Office of
the Assistant Secretary for Export
Administration, Telephone: 202–482–
5491, Email: Steven.Emme@bis.doc.gov.
SUPPLEMENTARY INFORMATION:
Background
This final rule is part of the
Administration’s Export Control Reform
Initiative (the “Initiative”), the objective
of which is to protect and enhance U.S.
national security interests. The Initiative
began in August 2009 when President
Obama directed the Administration to
conduct a broad-based review of the
U.S. export control system to identify
additional ways to enhance national
security. The Department of State’s
International Traffic in Arms
Regulations (ITAR) and its U.S.
Munitions List (USML) are being
amended to control only the items that
provide the United States with a critical
military or intelligence advantage or
otherwise warrant such controls, and
the Export Administration Regulations
(EAR) are being amended to control
military items that do not warrant
USML controls. These changes will
enhance national security by (i)
improving interoperability of U.S.
military forces with allied countries, (ii)
strengthening the U.S. industrial base
by, among other things, reducing
incentives for foreign manufacturers
to design out and avoid U.S.-origin content
and services, and (iii) allowing export
control officials to focus government
resources on transactions that pose
greater concern.

Pursuant to section 38(f) of the Arms
Export Control Act (AECA), the
President is obligated to review the
USML “to determine what items, if any,
no longer warrant export controls
under” the AECA. The President must
report the results of the review to
Congress and wait 30 days before
removing any such items from the
USML. The report must “describe the
nature of any controls to be imposed on
that item under any other provision of
law.” 22 U.S.C. 2778(0)(1).
Following the structure set forth in
the final rule entitled “Revisions to the
Export Administration Regulations:
Initial Implementation of Export Control
Reform” (78 FR 22660, April 16, 2013),
BIS published a proposed rule entitled
“Revisions to the Export Administration
Regulations (EAR): Control of Fire
Control, Range Finder, Optical, and
Guidance and Control Equipment the
President Determines No Longer
Warrant Control Under the United
States Munitions List (USML)” (80 FR
That proposed rule was published in
conjunction with a proposed rule
published by the Department of State’s
Directorate of Defense Trade Controls
/DDTC to propose controls for the
ITAR’s USML Category XII. After
reviewing public comments to the May
2015 rule, BIS published a second
proposed rule entitled “Revisions to the
Export Administration Regulations
(EAR): Control of Fire Control, Laser,
Imaging, and Guidance and Control
Equipment the President Determines No
Longer Warrant Control Under the
United States Munitions List (USML)”
(81 FR 8421) (“February 2016 rule”).

Simplify the EAR

Revisions To Further Harmonize

This second proposed rule was also
published in conjunction with a second
proposed rule published by DDTC to
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In response to the February 2016 rule,
BIS received twenty public comments.

Eleven commenters believed that the
February 2016 rule was an improvement
over the May 2015 rule, while no
commenters believed that the February
2016 rule was worse than the May 2015
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efforts, including the greater use of
“specially designed,” to reduce
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use in USML Category XII or the
corresponding 600 series entries in the
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that the revisions in the February 2016
rule created a more transparent and
predictable structure and reduced
collision and complexity associated
with terminology proposed in the May
2015 rule. With the changes made in the
February 2016 rule, many commenters
believed that the proposals would better
balance national security concerns
while reflecting technological
advancement and the increasing
commercial market demand for many
items in the laser, photonics, optics,
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general concerns regarding the February
2016 rule. Many commenters believed
that the increased controls proposed for
infrared detection items were still too
strict, overly complicated, and not
reflective of foreign availability and
licensing policies of Wassenaar-member
countries and non-Wassenaar countries.

To address some of these concerns, BIS
is amending some of the proposed
controls, as described further herein.
Additionally, to address concerns on
from ECCN 7A994, the 0% de minimis level for such sensors in § 734.4(a)(3), the restriction on the availability of license exceptions for such sensors in § 740.2(a)(9), references to the sensors in ECCNs 7E994 (Related Controls) and 9A991 (License Requirement Notes and Related Controls), and the reference to such sensors in Note 1 to the definition of “specially designed” in part 772.

BIS did not receive any public comments on QRS–11 sensors and thus adopts the changes as proposed in this final rule. To the extent that such sensors are not described on the USML, and the agencies do not believe that any of the sensors are described on the revised USML, one would follow the Order of Review in Supplement No. 4 to part 774 to determine whether the sensors may be captured under a 600 series ECCN or under a dual-use ECCN.

Retention of License Requirements and License Exception Eligibility for Certain Uncooled Thermal Imaging Cameras Controlled in ECCN 6A003

The February 2016 rule proposed to revise license requirements and license exception eligibility for certain uncooled thermal imaging cameras. Under the current provisions of § 742.6, the RS Column 1 reason for control in ECCN 6A003 does not apply to exports or reexports to countries in Country Group A:1 if certain uncooled thermal imaging cameras are fully packaged for use as consumer ready civil products or if such cameras with not more than 111,000 elements are to be embedded in civil products by authorized companies. Additionally, paragraph (b) of License Exception APR is available for such cameras when reexported to and among countries in Country Group A: 1 if certain uncooled thermal imaging cameras are fully packaged for use as consumer ready civil products or if such cameras with not more than 111,000 elements are to be embedded in civil products by authorized companies.

Two commenters expressed concerns about these proposed changes. One commenter stated that removing this authorization construct for such cameras would put U.S. industry at a competitive disadvantage with respect to companies in the European Union and Japan. The commenter noted that License Exception APR is not available for such cameras when reexported to and among countries in Country Group A: 1 if certain uncooled thermal imaging cameras are fully packaged for use as consumer ready civil products or if such cameras with not more than 111,000 elements are to be embedded in civil products by authorized companies. Additionally, paragraph (b) of License Exception APR is available for such cameras when reexported to and among countries in Country Group A: 1 if certain uncooled thermal imaging cameras are fully packaged for use as consumer ready civil products or if such cameras with not more than 111,000 elements are to be embedded in civil products by authorized companies.

One commenter further noted that if that change was not possible, then all items in 6A003 should be subject to an RS2 control rather than RS1 control due to foreign availability for such items and that the industry standard for number of elements has increased to 328,000. At this time, BIS is electing to maintain the current RS1 and RS2 controls for ECCN 6A003. BIS notes that the use of specially designed thermal imaging cameras, is sufficient at this time to address the commenters’ concerns.

Revisions To Increase Controls for Infrared Detection Items Subject to the EAR

To address the sensitivity of certain dual-use items related to infrared detection capability, the February 2016 rule included proposed restrictions for the export or reexport of several sensors and cameras, and related software and technology, that provide important night vision capability for military use but are also widely used in civil products and applications. This final rule adopts many of those proposals, with changes noted below, by amending §§ 734.6, 742.6, and 744.9 of the EAR. In addition, this final rule adds ECCN 0E987 and revises parts of ECCNs 0A987, 6A002, 6A003, 6A990, 6A993, 6D002, 6D003, 6D991, 6E001, 6E002, and 6E990.

Revisions to End-Use/End-User Controls in § 744.9

Section 744.9 requires a license for the export or reexport to any destination other than Canada for cameras controlled by ECCNs 6A003.b.3, 6A003.b.4.b, or 6A003.b.4.c when the exporter or reexporter knows or is informed that the item is intended to be used by a military end-user or to be incorporated into a military commodity controlled by ECCN 0A919, in addition to other applicable license requirements in the EAR.

The February 2016 rule proposed to revise § 744.9 to require a license for exports, reexports, or transfers (in-country) of commodities controlled by ECCNs 0A987 (incorporating items in ECCNs 6A002 and 6A003, or certain cameras in 6A003.a, 6A002, 6A003, 6A990, 6A993.a commodities meeting the criterion of Note 3.a to 6A003.b.4), 8A002.d.1.c. and 8A002.d.2., when the exporter, reexporter, or transferee knows or is informed that the item is intended to be used by a military end-user or to be incorporated into a military commodity controlled by ECCN 0A919. This final rule adopts these changes to § 744.9 with changes described below.

Three commenters made recommendations to address concerns regarding the proposed expansion of § 744.9. Two commenters requested that 9 Hz cameras in 6A993.a be removed from the scope of § 744.9. They asserted that including 9 Hz cameras would put U.S. companies at a competitive disadvantage since all other countries do not consider them to be dual use. Also, one of the commenters mentioned that adding 9 Hz cameras would greatly increase complexity and burden since such cameras are often low-cost consumer goods available through distributors and retail. Also, the commenter was unaware of any 9 Hz cameras being used in military commodities and recommended focusing § 744.9 only on those commodities that are easily incorporated into other items. BIS notes that while the commenter’s 9 Hz cameras may not be ideal for incorporation into a foreign military commodity, the U.S. Government is aware of 9 Hz cameras being used and advertised in foreign military commodities. Also, BIS believes that the end-use and end-user based controls in § 744.9 are sufficiently tailored to have less impact on U.S. companies as one must know or have reason to know that such items will be used by a military...
end user or incorporated into a foreign military commodity. However, to further narrow the scope of the control and provide greater clarity, BIS is adding new paragraph (a)(2) to note that the license requirement of § 744.9 does not apply to exports, reexports, or transfers (in-country) when the items described above are being exported, reexported, or transferred as part of a military deployment by a unit of the government of a country in Country Group A.1 (see Supplement No. 1 to part 740). Similar language is currently used in § 742.6(a)(3).

One commenter recommended removing the license requirement based on military end user but maintaining the license requirement based on incorporation into a foreign military commodity. The commenter noted that the control based on military end user can be confusing since the same item being used for the same purpose would not require a license in one scenario (e.g., security camera for a factory) but would require a license in another scenario (e.g., security camera for a military installation). BIS believes that the addition of paragraph (a)(2) will help partially address this concern. However, BIS is maintaining the license requirement based on military end user since it is a defined term, and BIS believes it is appropriate to require a license in such circumstances.

This final rule also makes additional conforming changes to § 744.9. On September 20, 2016, BIS published a final rule (81 FR 64656) revising the CCL to image changes to the Wassenaar Arrangement’s List of Dual-Use Goods and Technologies. As part of these revisions, BIS amended ECCN 8A002 to remove items previously controlled in 8A002.d.1.c and redesignate items previously controlled in 8A002.d.2 as 8A002.d. Since the February 2016 rule proposed that 8A002.d.1.c and d.2 items be subject to the license requirement of § 744.9, this final rule revises § 744.9 to refer to 8A002.d rather than 8A002.d.1.c and d.2. Further, this final rule makes one clarifying change to § 744.9. In order to more accurately describe the scope of the license requirement, this final rule revises the title of § 744.9 to “[r]estrictions on exports, reexports, and transfers (in-country) of certain cameras, systems, or related components.”

