

light their METs would incur additional costs and time delays and this affects their ability to compete with others in the market. As stated previously, the FAA is not amending the regulations to require notice for structures less than 200 feet AGL in non-airport environments. The FAA is providing this information to enhance the visibility of structures that otherwise may be difficult to see due to the terrain and the nature of specific operations conducted around these METs. While this guidance is not mandatory, the FAA anticipates that in the interest of aviation safety, developers and landowners will consider this guidance for METs erected in the environments described in this document.

III. Policy

The FAA recommends voluntary marking of METs less than 200 feet AGL in accordance with marking guidance contained in this document and Advisory Circular 70-7460-1, Obstruction Marking and Lighting. The FAA notes that historically this guidance has not been applied to the voluntary marking of METs less than 200 feet AGL. However, the FAA recognizes the need to address safety impacts to low-level flight operations due to the construction of METs in remote and rural areas, especially as agricultural spraying season approaches. Due to the growing concerns expressed by operators, associations representing agricultural operators, and state and local governments throughout the agricultural industry, the FAA believes that voluntary marking of METs less than 200 AGL in remote and rural areas enhance the visibility of these structures to low level agricultural operations in the vicinity of these towers.

The FAA recommends that landowners and developers use guidance contained in Advisory Circular 70/7460-1, Obstruction marking and Lighting for the voluntary marking of METs less than 200 feet AGL. METs should be painted in accordance to criteria contained in Chapter 3, paragraphs 30-33 of AC No. 70/7460-1, specifically, with alternate bands of aviation orange and white paint. In addition, paragraph 34 states that all markings should be replaced when faded or otherwise deteriorated. The FAA recommends that high visibility sleeves be installed on the outer guy wires of METs as described in this document. The FAA intends, at a future date, to amend the advisory circular to include guidance on sleeves. Additionally, the FAA recommends high visibility spherical marker (or cable) balls of aviation orange color are

attached to the guy wires. Spherical markers should be installed and displayed in accordance to guidance contained in this document and additional standards contained in Chapter 3, paragraph 34 of AC No. 70/70460-1. The FAA, however, recognizes various weather conditions and manufacturing placement standards may affect the placement and use of high visibility sleeves and/or spherical markers. Thus, flexibility is needed when determining sleeve length and marker placement on METs.

Issued in Washington, DC, on June 20, 2011.

Dennis E. Roberts,

Director, ATO Airspace Services, AJV-1.

[FR Doc. 2011-15746 Filed 6-23-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 740, 743 and 774

[Docket No. 110210131-1317-01]

RIN 0694-AF15

Export Controls for High Performance Computers: Wassenaar Arrangement Agreement Implementation for ECCN 4A003 and Revisions to License Exception APP

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This final rule revises the Export Administration Regulations (EAR) to implement changes made to the Wassenaar Arrangement's List of Dual Use Goods and Technologies (Wassenaar List) maintained and agreed to by governments participating in the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual Use Goods and Technologies (Wassenaar Arrangement, or WA) at the December 2009 WA Plenary Meeting (the Plenary) that relate to Export Control Classification Number (ECCN) 4A003. These changes agreed to at the Plenary pertain to raising the Adjusted Peak Performance (APP) for digital computers in ECCN 4A003. In accordance with the National Defense Authorization Act (NDAA) for FY 1998, the President's report for High Performance Computers was sent to Congress on February 7, 2011, to identify and set forth a justification for the new APP. This rule also makes corresponding revisions to License Exception APP, the de minimis rule,

and post shipment verification reporting requirements in the EAR.

Additionally, this rule moves Albania and Croatia from Computer Tier 3 to Computer Tier 1 in the section of the EAR dedicated to export control requirements for high performance computers. The Administration believes Albania and Croatia are eligible to be treated as Computer Tier 1 countries because their governments have made the necessary reforms to allow the countries to join the North Atlantic Treaty Organization, and have adopted accepted global standards in export controls.

DATES: *Effective Dates:* This rule is effective on June 24, 2011.

FOR FURTHER INFORMATION CONTACT: For general questions contact Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce at 202-482 2440 or by e-mail: sharron.cook@bis.doc.gov.

For technical questions contact: Joseph Young at 202-482-4197 or by e-mail at joseph.young@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

In July 1996, the United States and thirty-three other countries gave final approval to the establishment of a new multilateral export control arrangement called the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual Use Goods and Technologies (Wassenaar Arrangement or WA). The Wassenaar Arrangement contributes to regional and international security and stability by promoting transparency and greater responsibility in transfers of conventional arms and dual use goods and technologies, thus preventing destabilizing accumulations of such items. Participating states committed to exchange information on exports of dual use goods and technologies to non-participating states for the purposes of enhancing transparency and assisting in developing a common understanding of the risks associated with the transfers of these items. For more information on the Wassenaar Arrangement go to <http://www.wassenaar.org/>.

