§ 150.20 [Amended]

2. In § 150.20, paragraph (b)(1), first sentence, remove the words ''Except as specified in paragraph (c) of this section, shall'', add in their place ''shall'' and remove paragraphs (c) and (d).

Dated at Rockville, Maryland, this 28th day of December, 2000.

For the Nuclear Regulatory Commission.

Patricia G. Norry,
Acting Executive Director for Operations.
[FR Doc. 01–1079 Filed 1–18–01; 8:45 am]
BILLING CODE 7590–01–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 740, 742, and 748

[Docket No. 010112014–1014–01]

RIN 0694–AC41

Implementation of Presidential Announcement of January 10, 2001: Revisions to License Exception CTP

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) by revising License Exception CTP to reflect rapid technological advances in computing capability. This rule implements the President's sixth revision to U.S. export controls on high performance computers (HPCs), announced January 10, 2001. License Exception CTP is revised by removing Computer Tier 2 and merging its countries into Computer Tier 1. All HPCs continue to be eligible for export to a Computer Tier 1 country under License Exception CTP. Additionally, HPCs with CTP up to 85,000 MTOPS can be exported to Computer Tier 3 countries under License Exception CTP, and beginning March 20, 2001, exporters will no longer be required to submit National Defense Authorization Act (NDAA) advance notifications for HPCs with CTP exceeding 85,000 MTOPS. The NDAA advance notification will not be required for these computers, because exporters will be submitting a license for exports to Computer Tier 3 countries of HPCs with CTP exceeding 85,000 MTOPS. This rule also moves Lithuania from Computer Tier 3 to Computer Tier 1, effective May 19, 2001. The President's action will promote our national security, enhance the effectiveness of

our export control system and ease unnecessary regulatory burdens on both government and industry.

DATES: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Tanya Hodge Mottley in the Office of Strategic Trade and Foreign Policy Controls, Bureau of Export Administration, at (202) 482–1837.

SUPPLEMENTARY INFORMATION:

Background

On January 10, 2001, the President announced significant changes to U.S. export control policy for HPCs. The new policy continues the Administration's commitment, as announced on July 1, 1999, to review and update its HPC policy every six months in order to reflect rapid advancements in computer hardware, as well as identify any risk posed by HPC exports to certain end-users and countries. This policy strengthens America's high tech competitiveness, while maintaining export controls to protect U.S. national security.

The Administration, in consultation with the national security community and industry, has determined that additional adjustments are warranted. Effective immediately, all countries in Computer Tier 2 have been moved to Computer Tier 1. Computer Tier 2 has been deleted. Those countries formerly in Computer Tier 2 do not pose proliferation or security threats to the United States.

This rule implements the Administration's decision to increase License Exception CTP eligibility for HPC exports to countries in Computer Tier 3 by raising the CTP level to 85,000 MTOPS, to reflect the widespread availability of computers, including high performance computing capability attained by clustering numerous lower level personal computers together.

Effective March 20, 2001, this rule raises the advance notification requirement level for HPC exports to Computer Tier 3 countries from 28,000 to 85,000 MTOPS. As required by the NDAA, changes in the advance notification level for HPC exports to Tier 3 destinations are only effective 60 days following the President's submission of a report to Congress. In addition, this rule revises the support documentation requirements for computers exported to the People's Republic of China.

This rule removes Lithuania from Computer Tier 3 and places it in Computer Tier 1. However, due to the requirements in the 1998 National Defense Authorization Act (NDAA),

removing Lithuania from Computer Tier 3 is not effective until 120 days after the Congress receives a report justifying such a removal.

This rule revises the Export Administration Regulations by modifying computer exports under License Exception CTP, as follows:

1. Moving all Computer Tier 2 countries to Computer Tier 1;

2. Raising the CTP limit for computers eligible for License Exception CTP for exports and reexports to Computer Tier 3 destinations from ''28,000 MTOPS'' to ''85,000 MTOPS'';

3. Moving Lithuania to Tier 1 as of May 19, 2001;

4. Revising the CTP range for which NDAA notification is required for computers exported or reexported to Computer Tier 3 countries;

5. Revising the CTP level of computers for which PRC End-User Certificates are required as support documentation for export under License Exception CTP; and

6. Revising the CTP level of the computers that require post shipment verification reports for exports to Computer Tier 3 countries.