Revisions to ECCN 0A919 and § 734.4 for Foreign Military Commodities

ECCN 0A919 controls “military commodities” produced and located outside the United States that are not subject to the ITAR and incorporate one or more cameras controlled under ECCNs 6A003.b.3, 6A003.b.4.b, or 6A003.b.4.c. In addition, ECCN 0A919 controls such “military commodities” if they incorporate more than a de minimis amount of U.S.-origin 600 series content or are the direct products of U.S.-origin 600 series technology or software.

The February 2016 rule proposed to control the reexport of such military commodities that incorporate a wider group of infrared detection items on the CCL. Thus, the February 2016 rule proposed to re-structure the sub-paragraphs in the Items paragraph in that ECCN and expand 0A919 to control military commodities produced outside the United States that are not subject to the ITAR and incorporate commodities classified under ECCNs 6A002, 6A003, 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz as and thus meeting the criterion specified in Note 3.a to ECCN 6A003.b.4.b). BIS received no public comments on these changes, and this final rule maintains the proposed expansion of the scope of ECCN 0A919 with the clarification described below.

Section 734.4(a)(5) of the EAR currently provides that there is no de minimis level for foreign military commodities, i.e., those described in ECCN 0A919, that incorporate certain infrared detection items. The February 2016 rule proposed to amend the de minimis treatment for 0A919 items incorporating infrared detection content to make them consistent with 0A919 items incorporating 600 series content by limiting the 0% de minimis level to Country Group D:5 only. BIS received no public comments on this proposed revision. Thus, this final rule amends § 734.4(a)(5) to provide that there is no de minimis level for foreign-made military commodities incorporating one or more of the commodities described in ECCN 0A919.a.1 when destined for a country in Country Group D:5. When destined for a country outside of Country Group D:5, such 0A919 commodities would be subject to the 25% de minimis threshold. To reflect this change to § 734.4(a)(5), this final rule also revises 0A919.a.1 to clarify that the sub-paragraph captures foreign-made military commodities that “[i]ncorporate more than a de minimis amount of U.S.-origin controlled content classified under ECCNs 6A002, 6A003, 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion of Note 3.a to 6A003.b.4).”

Revisions to ECCN 0A987 and Establishment of ECCN 0E987

ECCN 0A987 controls certain optical devices for firearms and related components. The February 2016 rule proposed to revise ECCN 0A987 to specify that the entry controls laser aiming devices or laser illuminators “specially designed” for use on firearms, and having an operational wavelength exceeding 400 nm but not exceeding 710 nm. A proposed note to ECCN 0A987.f further specified that the entry does not control laser boresighting devices that must be placed in the bore or chamber to provide a reference for aligning the firearms sights. BIS received no public comments on these proposed changes and thus adopts them in this final rule.

The February 2016 rule also proposed to revise the Related Controls to refer readers to applicable controls in USML Category XII as well as the proposed license requirement for certain 0A987 items under § 744.9. BIS received no public comments on revisions to the Related Controls. This final rule amends the Related Controls paragraph to reflect revisions in the Department of State’s final rule regarding controls for weapons sights to advise that sighting devices using second generation image intensifier tubes having luminous sensitivity greater than 350 μA/lm, or third generation or higher image intensifier tubes, are subject to the ITAR. Moreover, this final rule adds a reference in the Related Controls to riflescopes subject to the ITAR under USML Category II(f). This final rule also retains the reference to the § 744.9 license requirement since that license requirement is being adopted under this final rule.

The February 2016 rule further proposed creating a new ECCN for technology required for the “development” or “production” of commodities controlled by ECCN 0A987, if such commodities incorporate a focal plane array or image intensifier tube. Such technology would be subject to RS Column 1 and Anti-Terrorism (AT) Column 1 controls. BIS received no public comments on this proposal and thus adopts the establishment of ECCN 0E987 as proposed.

Revisions to ECCN 6A002

ECCN 6A002 controls specified optical sensors or equipment and components therefor. The February 2016 rule proposed to maintain the existing reasons for control and did not include a worldwide BIS control that was first proposed in the May 2015 rule. Also, the February 2016 rule proposed
to add a reference to corresponding controls for focal plane arrays, image intensifier tubes, and related parts and components in USML Category XII(e) and a reference to the proposed license requirement in §744.9. This final rule makes those changes to 6A002, but clarifies that the type of focal plane arrays controlled in Category XII(e) are primarily infrared focal plane arrays. This final rule also adds a reference in the Related Controls to refer readers to space-qualified focal plane arrays subject to the ITAR in USML Category XV(e) to help readers understand the potential jurisdiction of various types of focal plane arrays. Additional limitations on the use of license exceptions for 6A002 items are addressed further herein.

BIS received five public comments on proposed changes to ECCN 6A002. One commenter supported the removal of the aforementioned worldwide RS control. Another commenter stated that it was unclear what two-dimensional focal plane arrays will be EAR99 or controlled on the CCL. Focal plane arrays are controlled based on the technical parameters in ECCN 6A002.

Two commenters requested that BIS evaluate whether square pixel one-dimensional focal plane arrays with a peak response in the wavelength range exceeding 1200 nm but not exceeding 3000 nm should be controlled in 6A002.a.3.d since they are used almost exclusively for commercial applications and are similar to other focal plane arrays that are EAR99.

Removing these square pixel focal plane arrays from 6A002 would require multilateral agreement at the Wassenaar Arrangement and thus exceeds the scope of this rule. However, commenters are welcome to submit additional information to BIS to help inform further discussion on whether a Wassenaar proposal to amend this ECCN is warranted.

Two commenters stated that BIS should carve out civil automotive focal plane arrays from being controlled under ECCN 6A002. The commenters asserted that this change would be consistent with other CCL technologies when used for civil automotive applications and would help ensure further research and development into collision avoidance systems. BIS does not accept this recommendation because such a change would require agreement with Wassenaar members and thus exceeds the scope of this rule. However, commenters are welcome to submit additional information to BIS to help inform further discussion on whether a Wassenaar proposal to amend this ECCN is warranted.

Revisions to ECCN 6A003

ECCN 6A003 controls specified cameras, systems or equipment and components therefor. As previously described, this final rule does not adopt the proposed changes to the authorization construct for certain uncooled thermal imaging cameras. Thus, this final rule does not amend the reasons for control in 6A003.

The February 2016 rule proposed to include additional changes to 6A003, such as adding a reference to USML Category XII and revising the reference to the license requirement in §744.9. BIS received no comments on these changes, and thus adopts them in this final rule. However, this final rule updates the reference to the ITAR in order to point out that cameras subject to the ITAR are found in USML Category XII(c) and (e). In addition, BIS is adding a License Requirement Note to provide further clarification on what constitutes a “camera” for purposes of classifying items under 6A003. The License Requirement Note provides that “[c]ommodities that are not subject to the ITAR but are of the type described in USML Category XII(c) are controlled as cameras in ECCN 6A003 when they incorporate a camera controlled in this ECCN.” This note is consistent with Interpretation 2 in §770.2, confirms BIS’s existing classification practice for items in 6A003, and is intended to link the more specific terminology of USML Category XII with the Wassenaar-based terminology of 6A003.

Three commenters also provided feedback and recommendations on other aspects of 6A003. One commenter was concerned that researchers may be burdened with additional license requirements for items deployed internationally for field research due to the removal of STA. BIS notes that this final rule does not remove STA availability for 6A003 items being exported or reexported to countries in Country Group A:5. The commenter also supported keeping the related technology control for “use” technology unchanged. While this rule does affect STA availability for related technology (see further below), the commenter is correct that all six elements of the definition of “use” technology must be met for that control to apply.

One commenter also requested that BIS revise 6A003 so that certain line-scan cameras incorporating one-dimensional square pixel focal plane arrays would not be controlled under 6A003. The commenter stated that such cameras are commonly used for commercial use. Another commenter requested that BIS add a note to exclude civil automotive infrared focal plane array systems from control under ECCN 6A003. As with the comments regarding similar items in 6A002, these changes to 6A003 would require agreement with Wassenaar members and exceed the scope of this rule. However, commenters are welcome to submit additional information to BIS to help inform further discussion on whether a Wassenaar proposal to amend this ECCN is warranted.

Revisions to ECCNs 6A990 and 6E990

ECCN 6A990 controls certain read-out integrated circuits (ROICs) that enable 3D automotive imaging and ranging. The February 2016 rule proposed to expand the scope of ROICs controlled under that ECCN by controlling ROICs that are specially designed for focal plane arrays controlled under ECCN 6A002.a.3. Such ROICs would be subject to an RS1 control but would be eligible for License Exception LVS. However, under the proposed rule, ROICs specially designed for civil automotive applications would not be controlled under 6A990.

One commenter expressed support for controlling ROICs “specially designed” for 6A002.a.3 focal plane arrays under the EAR rather than the ITAR. However, three commenters also expressed concerns or requested clarification on the proposals for ROICs in 6A990. One commenter opposed expanding the scope of 6A990 to include certain non-ITAR ROICs that are currently EAR99.

The commenter cited foreign availability for such ROICs that today may be exported without a license. BIS believes that expanding the scope of 6A990 is warranted to address military applications of dual-use ROICs. Also, BIS believes that industry will benefit from the clearer bright line control for ROICs in the State Department’s final rule, which should reduce the possibility of commercial ROICs becoming controlled under the ITAR. With respect to foreign availability, BIS plans to work with its interagency colleagues to propose a control for ROICs on the Wassenaar Arrangement Dual-Use List.

One commenter expressed confusion regarding the proposed note carving out ROICs specially designed for civil automotive applications from control under 6A990. The commenter believed that most or all ROICs used in civil automotive applications are part of general purpose infrared focal plane arrays that are used in numerous applications. Thus, it was unclear how a ROIC could be specially designed for only civil automotive applications. As a result of reviewing commodity...
jurisdiction determinations, BIS believes that there are ROIcs that have been specially designed for civil automotive applications. To the extent that a ROIC is specially designed for a general purpose focal plane array controlled under 6A002, then it would be controlled under 6A990.

One commenter also recommended that all ROIcs specially designed for civil applications be excluded from control under 6A990. For the reasons described above regarding concern over military applications and the added benefit of clarity of the potential impact of the ITAR on commercial ROIcs, BIS does not accept this recommendation. commercial ROIcs should be EAR99 and requested clarification on how commercial ROIcs would be controlled under the February 2016 rule. Under this final rule, ROIcs that are not ITAR controlled (i.e., are not infrared focal plane array ROIcs specially designed for a defense article) would be controlled under 6A990 if they are specially designed for a focal plane array in 6A002.a.3. If a ROIC is not specially designed for a 6A002.a.3 focal plane array, then the ROIC would be designated EAR99. Also, if a ROIC is specially designed for civil automotive applications, then the ROIC would also be designated EAR99.

One commenter also stated that the $500 LVS exception is reasonable but requested clarification on whether the value limit would apply to each ROIC or to a wafer of ROIcs. The $500 value limit does not apply to an individual ROIC or a wafer of ROIcs but rather to the actual total selling price of all 6A990 ROIcs in the same order. Section 740.3 describes the terms and conditions of using License Exception LVS, including the requirements for valuing the commodities at issue. In addition to properly valuing the order, orders may not be split to meet the applicable value limit, and the total value of exports per calendar year to the same ultimate or intermediate consignee may not exceed twelve times the value limit.