Many computers are exported and reexported using License Exception Adjusted Peak Performance (APP). The primary eligibility criteria considered for this license exception are destination country and the processing speed. In the past, the processing speed was measured using a formula that would result in the Composite Theoretical Performance (CTP) of a computer. Presently, the speed of computers is calculated using a formula that results in the Adjusted Peak Performance

(APP). The countries eligible for export or reexport under License Exception APP are divided into two groups or “Tiers”, (Tier 1 and Tier 3). Countries listed in Tier 1 are ally countries or countries that do not pose a national security, nuclear or missile threat to the United States. Tier 3 Countries are all other countries with the exception of the terrorist supporting countries listed in Country Group E:1 of Supplement No. 1 to part 740.

The National Defense Authorization Act (NDAA) Congressional Notification Requirement, Subsections 1211(d) and (e) of the National Defense Authorization Act (NDAA) for FY 1998 (Pub. L. 105–85, November 18, 1997, 111 Stat. 1932), provides that a new composite theoretical performance level for purposes of licensing exports of digital computers to Tier 3 countries may not take effect until sixty days after the President submits a report to Congress setting forth the new level and the justification for the new level. The President sent a report to Congress on February 7, 2011 that identifies and provides justification for a new 1.5 Weighted TeraFLOPS (WT) control level using the Adjusted Peak Performance (APP) formula.

Revisions to the Commerce Control List

This rule revises Export Control Classification Number (ECCN) 4A003 on the Commerce Control List (CCL) to implement the changes to the Wassenaar List of Dual Use Goods and Technologies agreed to at the December 2009 WA Plenary meeting. These changes are described in more detail below.

ECCN 4A003 is amended by:

- Revising the APP from 0.75 to 1.5 WT in the AT control paragraph of the License Requirements section to make it consistent with the revision in 4A003.b.
- Revising the APP from 0.75 to 1.5 WT (in two places) in **Note 1** of the License Requirements section, to make it consistent with a revision in 4A003.b.
- Revising the APP from 0.75 to 1.5 WT in 4A003.b to maintain control of leading edge computers, while decontrolling older computers.

Section 740.7 Computers (APP)

The WA members agreed at the 2009 Plenary to raise the “License Exception Adjusted Peak Performance” (APP) parameter in ECCNs 4D001 (0.25 WT), and 4E001 (0.25 WT), because of the advancement of computer technology. In License Exception APP, with regard to deemed exports of “development”

and “production” technology controlled by ECCN 4E001 and source code controlled by ECCN 4D001, BIS is raising the eligibility parameter (APP) from 0.5 WT to 1.5 WT for foreign nationals of Computer Tier 1 countries (with the exception of the countries listed in Section 740.7(c)(3)(i) that have unlimited APP for “development” and “production” technology and source code) and from 0.1 WT to 0.5 WT for foreign nationals of Computer Tier 3 countries, because of the advancement of high performance computer technology.

Albania and Croatia

This rule removes Albania and Croatia from Computer Tier 3 and places these countries in Computer Tier 1 in Section 740.7 License Exception APP. The requirements in the 1998 National Defense Authorization Act (NDAA) provides that the removal of a country from Tier 3 may take effect 120 days after Congress receives a report justifying such a removal. The President sent a report to Congress on February 7, 2011, therefore the 120 days have passed. Albania and Croatia have made significant progress in conforming to international nonproliferation norms and export control standards. Croatia is a member of the Australia Group, the Nuclear Suppliers Group, and the Wassenaar Arrangement. Albania has declared its adherence to the international export control regimes and is working on becoming a member of the regimes. Albania and Croatia are parties to the Nuclear Non-Proliferation Treaty, the Chemical Weapons Convention, and the Biological Weapons Convention. In addition, Albania and Croatia adhere to the Hague Code of Conduct and are now North Atlantic Treaty Organization (NATO) allies. This revision will result in fewer license applications, because Albania and Croatia will now be eligible for License Exception APP. In addition, the EAR will no longer require NDAA-based recordkeeping and post shipment verification reporting of exports of high performance computers to Albania and Croatia (see Section 743.2 of the EAR).

Section 734.4 “De minimis U.S. Content”

Foreign-made computers with an APP of 0.75 WT located in a foreign country are not eligible for the application of the *de minimis* rules when they contain U.S.-origin controlled semiconductors (other than memory circuits) classified under ECCN 3A001 and are destined to a country in Computer Tier 3 of Section 740.7 of the EAR. This rule increases the APP parameter from 0.75 WT to 1.5 WT

in harmonization with the revision made to ECCN 4A003.