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 be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This regulation involves collections previously approved by the Office of Management and Budget under control numbers 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 45 minutes per manual submission and 40 minutes per electronic submission. Miscellaneous and recordkeeping activities account for 12 minutes per submission. Information is also collected under OMB control number 0694–0107, ''National Defense Authorization Act,'' Advance Notifications and Post-Shipment Verification Reports, which carries a burden hour estimate of 15 minutes per report. This rule also involves collections of information under OMB control number 0694–0073, ''Export Controls of High Performance Computers'' and OMB control number 0694–0093, ''Import Certificates and End-User Certificates.''

3. This rule does not contain policies with Federalism implications as that

term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rule making, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rule making and an opportunity for public comment be given for this rule. Because a notice of proposed rule making and opportunities for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

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 Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Parts 740 and 748

Administrative practice and procedure, Exports, Foreign trade, Reporting and record keeping requirements.

15 CFR Part 742

Exports, Foreign trade.

Accordingly, parts 740, 742 and 748 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

1. The authority citation for 15 CFR Part 740 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

2. The authority citation for 15 CFR Part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; Pub.L. No. 106–398; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of November 10, 1999, 64 FR 61767, 3 CFR, 1999 Comp., p. 318; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

3. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

PART 740—[AMENDED]

4. Part 740 is amended by revising section 740.7, to read as follows:

§ 740.7 Computers (CTP).

(a) *Scope.* License Exception CTP authorizes exports and reexports of computers and specially designed components therefor, exported or reexported separately or as part of a system for consumption in Computer Tier countries as provided by this section. (Related equipment controlled under 4A003.d and .g is authorized under this License Exception, only when exported or reexported with these computers as part of a system.) You may not use this License Exception to export or reexport items that you know will be used to enhance the CTP beyond the eligibility limit allowed to your country of destination. When evaluating your computer to determine License Exception CTP eligibility, use the CTP parameter to the exclusion of other technical parameters for computers classified under ECCN 4A003.a, .b and .c, *except* of parameters specified as Missile Technology (MT) concerns or 4A003.e (equipment performing analog-to-digital conversions exceeding the limits in ECCN 3A001.a.5.a). This License Exception does not authorize the export or reexport of graphic accelerators or coprocessors, or of computers controlled for MT reasons.

(b) *Computer Tier 1.* (1) *Eligible countries.* The countries that are eligible to receive exports under this License Exception include Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Barbados, Bangladesh, Belgium, Belize, Benin, Bhutan, Bolivia, Botswana, Brazil, Brunei, Burkina Faso, Burma, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Czech Republic, Chile, Colombia, Congo, Costa Rica, Cote d'Ivoire, Cyprus, Denmark, Dominica, Dominican Republic, Ecuador, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Gabon, Finland, France, Gambia (The), Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hong Kong, Hungary, Iceland, Indonesia, Ireland, Italy, Jamaica, Japan, Kenya, Kiribati, Korea (Republic of), Lesotho, Liberia, Liechtenstein, Luxembourg,

Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritius, Mexico, Micronesia (Federated States of), Monaco, Mozambique, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Rwanda, St. Kitts & Nevis, St. Lucia, St. Vincent and Grenadines, Sao Tome & Principe, San Marino, Senegal, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, Spain, Sri Lanka, Surinam, Swaziland, Sweden, Switzerland, Taiwan, Tanzania, Togo, Tonga, Thailand, Trinidad and Tobago, Turkey, Tuvalu, Uganda, United Kingdom, Uruguay, Vatican City, Venezuela, Western Sahara, Western Samoa, Zaire, Zambia, and Zimbabwe. As of May 19, 2001, Lithuania is a Computer Tier 1 country.

(2) *Eligible computers.* The computers eligible for License Exception CTP to Tier 1 destinations are those having a Composite Theoretical Performance (CTP) greater than 6,500 Millions of Theoretical Operations Per Second (MTOPS).

(c) [Reserved]

(d) *Computer Tier 3.* (1) *Eligible countries.* The countries that are eligible to receive exports and reexports under this License Exception are Afghanistan, Albania, Algeria, Andorra, Angola, Armenia, Azerbaijan, Bahrain, Belarus, Bosnia & Herzegovina, Bulgaria, Cambodia, China (People's Republic of), Comoros, Croatia, Djibouti, Egypt, Georgia, India, Israel, Jordan, Kazakhstan, Kosovo (Serbian province of), Kuwait, Kyrgyzstan, Laos, Latvia, Lebanon, Lithuania, Macau, Macedonia (The Former Yugoslav Republic of), Mauritania, Moldova, Mongolia, Montenegro, Morocco, Oman, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, Tajikistan, Tunisia, Turkmenistan, Ukraine, United Arab Emirates, Uzbekistan, Vanuatu, Vietnam, and Yemen. As of May 19, 2001, Lithuania is moved to Computer Tier 1.