For the reasons stated above, this final rule revises ECCN 6A990 as proposed in the February 2016 rule, with one addition to the Related Controls paragraph. Since the ITAR also controls ROIcs under Category XVI(e)(3), this final rule adds a reference to those ROIcs as well as those controlled under Category XII(e). Also, since this final rule adopts the changes to §744.9 and 0A919, this final rule also maintains reference to those provisions in the Related Controls of this ECCN. Finally, additional limitations on the use of license exceptions for this ECCN are addressed further herein.

ECCN 6E990 controls technology required for the development or production of ROIcs controlled in 6A990. The February 2016 rule proposed to revise the Related Controls paragraph to reference the corresponding USML control for technical data directly related to ROIcs described in Category XII. BIS received no public comments on this revision and adopts it in this final rule, but makes one corresponding change. Since this final rule revises the Related Controls paragraph of 6A990 to refer to ROIcs controlled under Category XV, this final rule also refers to the applicable technical data control in Category XV for such ROIcs.

Revisions to 6A993

ECCN 6A993 controls cameras in 6A993.a having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion specified in Note 3.a to ECCN 6A003.b.4.b. The February 2016 rule proposed to revise the Related Controls paragraph to remind readers of the applicability of §744.9 and ECCN 0A919 to 9 Hz cameras. Since this final rule revises §744.9 and ECCN 0A919 to add 9 Hz cameras to those provisions, this final rule adopts the proposal to add references to those provisions in the Related Controls paragraph of 6A993.

BIS did not receive public comments on the Related Controls paragraph, but did receive two comments related to 6A993. One commenter stated that 6A993 should control cameras having an operating speed of 60 Hz or less and incorporating a focal plane array in 6A003.b.4.b with a maximum of 328,000 elements or less. BIS rejects this recommendation as this would require agreement with Wassenaar members and is beyond the scope of this rule. One commenter expressed concerns that 6A993 items could be pulled into the ITAR due to the use of specially designed for infrared focal plane arrays in the State Department’s second proposed rule. While the State Department’s final rule addresses this issue, BIS notes that the intent was to control uniquely military infrared detection items (even comparatively lower performing military items) on the ITAR; therefore the EAR controls the commercial and dual-use infrared detection items. Thus, the commenter’s concern is correct, but that was intended under the February 2016 rules as well as under these final rules.

Revisions to ECCNs 6D002, 6D003, and 6D991

The Wassenaar Arrangement’s List of Dual-Use Goods and Technologies imposes limited controls on software related to commodities controlled under ECCNs 6A002 and 6A003. As a result, the CCL currently has the following multilateral and unilateral software controls related to such items: ECCN 6D002 (software specially designed for the use of commodities controlled under ECCN 6A002.b), ECCN 6D003.c (software designed or modified for cameras incorporating focal plane arrays specified by ECCN 6A002.a.3.f and designed or modified to remove a frame rate restriction and allow the camera to exceed the frame rate specified in ECCN 6A003.b.4 Note 3.a), and ECCN 6D991 (software, n.e.s., specially designed for the development, production, or use of commodities controlled under ECCN 6A002.a.1.d or 6A990).

To address concerns regarding the lack of comprehensive software controls related to commodities controlled under ECCNs 6A002 and 6A003, the February 2016 rule proposed to consolidate existing, unilateral software controls and expand them to revise ECCN 6D991 to also control software, not elsewhere specified, that is specially designed for the development, production, or use of commodities controlled by ECCNs 6A002 or 6A003. The February 2016 rule proposed to make such software subject to the RS Column 1 reason for control. Also, the February 2016 rule proposed to remove eligibility to use License Exception TSR for the software described above in ECCNs 6D002 and 6D003.c. To prevent confusion over multiple ECCNs potentially controlling the same software, the February 2016 rule proposed to add language to the Related Controls paragraphs of ECCN 6D991 to confirm that software currently controlled under ECCNs 6D002 and 6D003.c would remain controlled under those provisions. To reflect this understanding, the February 2016 rule also proposed to revise the Related Controls paragraphs of ECCNs 6D002 and 6D003 to provide references to ECCNs 6D991.

Four commenters expressed concerns about the proposed revisions to the software controls described above. Two commenters recommended removing “use” software for 6A002 and 6A003 commodities from the scope of ECCN 6D991. One of those commenters stated that software field upgrades would be more challenging and costly, which would put U.S. suppliers at competitive disadvantage. The other commenter mentioned that even though...
typical operation software would be unlikely to meet all six elements of the definition of “use,” the control could create confusion. BIS agrees with the second commenter that it is unlikely that operation software would meet all six elements of “use.” Further, BIS believes that it is unlikely that software for field upgrades, which would likely be focused on camera maintenance, would include all six elements of “use” and thus be controlled. Therefore, BIS does not accept this recommendation.

Another commenter expressed concerns that the proposed expansion of 6D991 could affect software used in the production and testing of 6A003 and possibly 6A993 items, but the commenter noted it was unclear the extent to which the controls would apply to certain types of software due to difficulty in applying the definition of “specially designed” in the context of software. The commenter also expressed concerns on needing to get a license to provide field testing software to service centers. BIS notes that the intent of expanding 6D991, among other things, was to include software specially designed for the production of 6A003 cameras. This does not include software used for testing 6A003 cameras for purposes outside of the production or development process. Therefore, BIS believes that the scope of control in 6D991 is appropriate. With respect to applying the definition of “specially designed” to software, BIS notes that any software would be caught by paragraph (a) if it achieves the parameters described in the relevant USML or CCL entry as a result of “development” or if it is used in or with a commodity enumerated on the CCL or USML. Software is, however, eligible for the paragraph (b) releases. For example, if software used for the production of a controlled item has the same function, performance capabilities, and the same or equivalent form and fit, as software used in the production of an item controlled for AT reasons only, then such software would qualify for the release under paragraph (b)[5]. Note to paragraph (b)[3] also provides guidance on interpreting “form,” “fit,” “function,” and “performance capability” with respect to software. Finally, with respect to software for field testing centers, such software would have to meet all six elements of the definition of “use” in order to be controlled in 6D991.

One commenter stated that software used to operate a camera should be EAR99 and further expressed concern that a license would be required for software that interfaces with the arrays for either manufacturing or testing applications. Under the February 2016 proposed rule and this final rule, software simply used to operate a camera would not be controlled under 6D991 and would be EAR99. Again, all six elements of the “use” definition must be met in order to be considered “use” software under 6D991. In addition, BIS reiterates that software used for testing outside of the production or development process would not be captured by 6D991.

Software that is used to test during the production or development process and that meets the definition of “specially designed” would be controlled by 6D991.

One commenter opposed removing the ability to use License Exception TSR for 6D002 (software “specially designed” for the “use” of commodities controlled under ECCN 6A002.b) and 6D003.c. The commenter cited concerns about U.S. competitiveness and working cooperatively in Wassenaar countries. BIS believes that U.S. competitiveness will be greatly improved by the bright line approach in the State Department’s final rule for USML Category XII, which makes clear that commercial items (and related technology and software) are not generally intended to be controlled under the ITAR. BIS believes that removing TSR eligibility for these ECCNs is warranted.

This final rule revises ECCNs 6E001 and 6E002 as proposed, but amends the availability of License Exception TSR for certain technology related to 6A003 cameras. That change is described further below in response to public comments regarding License Exception STA.

Addition to Section 740.2

Section 740.2 sets forth restrictions on all license exceptions, and the February 2016 rule proposed a new restriction in §740.2(a)(7) that would apply to 6E001 or 6E002 technology required for the development or production of the following focal plane arrays: Photon detector, microbolometer detector, pyroelectric, or multispectral detector infrared focal plane arrays (IRFPAs), described in ECCN 6A002, having a peak response within the wavelength range exceeding 900 nm but not exceeding 3,000 nm, excluding lead sulfide or lead selenide infrared focal plane arrays having a peak response within the wavelength range exceeding 1,000 nm but not exceeding 5,000 nm and not exceeding 16 detector elements. Moreover, under the February 2016 rule, §740.2(a)(7) would apply to 6E001 or 6E002 technology required for the development or production of third generation image intensifier tubes or image intensifier tubes greater than third generation (e.g., EBAPS). BIS received no public comments on this provision and adopts it in this final rule. To provide further clarity, this final rule includes the full name for EBAPS, Electron Bombarded Active Pixel Sensor. As mentioned in the February 2016 rule and adopted in this final rule,
the 6E001 and 6E002 technology described above will be eligible for License Exception GOV under § 740.11(b)(2) of the EAR.

**Restrictions on the Use of License Exception APR**

License Exception APR currently authorizes specified reexports of items subject to the EAR by certain countries to specified destinations without individual licenses from BIS. The February 2016 rule proposed to increase the number of items ineligible for § 740.16(b) by including all items in ECCNs 6A002, 6A003, and 6A990 in the restrictions found in paragraph (a)(2) of that section. BIS received one general comment that opposed any reduction in the availability of license exceptions, but the commenter did not address any specific concerns regarding APR.

Consequently, BIS adopts the changes proposed for paragraph (a) of APR in this final rule and makes only slight revisions to that paragraph for clarity. As previously mentioned, this final rule retains the license requirement and license exception construct for certain uncooled thermal imaging cameras. This construct includes provisions in paragraph (b) of APR. However, this final rule adopts the non-substantive changes to paragraph (b) that were proposed in the February 2016 rule and rearranges the list of items to make the text clearer. BIS received no comments on the clarifying, non-substantive changes to § 740.16(b) and adopts them in this final rule while keeping the existing special provision for certain uncooled thermal imaging cameras in § 740.16(b)(3).

**Restrictions on the Use of License Exception STA**

Section 740.20(b)(2)(x) restricts the use of License Exception STA for specific commodities controlled by ECCN 6A002, as well as related technology controlled by 6E001 or 6E002. The February 2016 rule proposed to expand that restriction to include all items in the following ECCNs: 6A002; 6A990; 6D002 (for the use of commodities controlled under ECCN 6A002); 6D003.c; 6D991 (for the development, production, or use of commodities controlled under ECCNs 6A002, 6A003, or 6A990); 6E001 (for the development of commodities controlled under ECCNs 6A002 or 6A003); 6E002 (for the production of commodities controlled under ECCNs 6A002 or 6A003); and 6E990. Additionally, the February 2016 rule proposed to add new ECCN 6E990 (ROICs) to the list of items restricted from STA under § 740.20(b)(2)(ii).