Section 743.2 “High Performance Computers: Post Shipment Verification Reporting”

This section outlines special post-shipment reporting requirements for the export of certain computers to destinations in Computer Tier 3 of License Exception APP (Section 740.7 of the EAR). The reporting requirement applies to high performance computer exports to destinations in Computer Tier 3, as well as exports of commodities used to enhance computers previously exported or reexported to Computer Tier 3 destinations, where the APP is greater than 0.75 WT. This rule increases that APP level from 0.75 WT to 1.5 WT in accordance with the WA agreement to increase the APP level in ECCN 4A003.

Export Administration Act

Since August 21, 2001, the Export Administration Act of 1979, as amended, has been in lapse. However, the President has continued the EAR in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1707) through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 12, 2010, 75 FR 50681 (August 16, 2010).

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves two collections of information subject to the PRA. One of the collections has been approved by OMB under control number 0694–0088, “Multi Purpose Application,” and carries a burden hour estimate of 43.8 minutes for a manual or electronic submission. The other of the collections has been approved by OMB under control number 0694–0137, “Licensing Exceptions and Exclusions,” and carries a burden hour estimate of 21 minutes for a manual or electronic submission. Send comments regarding these burden estimates or any other aspect of these collections of information, including

suggestions for reducing the burden, to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to Jasmeet Seehra, OMB Desk Officer, by e-mail at *Jasmeet_K_Seehra@omb.eop.gov* or by fax to (202) 395-7285; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6622, Washington, DC 20230.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Immediate implementation of these amendments fulfills the United States' international obligation to the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual Use Goods and Technologies. The Wassenaar Arrangement contributes to international security and regional stability by promoting greater responsibility in transfers of conventional arms and dual use goods and technologies, thus preventing destabilizing accumulations of such items. The Wassenaar Arrangement consists of 44 member countries that act on a consensus basis and the changes set forth in this rule implement agreements reached at the December 2009 plenary session of the WA. Because the United States is a significant exporter of the items in this rule, implementation of this provision is necessary for the WA to achieve its purpose. Delaying implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by WA members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely manner. If this rulemaking was delayed to allow for notice and comment, it would prevent the United States from fulfilling its commitment to the WA in a timely manner and would injure the credibility of the United States in this and other multilateral regimes.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not

required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Ave., NW., Room 2099, Washington, DC 20230.

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 743

Administrative practice and procedure, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, Parts 734, 740, 743 and 774 of the Export Administration Regulations (15 CFR Parts 730 through 774) are amended as follows:

PART 734—[AMENDED]

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

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010); Notice of November 4, 2010, 75 FR 68673 (November 8, 2010).

§ 734.4 [Amended]

■ 2. Section 734.4 is amended by removing the phrase “0.75 Weighted TeraFLOPS (WT)” and adding in its place “1.5 Weighted TeraFLOPS (WT)” in paragraph (a)(1).

PART 740—[AMENDED]

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

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*;

E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

§ 740.7 [Amended]

■ 4. Section 740.7 is amended by:

■ a. Removing Albania and Croatia from the list of countries in paragraph (d)(1) and adding them in alphabetical order to paragraph (c)(1);

■ b. Removing the number “0.5” and adding in its place “1.5” in paragraph (c)(3)(ii); and

■ c. Removing the number “0.1” and adding in its place “0.5” in paragraph (d)(3)(i).

PART 743—[AMENDED]

■ 5. The authority citation for Part 743 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

§ 743.2 [Amended]

■ 6. Section 743.2 is amended by removing the phrase “0.75 Weighted TeraFLOPS (WT).” and adding in its place “1.5 Weighted TeraFLOPS (WT).” in paragraph (b).

PART 774—[AMENDED]

■ 7. The authority citation for Part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

■ 8. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 4—Computers, ECCN 4A003 is amended by revising the AT entry and **Notes 1 and 2** in the License Requirements section, and paragraph b. in the Items paragraphs of the List of Items Controlled section, to read as follows:

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

* * * * *

4A003 “Digital computers”, “electronic assemblies”, and related equipment therefor, as follows and specially designed components therefor.

License Requirements

* * * * *

| <i>Control(s)</i> | <i>Country chart</i> |
|---|--------------------------|
| * * * * | * |
| AT applies to entire entry (refer to 4A994 for controls on “digital computers” with a APP > 0.0128 but ≤ to 1.5 WT) | AT Column 1. |

Note 1: For all destinations, except those countries in Country Group E:1 of Supplement No. 1 to part 740 of the EAR, no license is required (NLR) for computers with an “Adjusted Peak Performance” (“APP”) not exceeding 1.5 Weighted TeraFLOPS (WT) and for “electronic assemblies” described in 4A003.c that are not capable of exceeding an “Adjusted Peak Performance” (“APP”) exceeding 1.5 Weighted TeraFLOPS (WT) in aggregation, except certain transfers as set forth in § 746.3 (Iraq).