(2) *Eligible computers.* The computers eligible for License Exception CTP to Tier 3 destinations are those having a CTP greater than 6,500 MTOPS, but less than or equal to 85,000 MTOPS, subject to the restrictions in paragraph (d)(3) of this section.

(3) *Eligible exports.* Only exports and reexports to permitted end-users and end-uses located in countries in Computer Tier 3. License Exception CTP does not authorize exports and reexports to Computer Tier 3 for nuclear, chemical, biological, or missile end-users and end-uses and military

end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR. Such exports and reexports will continue to require a license and will be considered on a case-by-case basis. Retransfers to these end-users and end-uses in eligible countries are strictly prohibited without prior authorization.

(4) *Supporting documentation.* Exporters are required to obtain a People's Republic of China (PRC) End-User Certificate before exporting computers described by paragraph (d)(2) of this section to the PRC, regardless of value. (See § 748.10(b)(3) of the EAR for information on obtaining the PRC End-User Certificate.) Exporters are required to provide the PRC End-User Certificate Number to BXA as part of their post-shipment report (see paragraph (d)(5)(v) of this section). When providing the PRC End-User Certificate Number to BXA, you must identify the transaction in the post shipment report to which that PRC End-User Certificate Number applies. The original PRC End-User Certificate shall be retained in the exporter's files in accordance with the recordkeeping provisions of § 762.2 of the EAR.

(5) *NDAA notification.* (i) *General requirement and procedures.* The National Defense Authorization Act (NDAA) of FY98 (Public Law 105–85, 111 Stat. 1629), enacted on November 18, 1997 requires advance notification of certain exports and reexports of computers to Computer Tier 3 countries. For each such transaction destined to Computer Tier 3, prior to using License Exception CTP, you must first notify BXA by submitting a completed Multipurpose Application Form (BXA–748P). The Multipurpose Application Form must be completed including all information required for a license application according to the instructions described in Supplement No. 1 to part 748 of the EAR, with two exceptions. You (the applicant as listed in Block 14) shall in Block 5 (Type of Application) mark the box "Other." This designator will permit BXA to route the NDAA notice into a special processing procedure. (Blocks 6 and 7, regarding support documentation, may be left blank.) BXA will not initiate the registration of an NDAA notice unless all information on the Multipurpose Application form is complete.

(A) *Prior to February 26, 2001*, advance notification is required for all exports and reexports of computers with a CTP greater than 12,500 but less than or equal to 85,000 MTOPS to Computer Tier 3 destinations. You must also provide a notice using this procedure prior to exporting or reexporting items

that you know will be used to enhance the CTP of a previously exported or reexported computer beyond 12,500 MTOPS, but less than or equal to 85,000 MTOPS.

(B) *Beginning on February 26, 2001 but prior to March 20, 2001*, advanced notification is required for export and reexport of computers with a CTP greater than 28,000 MTOPS, but less than or equal to 85,000 MTOPS to Computer Tier 3 destinations. You must also provide a notice using this procedure prior to exporting or reexporting items that you know will be used to enhance the CTP of a previously exported or reexported computer beyond 28,000 MTOPS, but less than or equal to 85,000 MTOPS.

(ii) *Action by BXA.* Within 24 hours of the registration of the NDAA notice, BXA will refer the notice for interagency review. Registration is defined as the point at which the notice is entered into BXA's electronic system.