Three commenters expressed concerns with those proposed restrictions. One commenter recommended that STA be allowed for all items in 6A002 and 6A990. The commenter noted that doing so would be consistent with continuing to allow STA for 6A003 cameras. Also, the commenter believed this restriction would put U.S. companies at a competitive disadvantage due to foreign availability for such items for which there are less restrictive controls, and that some development technology for 6A990 read-out integrated circuits (ROICs) is already publicly available. The commenter also noted that ROICs not subject to the ITAR have historically been EAR99. BIS does not accept this recommendation at this time. Items controlled in 6A002 and 6A990, while dual use, have important military applications, and thus removal of STA eligibility is warranted. However, after the effective date of this rule, BIS will assess licensing volumes and re-evaluate whether a change to STA eligibility is necessary. Further, BIS notes that while some items in 6A002 are only subject to NS2 and AT controls, so STA would not be needed to export or reexport to countries in Country Group A:1.

In addition to opposing the removal of STA for 6A002 and 6A990, one commenter also opposed the license exception's removal for ECCNs 6D002, 6D003, 6D991, 6E001, and 6E002. The commenter stated removing STA would hurt U.S. competitiveness, harm the ability to work internally and cooperatively within affiliates in Wassenaar countries, increase administrative burden, and could require licenses for providing field testing software to service centers. As previously mentioned, BIS believes that this software and technology has important military applications, and thus excluding the use of STA is warranted. Also, BIS believes that U.S. competitiveness will be greatly improved by the bright line approach in the State Department’s final rule for USML Category XII, which makes clear that commercial items (and related technology and software) are not generally intended to be controlled under the ITAR. With respect to providing field testing software, BIS believes that such software is unlikely to meet the definition of “use” and unlikely to be controlled under ECCNs 6D002, 6D003, or 6D991.

One commenter requested that BIS allow STA for 6E001 and 6E002 technology for civil automotive far infrared night vision systems at the camera level. The commenter mentioned that the company has used STA when civil automotive vehicle manufacturers have required audits on products and manufacturing, which includes sharing design and manufacturing technology with non-U.S. nationals. BIS accepts this recommendation in part. This final rule revises § 740.20(b)(2)(x) to remove STA eligibility as described in the February 2016 rule. However, this final rule revises the eligibility to use License Exception TSR under ECCNs 6E001 and 6E002 to allow technology for the integration of 6A003 cameras into camera systems specially designed for civil automotive applications. Under this change, this technology may be released to Country Group B destinations or nationals so long as all terms and conditions of TSR are complied with, including obtaining a written assurance. This ability to use TSR is limited to specific 6E001 or 6E002 technology related to 6A003 cameras, and does not apply to 6E001 or 6E002 technology related to 6A002 items within the 6A003 cameras.

**Revisions to Licensing Policy**

As previously mentioned, this final rule retains the provisions in § 742.6 that apply to the authorization construct for certain uncooled thermal imaging cameras. However, the February 2016 rule also proposed revisions to licensing policy for items controlled for RS reasons by revising § 742.6(b)(1) to include new licensing policy for 6E001 or 6E002 technology for the development or production of focal plane arrays or image intensifier tubes described in 6A002, or for 6E990 technology. Under the February 2016 rule, such technology would be subject to a presumption of denial for license applications for exports or reexports to countries in Country Group D:5. BIS received no public comments on this proposal and is adopting the proposed changes to § 742.6(b)(1) in this final rule.

BIS is also removing the heading in § 742.6(b)(1)(i), which was proposed in the February 2016 rule to read “9x515 and ‘600 series’ ECCNs.” BIS is making this change because that paragraph applies to more than just 9x515 and 600 series items. Finally, as described below under ECCN 7E611, this final rule removes the proposed worldwide RS control for 7E611.a, and thus removes proposed § 742.6(a)(8) and references to that paragraph in § 742.6(b)(1).
Establishment of “600 Series” for Military Fire Control, Laser, Imaging, and Guidance Items Under ECCNs 7A611, 7B611, 7D611, and 7E611

The May 2015 rule proposed establishing two separate 600 series controls in 6X615 and 7X611. The February 2016 rule proposed to consolidate those entries and establish a single “600 series” by revising ECCN 7A611 and adding new ECCNs 7B611, 7D611, and 7E611 for military fire control, laser, imaging, and guidance and control commodities, software, and technology. Two commenters supported this simplified structure, and this final rule adopts the proposed consolidation of 600 series controls under 7X611 ECCNs.

Since categories 6 and 7 of the CCL currently control certain laser, imaging, and guidance items, the February 2016 rule also proposed to amend ECCN 6A611 to refer readers to Category 7 to locate the appropriate controls. BIS received no comments on this revision. This final rule revises 6A611 to add the reference to 7A611, but this final rule revises the term “guidance and control” to “guidance” to conform to changes made in the State Department’s final rule. References to “control” are similarly removed throughout these 600 series entries to conform to the State Department’s final rule.

Three commenters provided comments on these proposed 600 series entries. Revisions to the proposed 600 series ECCNs are described below.

Establishment of ECCN 7A611

As described in the February 2016 rule, ECCN 7A611 would control military fire control, laser, imaging, and guidance and control equipment that would be removed from USML Category XII and that are not covered by an existing ECCN subject to controls for reasons other than AT reasons. This includes controlling certain guidance, navigation, or control systems; inertial measurement units; accelerometers; gyro or angular rate sensors; and gravity meters (gravimeters) in paragraphs .a through .e. Paragraph .x would control parts, components, accessories, and attachments that are specially designed for a commodity controlled by ECCN 7A611 (except 7A611.y) or a defense article in USML Category XII and not controlled elsewhere on the USML or in 7A611.y or 3A611.y. All items that would be controlled under 7A611.a–.x would be controlled for NS, RS, AT, and UN reasons. Paragraph .y, which would be controlled for AT reasons, would control specific parts, components, accessories, and attachments specially designed for a commodity subject to control in ECCN 7A611, or a defense article in USML Category XII and not elsewhere specified on the USML or in the CCL, and parts, components, accessories, and attachments specially designed therefor. The February 2016 rule did not include any items in 7A611.y. This final rule revises ECCN 7A611 with revisions to the February 2016 proposed rule as described below.

Two commenters provided recommendations or requested clarification on ECCN 7A611. One commenter pointed out that certain dual-use items controlled in CCL Category 7 may become controlled under 7A611 because such dual-use items would not qualify for the release in paragraph (b)(3) of the definition of “specially designed,” which applies to parts, components, accessories, or attachments that have the same function, performance capabilities, and the same or equivalent form and fit, as a commodity used in or with an item that is or was in production and is either not enumerated on the CCL or USML, or is described in an ECCN controlled only for AT reasons. Since many of the Category 7 parts and components are incorporated into Category 7 assemblies that are subject to NS or MT reasons, such parts and components would not be eligible for the (b)(3) release of specially designed.

To address this concern, BIS is revising and restructuring 7A611.x to specify that 7A611.x does not control items described in ECCNs 6A007, 6A107, 7A001, 7A002, 7A003, 7A101, 7A102, or 7A103. Essentially, this revision is an exception to the normal process of the Order of Review in which 600 series entries normally take precedence over dual-use entries in the CCL. BIS believes this change is warranted to address the concern raised by the commenter, and BIS believes that the dual-use controls provide sufficient levels of control to capture military items previously in USML Category XII that meet the parameters in one of the dual-use ECCNs listed above. As part of this change, BIS is also removing the entries that were proposed in 7A611.b–.e for inertial measurement units, accelerometers, gyro or angular rate sensors, and gravity meters (gravimeters). These items will be controlled under 7A611.x to the extent that they are specially designed and not controlled under the list of dual-use ECCNs in 7A103.b. BIS also adds text to 7A611.x to specifically name such items.

One commenter also questioned why 7A611 does not include the missile technology (MT) reason for control. BIS concurs that MT should be added to 7A611, and this final rule adds that control to the ECCN for commodities in 7A611.a that meet or exceed the parameters in 7A103.b or .c. Also, with the change described above to 7A611.x, ECCNs 6A107, 7A101, 7A102, and 7A103 will address those other items potentially controlled for MT reasons.

One commenter recommended that infrared optical elements, such as optical blanks and lenses, should not be controlled using “specially designed” under 7A611.x. Instead, the commenter believed that only certain germanium blanks and infrared lenses with certain resistivity should be controlled in 7A611. The commenter believed that all other optics blanks and infrared lenses should be EAR99. To support these recommendations, the commenter stated that applying “specially designed” would be burdensome since many of these products are made according to customer specifications and may have overlapping size, curvature, and fit requirements among both military and commercial customers. The commenter also believed that such controls would be more restrictive than the EU’s export control regime. BIS believes that the commenter’s recommended controls would not capture all optical blanks and infrared lenses that warrant control. Further, it is BIS’s understanding that such items would be controlled under ML 15 of the Wassenaar Arrangement if they are specially designed. Therefore, BIS does not accept this recommendation. To the extent that optical blanks or infrared lenses meet the definition of “specially designed,” they would be controlled under 7A611.x.

BIS is also making additional conforming changes. This final rule revises the Related Controls paragraph to add references to ECCNs 6A107 and 7A103 since those ECCNs control related items. Also, this final rule removes the sentence in the Related Controls regarding navigation and avionics equipment specially designed for military application. In the February 2016 rule, that sentence referred readers to ECCN 3A611, which is incorrect. Such equipment is currently controlled in ECCN 9A610. Additionally, this final rule removes the word “control” from “guidance, navigation, and control systems” in 7A611.a and from the first sentence in the Related Controls to conform with changes made to the State Department’s final rule.
Establishment of 7B611

The February 2016 rule proposed creating ECCN 7B611 to impose controls on test, inspection, and production equipment and related commodities specially designed for military fire control, laser, imaging, and guidance and control equipment. Paragraph .a would control such equipment specially designed for the development, production, repair, overhaul, or refurbishing of items controlled in ECCN 7A611 (except 7A611.y) or commodities in USML Category XII that are not enumerated in USML Category XII or controlled by a 600 series ECCN. Paragraph .b would control environmental test facilities specially designed for certification, qualification, or testing of commodities controlled in ECCN 7A611 (except 7A611.y) or commodities in USML Category XII that are not enumerated in USML Category XII or a 600 series ECCN. Paragraph .c would control field test equipment specially designed to evaluate or calibrate the operation of systems described in USML Category XII(a), (b), or (c). Paragraph .x would control parts, components, accessories, and attachments that are specially designed for such test, inspection and production equipment that are not enumerated on the USML or controlled by another 600 series ECCN. Items in ECCN 7B611 would be controlled for NS, RS, AT, and UN reasons.

BIS did not receive any public comments specific to ECCN 7B611. This final rule adopts the proposal to add 7B611 to the CCL, with three conforming changes. First, as previously mentioned, this final rule is revising references to “guidance and control” to just “guidance.” This final rule makes that change in the heading of the ECCN. Second, this final rule adds an MT control for 7B611.a commodities specially designed for 7A611.a commodities controlled for MT reasons. This change is being made to correspond to the addition of an MT control in 7A611.