Note 2: Special Post Shipment Verification reporting and recordkeeping requirements for exports of computers to destinations in Computer Tier 3 may be found in § 743.2 of the EAR.

* * * *

List of Items Controlled

* * * *

Items:

* * * *

b. “Digital computers” having an
“Adjusted Peak Performance” (“APP”) exceeding 1.5 weighted TeraFLOPS (WT);

* * * *

Dated: June 15, 2011.

Kevin J. Wolf,

*Assistant Secretary for Export
Administration.*

[FR Doc. 2011-15842 Filed 6-23-11; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. FDA-2003-N-0212; (formerly
Docket No. 2003N-0355)]

Medical Devices; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug
Administration (FDA) is issuing a final
regulation to confirm, with one change,
the interim final rule (IFR) entitled
“Medical Devices; Exception From

General Requirements for Informed
Consent.” This final rule confirms the
IFR’s establishment of a new exception
from the general requirements for
informed consent to permit the use of
investigational in vitro diagnostic
devices to identify chemical, biological,
radiological, or nuclear agents without
informed consent in certain
circumstances. FDA has created this
exception to help ensure that
individuals who may have been
exposed to a chemical, biological,
radiological, or nuclear agent are able to
benefit from the timely use of the most
appropriate diagnostic devices,
including those that are investigational.
This final rule adds a requirement that
the investigator submit the required
documentation to FDA, in addition to
submitting it to the reviewing
Institutional Review Board (IRB).

DATES: The rule is effective June 24,
2011.

FOR FURTHER INFORMATION CONTACT:

Claudia M. Gaffey, Center for Devices
and Radiological Health, Food and Drug
Administration, 10903 New Hampshire
Ave., Bldg. 66, rm. 5516, Silver Spring,
MD 20993-0002, 301-796-6196.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of Final Rule

In the **Federal Register** of June 7, 2006
(71 FR 32827), FDA published an
Interim Final Rule that established an
exception from the general requirements
for informed consent to permit the use
of investigational in vitro diagnostic
devices to identify chemical, biological,
radiological, or nuclear agents without
informed consent in specified
circumstances. The IFR amended 21
CFR 50.23, to add paragraph (e). The
rule was issued under the authority set
forth in section 520(g)(3)(D) of the
Federal Food, Drug, and Cosmetic Act
(the FD&C Act) (21 U.S.C. 360j(g)(3)(D)).
FDA gave interested parties 60 days to
comment on the IFR. FDA is publishing
this final rule that incorporates one
change in response to comments that
the rule did not protect against misuse
of the exception. This change is
described in section II of this document.

B. Legal Authority

This regulation is being issued under
the statutory authority provided in
section 520(g)(3)(D) of the FD&C Act,
which outlines the criteria under which
an exemption from informed consent
may be permissible. Under section
520(g)(3)(D) of the FD&C Act, informed
consent is required unless the
investigator determines the following in
writing: (1) There exists a life

threatening situation involving the
human subject of such testing which
necessitates the use of such device; (2)
it is not feasible to obtain informed
consent from the subject; and (3) there
is not sufficient time to obtain such
consent from the subject’s legally
authorized representative. Further, a
licensed physician uninvolved in the
testing must agree with this three-part
determination in advance of using the
device unless use of the device is
required to save the life of the human
subject of such testing and there is not
sufficient time to obtain such
concurrence.

II. Highlights of Final Rule

The preamble to the IFR described the
provisions of this rule in detail (71 FR
32827). In issuing this final rule, FDA is
making one change to the IFR, in
response to comments that the rule did
not protect against misuse of this
limited exception from informed
consent requirements. In response to
those concerns, FDA is adding a
requirement that investigators also send
the required documentation to FDA, not
just to the reviewing IRB. This new
requirement provides an additional
level of oversight to help ensure that the
limited exception criteria are met.

III. Comments on the IFR

The Agency received comments on
the IFR from nine different entities.
Comments were received from four
individual consumers, two from
consumer groups, and one each from a
health professional, a health
professional group, and a local
government. A summary of the
comments received, grouped by subject
matter follows.

A. General Comments

(Comment 1) Three comments
expressed support for the IFR, noting
that the rule is needed and greatly
improves the ability of public health
laboratories to respond to a public
health emergency. In contrast, six
comments expressed general concern
that the rule presents too much risk to
the consumer. Some comments raised
issues that are beyond the scope of this
rulemaking. For example, one of these
comments suggested that informed
consent documents have a line
addressing in vitro diagnostic testing;
another encouraged the production of
templates to easily provide the detailed
information required to be included in
the reports.

(Response) FDA agrees with the
comments recognizing that the rule will
enable better response in public health
emergencies. FDA also shares the