(iii) *Review by other departments or agencies.* The Departments of Defense, Energy, and State have the authority to review the NDAA notice. Objections by any department or agency must be received by the Secretary of Commerce within nine days of the referral. Unlike the provisions described in § 750.4(b) of the EAR, there are no provisions for stopping the processing time of the NDAA notice. If, within 10 days after the date of registration, any reviewing agency provides a written objection to the export or reexport of a computer, License Exception CTP may not be used. In such cases, you will be notified that a license is required for the export or reexport. The NDAA notice will then be processed by BXA as a license application in accordance to the provisions described in § 750.4 of the EAR, and the licensing policies set forth in the Export Administration Regulations. Its NDAA notice number will be changed to a license application number. BXA may at this time request additional information to properly review the license application. If BXA confirms that no objection has been raised within the 10-day period (as described in paragraph (d)(5)(iv) of this section), you may proceed with the transaction on the eleventh day following date of registration. (Note that the fact that you have been advised to proceed with the transaction does not exempt you from other licensing requirements under the EAR, such as those based on knowledge of a prohibited end-use or end-user as referenced in general prohibition five (part 736 of the EAR) and set forth in part 744 of the EAR.)

(iv) *Status of pending advance notification requests.* You must contact BXA's System for Tracking Export License Applications ("STELA") at (202) 482–2752. (See § 750.5 of the EAR for procedures to access information on STELA.) STELA will provide the date of registration of the NDAA notice. If no departments or agencies raise objections within the 10-day period, STELA will provide you on the eleventh day following date of registration with confirmation that no objections have been raised and you may proceed with the transaction. BXA will subsequently issue written confirmation to you. If a license is required, STELA will notify you that an objection has been raised and a license is required. The NDAA notice will be processed as a license application. In addition, BXA may provide notice of an objection by telephone, fax, courier service, or other means.

(v) *Post-shipment verification.* This section outlines special post-shipment reporting requirements for exporters of certain computers to destinations in Computer Tier 3. Post-shipment reports must be submitted in accordance with the provisions of this paragraph (d)(5)(v), and all relevant records of such exports must be kept in accordance with part 762 of the EAR.

(A) Exporters must file post-shipment reports for computer exports, as well as exports of items used to enhance previously exported or reexported computers, according to the following schedule:

(*1*) For exports occurring prior to February 26, 2001, where the CTP is greater than 12,500 MTOPS; and

(*2*) For exports on or after February 26, 2001, but prior to March 20, 2001, where the CTP is greater than 28,000 MTOPS.

(B) *Information that must be included in each post-shipment report.* No later than the last day of the month following the month in which the export takes place, the exporter must submit the following information to BXA at the address listed in paragraph (d)(5)(v)(C) of this section:

(*1*) Exporter name, address, and telephone number;

(*2*) NDAA notification number;

(*3*) Date of export;

(*4*) End-user name, point of contact, address, telephone number;

(*5*) Carrier;

(*6*) Air waybill or bill of lading number;

(*7*) Commodity description, quantities—listed by model numbers, serial numbers, and CTP level in MTOPS; and

(*8*) Certification line for exporters to sign and date. The exporter must certify that the information contained in the report is accurate to the best of his or her knowledge.

Note to paragraph (d)(5)(v)(B) of this section: For exports authorized under License Exception CTP to the People's Republic of China (PRC), you must submit the PRC End-User Certificate Number identifying the transaction for which the End-User Certificate Number applies.

(C) *Mailing address.* A copy of the post-shipment report[s] required under paragraph (d)(5)(v) of this section shall be delivered to one of the following addresses. Note that BXA will not accept reports sent C.O.D.

(*1*) For deliveries by U.S. postal service: U.S. Department of Commerce, Bureau of Export Administration, P.O. Box 273, Washington, D.C. 20044, Attn: Office of Enforcement Analysis HPC Team, Room 4065.

(*2*) For courier deliveries: U.S. Department of Commerce, Office of Enforcement Analysis HPC Team, 14th Street and Constitution Ave., NW, Room 4065, Washington, DC 20230.

(e) *Restrictions.* (1) *Access by certain foreign nationals.* Computers eligible for License Exception CTP may not be accessed either physically or computationally by nationals of Cuba, Iran, Iraq, Libya, North Korea, Sudan or Syria, except commercial consignees described in Supplement No. 3 to part 742 of the EAR are prohibited only from giving such nationals user-accessible programmability.

(2) *Reexport and retransfers.* Computers eligible for License Exception CTP may not be reexported/ retransferred without prior authorization from BXA i.e., a license, a permissive reexport, another License Exception, or "No License Required". This restriction must be conveyed to the consignee, via the Destination Control Statement, see § 758.6 of the EAR. Additionally, the end-use and end-user restrictions in paragraph (d)(3) of this section must be conveyed to any consignee in Computer Tier 3.