Establishment of 7E611 and Revisions to § 742.6 for Licensing 600 Series Items

The February 2016 rule proposed adding ECCN 7E611 to control technology required for the development, production, operation, installation, maintenance, repair, overhaul, or refurbishing of items controlled by 7A611, 7B611, or 7D611. Such technology would be controlled for NS, RS, AT, and UN reasons, but certain technology described in proposed 7E611.a (technology required for the development or production of commodities controlled by proposed 7A611.a–.e) would be subject to a worldwide RS reason for control, pursuant to proposed text added to § 742.6(a)(8). All other technology in 7E611, other than 7E611.y, would be subject to an RS Column 1 control. Any technology added to 7E611.y would be controlled for AT reasons only.

When adding the worldwide RS control to 7E611 in the February 2016 rule, BIS believed that the worldwide RS control would only affect technical data currently controlled in USML Category XIII(f) that is not eligible for the Canadian exemption under Supplement No. 1 to part 126 of the ITAR. As described in proposed § 742.6(b)(1), proposed 7E611.a technology would be subject to the same licensing policy as other 600 series items. In addition, License Exception STA would not be available for 7E611.a technology but would be available for technology in 7E611.b or .c for exports or reexports to Country Group A:5.

BIS received one public comment pertaining to ECCN 7E611, and that commenter supported limiting a worldwide RS control to technology proposed to be controlled in 7E611.a. However, by revising 7A611.x so that it does not control items described in ECCNs 6A007, 6A107, 7A001, 7A002, 7A003, 7A101, 7A102, or 7A103, this final rule significantly reduces the scope of items in 7A611 and related technology. Consequently, BIS believes that the proposed worldwide RS control is no longer warranted. This final rule removes the worldwide RS control in 7E611 and § 742.6(a)(8), removes the restriction on the use of License Exception STA for Country Group A:5, and restructures the items paragraph to match the normal structure for a 600 series technology ECCN. ECCN 7E611.y will control specific technology required for the production, development, operation, installation, maintenance, repair, or overhaul of commodities or software controlled by ECCNs 7A611.y or 7D611.y.

This final rule also adds an MT control for technology for 7E611.a technology if required for items controlled for MT reasons in 7A611.a, 7B611.a, or 7D611.a. This change is being made to correspond to the addition of an MT control in 7A611, 7B611, and 7D611.

Revisions to Other Existing ECCNs

The February 2016 rule proposed to revise many existing dual-use ECCNs to provide cross references to USML Category XII for similar items subject to the ITAR. BIS received no public comments on the proposed changes to the Related Controls paragraphs of those dual-use ECCNs. Therefore, this final rule revises the Related Controls to cross-reference similar items subject to the ITAR in ECCNs 6A004, 6A005, 6A007, 6A107, 7A001, 7A002, 7A003, 7A005, 7A101, and 7A102. The February 2016 rule also proposed to revise the Related Controls paragraph in ECCN 8A002 to refer readers to the potential license requirement in § 744.9, which would apply to commodities in 8A002.d.1.c or .d.2. Since this final rule adopts the proposed increase in scope of § 744.9 for 8A002.d items, this final rule also revises the Related Controls reference to that section in 8A002.

BIS also proposed to revise the Related Controls paragraph of ECCN 2A984, which controls certain concealed object detection equipment. This final rule maintains the cross reference to USML Category XII(c) for
related terahertz imaging systems subject to the ITAR, but moves the reference to the first sentence of the Related Controls paragraph.

Additionally, this final rule also revises the scope of control of ECCN 2A984. The State Department’s February 2016 rule proposed to change the scope of terahertz imaging systems subject to the ITAR by controlling those that have a peak response in the frequency range exceeding 30 GHz but not exceeding 3000 GHz, and having a resolution less (better) than 0.1 milliradians at a standoff range of 100 m. This would have led to an inadvertent result where terahertz imaging systems having a peak response in the frequency range exceeding 30 GHz but not exceeding 3000 GHz, and having a resolution of 0.1 to 0.5 milliradians at a standoff range of 100 m would be designated EAR99, while less capable terahertz imaging systems would be controlled under 2A984. To address this gap, this final rule amends the heading of 2A984 to control concealed object detection equipment operating in the frequency range from 30 GHz to 3000 GHz and having a spatial resolution of 0.1 milliradian up to and including 1 milliradian at a standoff distance of 100 meters (and parts and components not elsewhere specified), and makes conforming changes to the related controls section.

Finally, BIS proposed to revise ECCN 6A008 to add a sentence to the Related Controls paragraph for certain laser detection and ranging (LADAR), light detection and ranging (LIDAR), or range-gated systems subject to the ITAR. One commenter recommended that BIS expand an existing sentence in the Related Controls on car radar designed for collision avoidance to provide that 6A008 does not control civil automotive radar or LIDAR. BIS does not accept this recommendation as making this change would require agreement with other Wassenaar members. Therefore, this final rule revises the Related Controls paragraph as proposed.

Export Administration Act

Although the Export Administration Act 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 4, 2016, 81 FR 52587 (August 8, 2016), 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, 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 designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

2. 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 OMB control number. This proposed rule would affect two approved collections: Simplified Network Application Processing + System (control number 0694–0088), which includes, among other things, license applications, and License Exceptions and Exclusions (0694–0137).

As stated in a proposed rule published on July 15, 2011 (76 FR 41958) (“July 15 proposed rule”), BIS initially believed that the combined effect of all rules to be published adding items to the EAR that will be removed from the ITAR as part of the Administration’s Export Control Reform Initiative would increase the number of license applications to be submitted by approximately 16,000 annually. As the review of the USML has progressed, the interagency group has gained more specific information about the number of items that will come under BIS jurisdiction and whether those items would be eligible for export under license exceptions. As of June 21, 2012, BIS revised that estimate to an increase in license applications of 30,000 annually, resulting in an increase in burden hours of 8,500 (30,000 transactions at 17 minutes each) under control number 0694–0088. BIS continues to believe that its revised estimate is accurate.

Some items formerly on the USML would become eligible for License Exception STA under this rule. As stated in the July 15 proposed rule, BIS believes that the increased use of License Exception STA resulting from the combined effect of all rules to be published adding items to the EAR that would be removed from the ITAR as part of the Administration’s Export Control Reform Initiative would increase the burden associated with control number 0694–0137 by about 23,858 hours (20,450 transactions at 1 hour and 10 minutes each).

BIS expects that this increase in burden would be more than offset by a reduction in burden hours associated with approved collections related to the ITAR. This proposed rule addresses controls on fire control, laser, imaging, and guidance and control items. With few exceptions, most exports of such items, even when destined to NATO member states and other close allies, require State Department authorization. In addition, the exports of technology necessary to produce such items in the inventories of the United States and its NATO and other close allies require State Department authorizations. Under the EAR, as proposed, such technology that would be subject to the EAR would become eligible for export to NATO member states and other close allies under License Exception STA unless otherwise specifically excluded. Use of License Exception STA imposes a paperwork and compliance burden because, for example, exporters must furnish information about the item being exported to the consignee and obtain from the consignee an acknowledgement and commitment to comply with the EAR. However, the Administration believes that complying with the requirements of STA is likely less burdensome than applying for licenses. For example, under License Exception STA, a single consignee statement can apply to an unlimited number of products, need not have an expiration date, and need not be submitted to the government in advance for approval. Suppliers with regular customers can tailor a single statement and assurance to match their business relationship rather than applying repeatedly for licenses with every purchase order to supply reliable customers in countries that are close allies or members of export control regimes or both.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement
Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq., generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, however, if the head of an agency (or his or her designee) certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, submitted a memorandum to the Chief Counsel for Advocacy, Small Business Administration, certifying that the May 5 proposed rule would not have a significant impact on a substantial number of small entities. The rationale for that certification was set forth in the preamble to that proposed rule.

Although BIS received no comments on that rationale, and has accordingly made no changes to the proposed rule based on the RFA certification, BIS has determined that, in the interest of openness and transparency, it will briefly restate the rationale behind the certification here.

This proposed rule is part of the Administration’s Export Control Reform Initiative, which seeks to revise the USML to a positive list—one that does not use “negative control” for items listed—and to move some items that the President has determined no longer merit control under the ITAR to control under the CCL.

Although BIS does not collect data on the size of entities that apply for and are issued export licenses, and is therefore unable to estimate the exact number of small entities—as defined by the Small Business Administration’s regulations implementing the RFA—BIS acknowledges that some small entities may be affected by this proposed rule.

The main effects on small entities resulting from this rule will be in application times, costs, and delays in receiving licenses to export goods subject to the CCL. However, while small entities may experience some costs and time delays for exports due to the license requirements of the CCL, these costs and delays will likely be significantly less than they were for items previously subject to the USML. BIS believes that in fact this rule will result in reduced administrative costs and delays for exports of items that will, upon this rule’s implementation, be subject to the EAR rather than the ITAR. Currently, USML applicants must pay to use the USML licensing procedure even if they never actually are authorized to export. Registration fees for manufacturers and exporters of articles on the USML start at $2,250 per year, increase to $2,750 for organizations applying for one to ten licenses per year and further increases to $2,750 plus $250 per license application (subject to a maximum of three percent of total application value) for those who need to apply for more than ten licenses per year. By contrast, BIS is statutorily prohibited from imposing licensing fees. In addition, exporters and reexporters of goods that would become subject to the EAR under this rule would need fewer licenses because their transactions would become eligible for license exceptions that were not available under the ITAR. Additionally, the ITAR controls parts and components even when they are incorporated—in any amount—into a foreign-made product. That limitation on the use of US-made goods subject to the ITAR discouraged foreign manufacturers from importing US goods. However, the EAR has a de minimis exception for US-manufactured goods that are incorporated into foreign-made products. This exception may benefit small entities by encouraging foreign producers to use more US-made items in their goods.

Even where an exporter or reexporter would need to obtain a license under the EAR, that process is both cheaper and more flexible than obtaining a license under the ITAR. For example, unlike the ITAR, the EAR does not require license applicants to provide BIS with a purchase order with the application, meaning that small (or any) entities can enter into negotiations or contracts for the sale of goods without having to caveat any sale presentations with a reference to the need to obtain a license under the ITAR before shipment can occur. Second, the EAR allows license applicants to obtain licenses to cover all expected exports or reexports to a particular consignee or the license and reexporter’s licensees for those who need to apply for more than ten licenses per year. By contrast, BIS is statutorily prohibited from imposing licensing fees. In addition, exporters and reexporters of goods that would become subject to the EAR under this rule would need fewer licenses because their transactions would become eligible for license exceptions that were not available under the ITAR. Additionally, the ITAR controls parts and components even when they are incorporated—in any amount—into a foreign-made product. That limitation on the use of US-made goods subject to the ITAR discouraged foreign manufacturers from importing US goods. However, the EAR has a de minimis exception for US-manufactured goods that are incorporated into foreign-made products. This exception may benefit small entities by encouraging foreign producers to use more US-made items in their goods.

In short, BIS expects that the changes to the EAR proposed in this rule will have a positive effect on all affected entities, including small entities. While BIS acknowledges that this rule may have some cost impacts to small (and other) entities, those costs are more than offset by the benefits to the entities from the licensing procedures under the EAR, which are much less costly and less time consuming than the procedures under the ITAR. Accordingly, the Chief Counsel for Regulation for the Department of Commerce has certified that this rule, if implemented, will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required, and none has been prepared.

List of Subjects
15 CFR Part 734
Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.
15 CFR Part 740
Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.
15 CFR Part 742
Exports, Terrorism.
15 CFR Part 744
Exports, Reporting and recordkeeping requirements, Terrorism.
15 CFR Part 772
Exports.
15 CFR Part 774
Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 734—[AMENDED]

1. The authority citation for part 734 continues to read as follows:


2. Section 734.4 is amended by removing and reserving paragraph (a)(3) and revising paragraph (a)(5).

The revision reads as follows:

§ 734.4 De minimis U.S. content.
(a) * * *
(5) There is no de minimis level for foreign-made "military commodities" incorporating one or more of the commodities described in ECCN 0A991.a.1 when destined for a country listed in Country Group D:5 of Supplement No. 1 to part 740 of the EAR. * * * * *
PART 740—[AMENDED]

3. The authority citation for part 740
continues to read as follows:


4. Section 740.2 is amended by adding paragraph (a)(7) and removing and reserving paragraph (a)(9).

The additions read as follows:

§ 740.2 Restrictions on All License
Exceptions.

(a) * * *

(7) With the exception of License
Exception GOV (§ 740.11(b)(2)), license
exceptions are not available for the
following 6E001 or 6E002 technology:

(i) Technology required for the
“development” or “production” of
photon detector, microbolometer
detector, pyroelectric, or multispectral
detector, infrared focal plane arrays
(IRFPA), described in ECCN 6A002,
having a peak response within the
wavelength range exceeding 900 nm but
not exceeding 30,000 nm, excluding
lead sulfide or lead selenide IRFPAs
having a peak response within the
wavelength range exceeding 1,000 nm
but not exceeding 5,000 nm and not
exceeding 16 detector elements; or

(ii) Technology required for the
“development” or “production” of third
generation or greater (e.g., Electron
Bombarded Active Pixel Sensor
(EBAPS)) image intensifier tubes
described in ECCN 6A002.

* * * * *

5. Section 740.16 is amended by
revising paragraphs (a)(2) and (b)(1)
through (3) to read as follows:

§ 740.16 Additional permissible reexports
(APR).

(a) * * *

(2) The commodities being reexported
are not controlled for NP, CB, MT, SI or
CC reasons or described in ECCNs
6A919, 3A001.b.2 or b.3 (except those
that are being reexported for use in civil
telecommunications applications),
6A002, 6A003, or 6A990; and

* * * * *

(b) * * *

(1) Eligible commodities may be
reexported to and among destinations in
Country Group A:1 and Hong Kong for
use or consumption within a destination in
Country Group A:1 (see Supplement
No. 1 to part 740) or Hong Kong, or for
reexport from such country in
accordance with other provisions of the
EAR.

* * * * *

(2) Commodities not eligible for
reexport under paragraph (b)(1) are:

(i) Commodities controlled for nuclear
nonproliferation or missile technology
reasons;

(ii) Commodities in 3A001.b.2 or b.3
(except those that are being reexported
for use in civil telecommunications
applications);

(iii) “Military commodities”
described in ECCN 0A919;

(iv) Commodities described in ECCN
0A987 that incorporate an image
intensifier tube;

(v) Commodities described in ECCNs
6A002 or 6A990.

(3) Cameras described in ECCNs
6A003 may be exported or reexported to
and among countries in Country Group
A:1 (see Supplement No. 1 to this part)
if:

(i) Such cameras are fully packaged
for use as consumer ready civil
products; or

(ii) Such cameras with not more than
110,000 elements are to be embedded in
civil products.

* * * * *

6. Section 740.20 is amended by
revising paragraphs (b)(2)(ii) and
(b)(2)(x), to read as follows:

§ 740.20 License Exception Strategic
Trade Authorization (STA).

(a) * * * * *

(b) * * *

(2) * * *

(ii) License Exception STA may not be
used for any item controlled under
ECCNs 0A981, 0A982, 0A983, 0A985,
0E982, or 0E987.

* * * * *

(x) License Exception STA may not be
used for items controlled by ECCNs
6A002; 6A990; 6D002 (software
“specially designed” for the “use” of
commodities controlled under
6A002.b); 6D003.c; 6D991 (software
“specially designed” for the “development,”
“production,” or “use” of commodities
controlled under 6A002, 6A003, or
6A990); 6E001 (“technology” for the
“development” of commodities
controlled under ECCNs 6A002 or
6A003); 6E002 (“technology” for the
“production” of commodities controlled
under ECCNs 6A002 or 6A003);
and 6E990.

* * * * *

PART 742—[AMENDED]

7. The authority citation for part 742
continues to read as follows: 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
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. 13026, 61 FR 58767, 3 CFR,
1996 Comp., p. 228; E.O. 13222, 66 FR
44025, 3 CFR, 2001 Comp., p. 783;
Presidential Determination 2003–23, 68
FR 26459, 3 CFR, 2004 Comp., p. 320;
Notice of November 12, 2015, 80 FR
70667 (November 13, 2015); Notice of
August 4, 2016, 81 FR 52587 (August 8,
2016).

8. Section 742.6 is amended by
revising paragraph (b)(1) to read as
follows:

§ 742.6 Regional stability.

* * * * *

(b) * * *

(1) Licensing policy for RS Column 1
items. (i) Applications for exports and
reexports of 9x515 and “600 series”
items will be reviewed on a case-by-case
basis to determine whether the
transaction is contrary to the national
security or foreign policy interests of the
United States, including the foreign
policy interest of promoting the
observance of human rights throughout
the world. Other applications for
exports and reexports described in
paragraph (a)(1), (2), (6), or (7) of this
section will be reviewed on a case-by-
case basis to determine whether the
export or reexport could contribute
directly or indirectly to any country’s
military capabilities in a manner that
would alter or destabilize a region’s
military balance contrary to the foreign
security or foreign policy interests of the
United States. Applications for
reexports of items described in paragraph
(a)(3) of this section will be reviewed
applying the policies for similar
commodities that are subject to the ITAR.
Applications for export or reexport of items
classified under any 9x515 or “600 series”
ECCN requiring a license in accordance with
paragraph (a)(1) of this section will also be
reviewed consistent with United States
arms embargo policies in §126.1 of
the ITAR if destined to a country set
forth in Country Group D:5 in
Supplement No. 1 to part 740 of
the EAR. Applications for export or reexport of
“parts,” “components,”
“accessories,” “attachments,”
“software,” or “technology” “specially
designed” or otherwise required for the
F–14 aircraft will generally be denied.
When destined to the People’s Republic
of China or a country listed in Country
Group E:1 in Supplement No. 1 to part
740 of the EAR, items classified under
any 9x515 ECCN will be subject to a
policy of denial.

(ii) Applications for exports and
reexports to a country listed in Country
Group D:5 (in Supplement No. 1 to part
740 of the EAR, reexports to a country listed in Country
Group D:5 (in Supplement No. 1 to part
740 of the EAR) of technology controlled under 6E001 for the development of focal plane arrays or image intensifier tubes described in 6A002, technology controlled under 6E002 for the production of focal plane arrays or image intensifier tubes described in 6A002, or technology controlled under 6E990 will be reviewed with a presumption of denial.

PART 744—[AMENDED]

9. The authority citation for part 744 continues to read as follows:


10. Section 744.9 is amended by revising the section heading and paragraphs (a) and (b) to read as follows:

§744.9 Restrictions on exports, reexports, and transfers (in-country) of certain cameras, systems, or related components.

(a) General prohibitions. (1) In addition to the applicable license requirements for national security, regional stability, anti-terrorism and United Nations embargo reasons in §§742.4, 742.6, 742.8, 746.3 of the EAR, a license is required for the export, reexport, or transfer of commodities described in ECCNs 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion of Note 3.a to 6A003.b.4), or commodities controlled by 6A993.a that meet the criterion of Note 3.a to 6A003.b.4), 6A002, 6A003, 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion of Note 3.a to 6A003.b.4), or 6A002.d to specified end users, because BIS has determined that there is an unacceptable risk of diversion to the users or unauthorized incorporation into the “military commodities” described in paragraph (a) of this section. Specific notice is to be given only by, or at the direction of, the Deputy Assistant Secretary for Export Administration. When such notice is provided orally, it will be followed by a written notice within two working days signed by the Deputy Assistant Secretary for Export Administration.

PART 772—[AMENDED]

11. The authority citation for part 772 continues to read as follows:


12. Section 772.1 is amended by revising the last sentence in Note 1 to the definition of “specially designed.” to read as follows:

§772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

Specially designed. * * *

Note 1: * * * For purposes of “specially designed,” ECCNs 0B986, 0B989, 0D999, 1B999, 1C992, 1C995, 1C997, 1C999, 6A998 (except for .h), and 9A991 are treated as ECCNs controlled exclusively for AT reasons.

PART 774—[AMENDED]

13. The authority citation for part 774 continues to read as follows:


Supplement No. 1 to Part 774 [Amended]

14. In Supplement No. 1 to part 774, Category 0, ECCN 0A919 is amended by revising the Items paragraph of the List of Items Controlled section to read as follows:

0A919 “Military commodities” located and produced outside the United States as follows (see List of Items Controlled).

Items: a. “Military commodities” produced and located outside the United States that are not subject to the International Traffic in Arms Regulations (22 CFR parts 120–130) and having any of the following characteristics: a.1. Incorporate more than a de minimis amount of U.S.-origin controlled content classified under ECCNs 6A002, 6A003, 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion of Note 3.a to 6A003.b.4), or 6A002.d to specified end users, because BIS has determined that there is an unacceptable risk of diversion to the users or unauthorized incorporation into the “military commodities” described in paragraph in the List of Items Controlled.

PART 774—[AMENDED]

15. In Supplement No. 1 to part 774, Category 0, ECCN 0A987 is amended by:

a. Revising the Related Controls paragraph in the List of Items Controlled section;

b. Revising paragraph f. in the Items paragraph in the List of Items Controlled section; and

c. Adding a note to 0A987.f.

The revisions and addition read as follows:

0A987 Optical sighting devices for firearms (including shotguns controlled by 0A986); and “components” as follows (See List of Items Controlled).

* * * * *
16. In Supplement No. 1 to part 774, Category 0, add ECCN 0E987 between ECCN 0E984 and EAR99 to read as follows:

0E987 “Technology” “required” for the “development,” or “production” of commodities controlled by 0A987 that incorporate a focal plane array or image intensifier tube.