(f) *Reporting requirements.* In addition to the reporting requirements set forth in paragraph (d) of this section, see § 743.1 of the EAR for additional reporting requirements of certain items under License Exception CTP.

PART 742—[AMENDED]

5. Section 742.12 is amended by removing the second sentence in paragraph (d); revising paragraph (a); removing and reserving paragraph

(b)(2); and revising paragraph (b)(3) to read as follows:

§ 742.12 High performance computers.

(a) *License and recordkeeping requirements.* (1) This section contains special provisions for exports, reexports, and certain intra-country transfers of high performance computers, including software, and technology. This section affects the following ECCNs: 4A001; 4A002; 4A003; 4D001; 4D002; and 4E001. Licenses are required under this section for ECCN's having an "XP" under "Reason for Control" when License Exception CTP is not available (see § 740.7 of the EAR). License requirements reflected in this section are based on particular destinations, end-users, or end-uses. For the calculation of CTP, see the Technical Note that follows the Advisory Notes for Category 4 in the Commerce Control List. Note that License Exception CTP contains restrictions on access by nationals of certain countries, and on reexports and transfers of computers.

(2) In recognition of the strategic and proliferation significance of high performance computers, a license is required for the export or reexport of high performance computers to destinations, end-users, and end-uses, as specified in this section and on the CCL. These license requirements supplement requirements that apply for other control reasons, such as nuclear nonproliferation provided in section 742.3 of the EAR. The license requirements described in this section 742.12 are not reflected on the Country Chart (Supplement No. 1 to part 738 of the EAR). Three Computer Country Tiers have been established for the purposes of these controls. Countries included in Computer Tiers 1 and 3 are listed in License Exception CTP in section 740.7 of the EAR. As of January 19, 2001 there is no longer a Computer Tier 2, and countries that were in Tier 2 are incorporated into Computer Tier 1. Computer Tier 4 consists of Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.

(3) Exporters must keep accurate records of each export to countries not included in Country Group A:1 (see Supplement No. 1 to part 740 of the EAR) of a computer with a CTP greater than 6,500 MTOPS. These records must be submitted semiannually to BXA and must contain the information as described in § 743.1 of the EAR.

(b) * * *

(1) * * *

(2) [Reserved]

(3) Computer Tier 3. (i) *License requirement.* (A) A license is required to export or reexport computers to

countries in Computer Tier 3 to nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR in Computer Tier 3 countries.

(B) A license is required to export or reexport computers with a CTP greater than 85,000 MTOPS to a country in Computer Tier 3.

(C) Prior to February 26, 2001, a license may be required to export or reexport computers with a CTP greater than 12,500 MTOPS to countries in Computer Tier 3 pursuant to the NDAA (see § 740.7(d)(5) of the EAR). Beginning on February 26, 2001 but prior to March 20, 2001, a license may be required to export or reexport computers with a CTP greater than 28,000 MTOPS but less than or equal to 85,000 MTOPS to countries in Computer Tier 3 pursuant to the NDAA.

(ii) *Licensing policy for nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses.* License applications for exports and reexports to nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR in countries in Computer Tier 3 will be reviewed on a case-by-case basis using the following criteria:

(A) The presence and activities of countries and end-users of national security and proliferation concern and the relationships that exist between the government of the importing country and such countries and end-users;

(B) The ultimate consignee's participation in, or support of, any of the following:

(*1*) Activities that involve national security concerns; or

(*2*) Nuclear, chemical, biological or missile proliferation activities described in part 744 of the EAR;

(C) The extent to which the importing country is involved in nuclear, chemical, biological, or missile proliferation activities described in part 744 of the EAR;

(D) The end-user, whether the end-use is single-purpose or multiple-purpose.

(iii) *Licensing policy for other end-users and end-uses.* License applications for exports and reexports to other end-uses and end-users located in Computer Tier 3 countries will generally be approved, except there is a presumption of denial for all applications for exports and reexports of computers having a CTP greater than 6,500 MTOPS destined to Indian and Pakistani entities determined to be

involved in nuclear, missile, or military activities included in Supplement No. 4 to part 744 (Entity List). All license applications for exports and reexports to India and Pakistan not meeting these criteria for presumption of denial will be considered on a case-by-case basis under other licensing policies set forth in the EAR applicable to such computers.