Related Controls: (1) See USML Category XII(e) for infrared focal plane arrays, image intensifier tubes, and related parts and components, subject to the ITAR. (2) See USML Category XV(e) for space-qualified focal plane arrays subject to the ITAR. (3) See also ECCNs 6A102, 6A202, and 6A992. (4) Section 744.9 imposes a license requirement on commodities described in 6A002 if being exported, reexported, or transferred (in-country) for use by a military end-user or for incorporation into an item controlled by ECCN 0A919.

List of Items Controlled
Related Controls: (1) Concealed object detection equipment operating in the frequency range from 30 GHz to 3000 GHz and having a spatial resolution of 0.1 milliradian up to and including 1 milliradian at a standoff distance of 100 meters; and “parts” and “components,” n.e.s.

17. In Supplement No. 1 to part 774, Category 2, ECCN 2A984 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

2A984 Concealed object detection equipment operating in the frequency range from 30 GHz to 3000 GHz and having a spatial resolution of 0.1 milliradian up to and including 1 milliradian at a standoff distance of 100 meters; and “parts” and “components,” n.e.s.

Note: 0A987.f does not control laser boresighting devices that must be placed in the bore or chamber to provide a reference for aligning the firearms sights.

List of Items Controlled
Related Controls: (1) See USML Category XII(e) for infrared focal plane arrays, image intensifier tubes, and related parts and components, subject to the ITAR. (2) See USML Category XV(e) for space-qualified focal plane arrays subject to the ITAR. (3) See also ECCNs 6A102, 6A202, and 6A992. (4) Section 744.9 imposes a license requirement on commodities described in 6A002 if being exported, reexported, or transferred (in-country) for use by a military end-user or for incorporation into a commodity controlled by ECCN 0A919.

18. In Supplement No. 1 to part 774, Category 6, ECCN 6A002 is amended by:

a. Removing the “Special Conditions for STA” section; and

b. Revising the Related Controls paragraph in the List of Items Controlled section.

The revision reads as follows:

6A002 Optical sensors and equipment and “components” therefor, as follows (see List of Items Controlled).

19. In Supplement No. 1 to part 774, Category 6, ECCN 6A003 is amended by:

a. Adding a License Requirement Note in the License Requirements section;

b. Revising notes 3 and 4 in the Related Controls paragraph in the List of Items Controlled section; and

c. Adding note 5 to the Related Controls paragraph in the List of Items Controlled section.

The additions and revisions read as follows:

6A003 Cameras, systems or equipment, and “components” therefor, as follows (see List of Items Controlled).

20. In Supplement No. 1 to part 774, Category 6, ECCN 6A004 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

6A004 Optical equipment and “components,” as follows (see List of Items Controlled).

21. In Supplement No. 1 to part 774, Category 6, ECCN 6A005 is amended by revising the last two sentences in the Related Controls paragraph in the List of Items Controlled section to read as follows:

6A005 “Lasers,” “components” and optical equipment, as follows (see List of Items Controlled), excluding items that are subject to the export licensing authority of the Nuclear Regulatory Commission (see 10 CFR part 110).

22. In Supplement No. 1 to part 774, Category 6, ECCN 6A007 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:
6A007 Gravity meters (gravimeters) and gravity gradiometers, as follows (see List of Items Controlled).

List of Items Controlled

Related Controls: (1) See USML Category XII(d) for certain gravity meters (gravimeters) and gravity gradiometers subject to the ITAR. (2) See also ECCNs 6A107, 6A997, and 7A611.

23. In Supplement No. 1 to part 774, Category 6, ECCN 6A008 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

6A008 Radar systems, equipment and assemblies, having any of the following (see List of Items Controlled), and “specially designed” “components” therefor.

List of Items Controlled

Related Controls: (1) This entry does not control: Secondary surveillance radar (SSR); Car radar designed for collision prevention; Displays or monitors used for Air Traffic Control (ATC) having no more than 12 resolvable elements per mm; Meteorological (weather) radar. (2) See also ECCNs 6A108 and 6A998. ECCN 6A998 controls, inter alia, the Light Detection and Ranging (LIDAR) equipment excluded by the note to paragraph j of this ECCN (6A008). (3) See USML Category XII(b) for certain LIDAR, Laser Detection and Ranging (LADAR), or range-gated systems subject to the ITAR.

24. In Supplement No. 1 to part 774, Category 6, ECCN 6A107 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

6A107 Gravity meters (gravimeters) or gravity gradiometers, other than those controlled by 6A007, designed or modified for airborne or marine use, as follows, (see List of Items Controlled) and “specially designed” “parts” and “components” therefor.

List of Items Controlled

Related Controls: See USML Category XII(d) for certain gravity meters (gravimeters) or gravity gradiometers subject to the ITAR. See also ECCN 7A611.

25. In Supplement No. 1 to part 774, Category 6, ECCN 6A611 is revised to read as follows:

6A611 Acoustic systems and equipment, radar, and “parts,” “components,” “accessories,” and “attachments” “specially designed” therefor, “specially designed” for a military application that are not enumerated in any USML category or other ECCN are controlled by ECCN 3A611. Military fire control, laser, imaging, and guidance equipment that are not enumerated in any USML category or ECCN are controlled by ECCN 7A611.

26. In Supplement No. 1 to part 774, Category 6, ECCN 6A990 is revised to read as follows:

6A990 Read-out integrated circuits, as follows (see List of Items Controlled).

License Requirements

Reason for Control: RS, AT

<table>
<thead>
<tr>
<th>Control(s)</th>
<th>Country chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS applies to entire entry</td>
<td>RS Column 1</td>
</tr>
<tr>
<td>AT applies to entire entry</td>
<td>AT Column 1</td>
</tr>
</tbody>
</table>

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: $500
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: (1) See USML Categories XII(e) and XV(e)(3) for read-out integrated circuits “subject to the ITAR.” (2) See ECCN 0A919 for foreign made military commodities that incorporate commodities described in 6A990. (3) Section 744.9 imposes a license requirement on commodities described in 6A990 if being exported, reexported, or transferred (in-country) for use by a military end-user or for incorporation into a commodity controlled by ECCN 0A919.

27. In Supplement No. 1 to part 774, Category 6, ECCN 6A993 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

6A993 Cameras, not controlled by 6A003 or 6A203, as follows (see List of Items Controlled).

List of Items Controlled

Related Controls: (1) See ECCN 0A919 for foreign made military commodities that incorporate cameras described in 6A993.a that meet the criteria specified in Note 3.a to 6A003.b.4.b (i.e., having a maximum frame rate equal to or less than 9 Hz). (2) Section 744.9 imposes license requirements on cameras described in 6A993.a as a result of meeting the criteria specified in Note 3.a to 6A003.b.4.b (i.e., having a maximum frame rate equal to or less than 9 Hz) if being exported, reexported, or transferred (in-country) for use by a military end-user or for incorporation into a commodity controlled by ECCN 0A919.

28. In Supplement No. 1 to part 774, Category 6, ECCN 6D002 is amended by revising the TSR paragraph in the List Based License Exceptions section and the Related Controls paragraph in the List of Items Controlled section to read as follows:

6D002 “Software” “specially designed” for the “use” of equipment controlled by 6A002.b, 6A008 or 6B008.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for the following: (1) Items controlled for MT reasons; (2) “Software” “specially designed” for the “use” of “space-qualified” “laser” radar or Light Detection and Ranging (LIDAR) equipment described in 6A008.j; or (3) “Software” “specially designed” for the “use” of commodities controlled by 6A002.b.

List of Items Controlled

Related Controls: (1) “Software” “specially designed” for the “use” of “space-qualified” LIDAR “equipment” “specially designed” for surveying or for meteorological observation, released from control under the note in 6A008.j, is controlled in 6D991. (2) See also ECCNs 6D102, 6D991, and 6D992.

29. In Supplement No. 1 to part 774, Category 6, ECCN 6D003 is amended by revising the TSR paragraph in the List Based License Exceptions section and the Related Controls paragraph in the List of Items Controlled section to read as follows:

6D003 Other “software” as follows (see List of Items Controlled).

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except for 6D003.c and exports or reexports to destinations outside of those countries listed in Country Group A:5 (See Supplement No. 1 to part 740 of the EAR) for “software” as follows (see List of Items Controlled).

List of Items Controlled
**Related Controls:** See also ECCNs 6D103, 6D991, and 6D993.

<table>
<thead>
<tr>
<th>ECCN</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6D991</td>
<td>“Software,” n.e.s., “specially designed” for the “development”, “production”, or “use” of commodities controlled by 6A002, 6A003, 6A990, 6A991, 6A996, 6A997, or 6A998.</td>
</tr>
</tbody>
</table>

**License Requirements**

**Reason for Control:** RS, AT

<table>
<thead>
<tr>
<th>Control(s)</th>
<th>Country chart (see supp. No. 1 to part 738)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS applies to “software” for commodities controlled by 6A002, 6A003, 6A990, or 6A998.b.</td>
<td><strong>RS Column 1</strong></td>
</tr>
<tr>
<td>RS applies to “software” for commodities controlled by 6A998.c.</td>
<td><strong>RS Column 2</strong></td>
</tr>
<tr>
<td>AT applies to entire entry, except “software” for commodities controlled by 6A991</td>
<td><strong>AT Column 1</strong></td>
</tr>
<tr>
<td>AT applies to “software” for commodities controlled by 6A991</td>
<td><strong>AT Column 2</strong></td>
</tr>
</tbody>
</table>

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

**CIV:** N/A

**TSR:** N/A

**List of Items Controlled**

**Related Controls:** See also USML Categories XII(e) or XV(e)(1) to (3) for accelerometers subject to the ITAR under USML Category XV(e)(3).

**List of Items Controlled**

**Related Controls:** (1) Technical data directly related to satellites and all other items described in USML Category XV are subject to the ITAR under USML Category XV(f). (2) Technical data directly related to laser systems, infrared imaging systems, and all other items described in USML Category XII are subject to the ITAR under USML Category XII(f). (3) See also 6E992.

**List of Items Controlled**

**Related Controls:** Technical data directly related to read-out integrated circuits described in USML Categories XII(e) or XV(e)(3) is subject to the ITAR under USML Categories XII(f) or XV(f), respectively.

**List of Items Controlled**

**Related Controls:** (1) See USML Category XIII(e) for accelerometers subject to the ITAR. (2) See also ECCNs 7A101, 7A611, and 7A994. (3) For angular or rotational accelerometers, see ECCN7A001.b. (4) MT
controls do not apply to accelerometers that are "specially designed" and
developed as Measurement While Drilling (MWD) sensors for use in downhole well
service applications.

35. In Supplement No. 1 to part 774, Category 7, ECCN 7A002 is amended by
revising the Related Controls paragraph in the List of Items Controlled section to
read as follows:

7A002 Gyros or angular rate sensors,
having any of the following (see List of
Items Controlled) and "specially
designed" "components" therefor.

List of Items Controlled
Related Controls: (1) See USML Category
XII(e) for gyros or angular rate sensors
subject to the ITAR. (2) See also ECCNs
7A101, 7A611, and 7A994. (3) For angular
or rotational accelerometers, see ECCN
7A001.b.

36. In Supplement No. 1 to part 774, Category 7, ECCN 7A003 is amended by
revising the Related Controls paragraph in the List of Items Controlled section to
read as follows:

7A003 "Inertial measurement equipment or
systems," having any of the following (see List of Items Controlled).

List of Items Controlled
Related Controls: (1) See also ECCNs 7A103,
7A611, and 7A994. (2) See USML
Category XII(d) for guidance or
navigation systems subject to the ITAR.

37. In Supplement No. 1 to part 774, Category 7, amend ECCN 7A005 by
revising the Related Controls paragraph in the List of Items Controlled section to
read as follows:

7A005 Global Navigation Satellite Systems
(GNSS) receiving equipment having any of the following (see List of Items
Controlled) and "specially designed" "components" therefor.

List of Items Controlled
Related Controls: (1) See also ECCNs 7A105
and 7A994. Typically commercially
available GNSS receivers do not employ
decryption or adaptive antennas and are
classified as 7A994. (2) See USML Category
XII(d) for GNSS receiving equipment subject to the ITAR.

38. In Supplement No. 1 to part 774, Category 7, ECCN 7A101 is amended by
revising the Related Controls paragraph in the List of Items Controlled section to
read as follows:

7A101 Accelerometers, other than those
controlled by 7A001 (see List of Items
Controlled), and "specially designed"
"parts" and "components" therefor.

List of Items Controlled
Related Controls: (1) See USML Category
XII(e) for accelerometers subject to the
ITAR. (2) See also ECCNs 7A001 and
7A611. (3) This entry does not control
accelerometers that are "specially
designed" and developed as MWD
(Measurement While Drilling) sensors for
use in downhole well service operations.

39. In Supplement No. 1 to part 774, Category 7, ECCN 7A102 is amended by
revising the Related Controls paragraph in the List of Items Controlled section to
read as follows:

7A102 Gyros, other than those controlled
by 7A002 (see List of Items Controlled),
and "specially designed" "parts" and
"components" therefor.

List of Items Controlled
Related Controls: (1) See USML Category
XII(e) for gyros or angular rate sensors
subject to the ITAR. (2) See also ECCNs
7A002, 7A611, and 7A994.

40. In Supplement No. 1 to part 774, Category 7, ECCN 7A611 is revised to read as follows:

7A611 Military fire control, laser, imaging,
and guidance equipment, as follows (see List of Items Controlled).

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

Control(s) Country chart (see supp. No. 1 to part 738)
NS applies to entire entry except
7A611.y NS Column 1
MT applies to com-
modities in
7A611.a that meet or exceed the param-
eters in 7A103.b or c.
MT Column 1
RS applies to entire entry except
7A611.y RS Column 1
AT applies to entire entry.
AT Column 1
UN applies to entire entry except
7A611.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: Paragraph [c](2) of License Exception
STA (§ 740.20(c)(2) of the EAR) may not be
used for any item in 7A611.

List of Items Controlled
Related Controls: (1) Military fire control,
laser, imaging, and guidance equipment
that are enumerated in USML Category XII,
and technical data (including software)
directly related thereto, are subject to the
ITAR. (2) See Related Controls in ECCNs
0A987, 2A984, 6A002, 6A003, 6A004,
6A005, 6A007, 6A008, 6A107, 7A001,
7A002, 7A003, 7A005, 7A101, 7A102, and
7A103. (3) See ECCN 3A611 and USML
Category XI for controls on countermeasure
equipment. (4) 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. Guidance or navigation systems, not
elsewhere specified on the USML, that are
"specially designed" for a defense article on
the USML or for a 600 series item.
b. to w. [RESERVED]
x. "Parts," "components," "accessories," and
"attachments," including
accelerometers, gravity meters (gravimeters), and inertial
measurement units (IMUs), that are
"specially designed" for defense articles
to control USML Category XII or items
to control 7A611, and that are NOT:
1. Enumerated or controlled in the USML
or elsewhere within ECCN 7A611;
2. Described in ECCNs 6A007, 6A107,
7A001, 7A002, 7A003, 7A101, 7A102 or
7A103; or
3. Elsewhere specified in ECCN 7A611.y or
3A611.y.
y. Specific "parts," "components," "accessories," and
"attachments" "specially designed" for a commodity subject to control
in this ECCN or a defense article in Category
XII and not elsewhere specified on the USML
or in the CCL, as follows, and "parts," "components," "accessories," and
"attachments" "specially designed" therefor:
y.1 [RESERVED]

41. In Supplement No. 1 to part 774, Category 7, ECCN 7A994 is revised to read as follows:

7A994 Other navigation direction finding
equipment, airborne communication
equipment, all aircraft inertial
navigation systems not controlled under
7A003 or 7A103, and other avionic
equipment, including "parts" and
"components," n.e.s.

License Requirements
Reason for Control: AT

Control(s) Country chart (see supp. No. 1 to part 738)
AT applies to entire AT Column 1
entry.
License Requirement Notes:
- Typically commercially available GPS do not employ decryption or adaptive antenna
- and are classified as 7A904.

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 7A005 and 7A105.
Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

42. In Supplement No. 1 to part 774, Category 7, add ECCN 7B611 between ECCNs 7B103 and 7B994 to read as follows:

7B611 Test, inspection, and production commodities “specially designed” for military fire control, laser, imaging, and guidance equipment, as follows (see List of Items Controlled).

Related Controls: See 7A005 and 7A105.
Related Definitions: N/A

Items: N/A

43. In Supplement No. 1 to part 774, Category 7, add ECCN 7D611 between ECCNs 7D103 and 7D994 to read as follows:

7D611 “Software” “specially designed” for commodities controlled by 7A611 or equipment controlled by 7B611, as follows (see List of Items Controlled).

Related Controls: See 7A005 and 7A105.
Related Definitions: N/A

Items: N/A

44. In Supplement No. 1 to part 774, Category 7, add ECCN 7E611 between ECCNs 7E104 and 7E994 to read as follows:

7E611 “Technology” “required” for the “development,” “production,” operation, installation, maintenance, repair, overhaul or refurbishing of commodities controlled by 7A611, commodities controlled by 7B611, or software controlled by 7D611, as follows (see List of Items Controlled).

Related Controls: See 7A005 and 7A105.
Related Definitions: N/A

Items: N/A

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: 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 7B611.

List of Items Controlled

Related Controls: N/A
Related Definitions: N/A

Items: N/A

45. In Supplement No. 1 to part 774, Category 7, ECCN 7E994 is amended by revising the Related Controls paragraph.
in the List of Items Controlled section to read as follows:

**7E994** “Technology,” n.e.s., for the “development,” “production”, or “use” of navigation, airborne communication, and other avionics equipment.

List of Items Controlled

- **List of Items Controlled**
- **Related Controls:** N/A

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**46.** In Supplement No. 1 to part 774, Category 8, ECCN 8A002 is amended by adding a sentence to the end of the Related Controls paragraph in the List of Items Controlled section to read as follows:

**8A002** Marine systems, equipment, “parts” and “components,” as follows (see List of Items Controlled).

List of Items Controlled

- **List of Items Controlled**
- **Related Controls:** N/A

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**47.** In Supplement No. 1 to part 774, Category 9, ECCN 9A991 is amended by:

- **a.** Removing the License Requirement Notes paragraph in the License Requirements section, and
- **b.** Revising the Related Controls paragraph in the List of Items Controlled section.

The revision reads as follows:

**9A991** “Aircraft,” n.e.s., and gas turbine engines not controlled by 9A001 or 9A101 and “parts” and “components,” n.e.s. (see List of Items Controlled).

List of Items Controlled

- **List of Items Controlled**
- **Related Controls:** N/A

Dated: September 15, 2016.

Kevin J. Wolf,
Assistant Secretary of Commerce for Export Administration.
[FR Doc. 2016–24220 Filed 10–11–16; 8:45 am]

BILLING CODE 3510–33–P

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 807 and 812**

[Docket No. FDA–2016–N–2518]

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**Medical Devices; Custom Devices; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is amending its regulations on the definition of a custom device so as to include new enumerated statutory requirements for custom devices under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). This new provision, under FDASIA, amends the existing custom device exemption and introduces new concepts and procedures applicable to custom devices. This action is being taken to align the regulations with the FD&C Act.

**DATES:** This rule is effective October 12, 2016.

FOR FURTHER INFORMATION CONTACT:
Erica B. Payne, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5520, Silver Spring, MD 20993, 301–796–3999.

**SUPPLEMENTARY INFORMATION:**

I. Background

On July 9, 2012, section 617 of FDASIA (Pub. L. 112–144), amended the FD&C Act (21 U.S.C. 301 et seq.), to require changes in the implementation of the custom device exemption under section 520(b) of the FD&C Act (21 U.S.C. 360(b)) (Ref. 1). Under the revised provision, as under the original custom device exemption, a device that meets the qualification of a custom device is exempt from 510(k) and Premarket Approval (PMA) submissions under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) (see also §§ 807.85 and 812.3(b) (21 CFR 807.85 and 812.3(b)). Because of the amendments to section 520(b) of the FD&C Act, the current regulatory definition for a custom device, set forth in §§ 807.85(a) and 812.3(b), is no longer consistent with the statute. This technical amendment will correct the regulations by revising the definition of a custom device to restate the statute. Under existing regulations at § 807.85(a), a custom device is exempt from premarket notification under section 510(k) of the FD&C Act. In the Federal Register of August 23, 1977 (42 FR 42520 at 42523), FDA published a final rule establishing the form and manner for 510(k) premarket notifications, which identified a custom device as an exemption from the premarket approval requirement because a principal purpose for requiring 510(k) premarket notification is absent. The final rule explained that the exemption for manufacturers of custom devices is intended to apply only to those who are manufacturing a custom device to fit the needs of a particular patient, so the manufacturer will not be required to file a premarket notification for each particular device.

In the Federal Register of January 18, 1980 (45 FR 3732 at 3740), FDA published a final rule setting forth the rules and conditions under which investigations for medical devices involving human subjects may be exempt from certain requirements of the FD&C Act. The 1980 final rule provided clarification for the definition of “custom devices” under § 812.3(b) for Investigational Device Exemptions (IDE) unless used to determine safety and effectiveness for commercial distribution. A device used to conduct a clinical trial cannot qualify as a custom device.

Section 520(b) of the FD&C Act, as amended by section 617 of FDASIA, changed some of the criteria to qualify for the custom device exemption, which is different from the criteria currently described in the regulations. The amendment to section 520(b) of the FD&C Act states that a device will qualify as a “custom device” by meeting new enumerated statutory requirements, including, among others, the following for each device: (1) Is created or modified in order to comply with the order of an individual physician or dentist (or other specially qualified person); (2) necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515 of the FD&C Act; (3) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution; (4) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat; (5) either (a) is intended to meet the special needs of such physician or dentist in the course of the professional practice of such physician or dentist (or other specially qualified person as designated) in the course of their professional practice or (b) is intended