(iv) *Post-shipment verification.* This section outlines special post-shipment reporting requirements for exporters of certain computers to destinations in Computer Tier 3. Post-shipment reports must be submitted in accordance with the provisions of this paragraph (b)(3)(iv), and all relevant records of such exports must be kept in accordance with part 762 of the EAR.

(A) Exporters must file post-shipment reports for computer exports, as well as exports of items used to enhance previously exported or reexported computers, according to the following schedule:

(*1*) For exports occurring prior to February 26, 2001, where the CTP is greater than 12,500 MTOPS;

(*2*) For exports on or after February 26, 2001, but before March 20, 2001 where the CTP is greater than 28,000 MTOPS; and

(*3*) For exports on or after March 20, 2001 where the CTP is greater than 85,000 MTOPS.

(B) *Information that must be included in each post-shipment report.* No later than the last day of the month following the month in which the export takes place, the exporter must submit the following information to BXA at the address listed in paragraph (b)(3)(iv)(C) of this section:

(*1*) Exporter name, address, and telephone number;

(*2*) License number;

(*3*) Date of export;

(*4*) End-user name, point of contact, address, telephone number;

(*5*) Carrier;

(*6*) Air waybill or bill of lading number;

(*7*) Commodity description, quantities—listed by model numbers, serial numbers, and CTP level in MTOPS; and

(*8*) Certification line for exporters to sign and date. The exporter must certify that the information contained in the report is accurate to the best of his or her knowledge.

(C) *Mailing address.* A copy of the post-shipment report[s] required under paragraph (b)(3)(iv)(A) of this section shall be delivered to one of the following addresses. Note that BXA will not accept reports sent C.O.D.

(*1*) For deliveries by U.S. postal service: U.S. Department of Commerce, Bureau of Export Administration, P.O. Box 273, Washington, D.C. 20044, Attn: Office of Enforcement Analysis HPC Team, Room 4065.

(*2*) For courier deliveries: U.S. Department of Commerce, Office of Enforcement Analysis HPC Team, 14th Street and Constitution Ave., NW, Room 4065, Washington, DC 20230.

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PART 748—[AMENDED]

6. Section 748.10 is amended by revising paragraph (b)(3) as follows:

§ 748.10　Import and end-user certificates.

*　*　*　*　*

(b) * * *

(3) Your transaction involves an export to the People's Republic of China (PRC) of a computer. You must obtain a PRC End-User Certificate, regardless of dollar value, as follows:

(i) For exports of computers as described by § 740.7(d)(2) of the EAR, regardless of value, to the People's Republic of China. (See paragraph (c) of this section for information on obtaining the PRC End-User Certificate.) Exporters are required to obtain a PRC End-User Certificate before exporting computers to the PRC. In addition, exporters are required to provide the PRC End-User Certificate Number to BXA as part of their post-shipment report (see § 740.7(d)(5)(v) of the EAR). When providing the PRC End-User Certificate Number to BXA, you must identify the transaction in the post shipment report to which that PRC End-User Certificate Number applies. The original PRC End-User Certificate shall be retained in the exporter's files in accordance with the recordkeeping provisions of § 762.2 of the EAR.

(ii) For exports of computers that require license applications.

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Dated: January 16, 2001.

Matthew S. Borman,

Acting Deputy Assistant Secretary for Export Administration.

[FR Doc. 01–1623 Filed 1–16–01; 4:49 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 807, and 1271

[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require human cells, tissue, and cellular and tissue-based product establishments to register with the agency and list their human cells, tissues, and cellular and tissue-based products. FDA is also amending the registration and listing regulations that currently apply to human cells, tissues, and cellular and tissue-based products regulated as drugs, devices, and/or biological products. These actions are being taken to establish a unified registration and listing program for human cells, tissues, and cellular and tissue-based products.

DATES: The regulation is effective April 4, 2001, except for 21 CFR 207.20(f), 807.20(d), and 1271.3(d)(2), which are effective on January 21, 2003.

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SUPPLEMENTARY INFORMATION:

I. Introduction

We, FDA, are putting in place a comprehensive new system of regulation for human cells, tissues, and cellular and tissue-based products. The goal of the new approach is to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products. Under the new system, the regulation of different types of human cells, tissues, and cellular and tissue-based products will be commensurate with the public health risks presented, enabling us to use our resources more effectively. Consolidating the regulation of human cells, tissues, and cellular and tissue-based products into one regulatory program is expected to lead to increased consistency and greater efficiency. Together, these planned improvements will increase the safety of human cells,