

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 action does not impact any information collection or recordkeeping requirements under the PRA.

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

4. BIS finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and an opportunity for public comment on this action because this action merely redesignates existing regulatory text in the Code of Federal Regulations and therefore notice and comment are unnecessary. Furthermore, because this action makes no substantive changes, it does not constitute a substantive rule, and it is not subject to the requirement for a 30-day delay in effective date under 5 U.S.C. 553(d).

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

List of Subjects in 15 CFR Parts 7 and 791

Administrative practice and procedure, Business and industry, Communications, Computer technology, Critical infrastructure, Executive orders, Foreign persons, Investigations, National security, Penalties, Technology, Telecommunications.

Subtitle A—Office of the Secretary of Commerce

PART 7—SECURING THE INFORMATION AND COMMUNICATIONS TECHNOLOGY AND SERVICES SUPPLY CHAIN

■ 1. The authority citation for part 7 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; 50 U.S.C. 1601 *et seq.*; E.O. 13873, 84 FR 22689; E.O. 14034, 86 FR 31423.

PART 7—[REDESIGNATED AS PART 791]

■ 2. Redesignate part 7 as part 791, according to the following table:

Part 7	Part 791
Subpart A	Subpart A
§§ 7.1 through 7.7	§§ 791.1 through 791.7.
Subpart B	Subpart B
§§ 7.100 through 7.110. ...	§§ 791.100 through 791.110
Subpart C	Subpart C
§ 7.200	§ 791.200.

§ 791.102 Confidentiality of information.

■ 3. In newly redesignated § 791.102 amend paragraph (c) by removing “§ 7.109 of this part” and adding “§ 791.109” in its place.

§ 791.103 Initial review of ICTS Transactions.

■ 4. In newly redesignated § 791.103:
 ■ a. Amend paragraph (a) by removing “§ 7.100(a)” and adding “§ 791.100(a)” in its place;
 ■ b. Amend paragraph (b) introductory text by removing “§ 7.3(a) of this part” and adding “§ 791.3(a)” in its place; and
 ■ c. Amend paragraph (b)(2) by removing “§ 7.100(a)” and adding “§ 791.100(a)” in its place.

§ 791.104 First interagency consultation.

■ 5. In newly redesignated § 791.104, remove “§ 7.103” and add “§ 791.103” in its place and remove the two instances of “§ 7.103(c)” and add “§ 791.103(c)” in their place.

§ 791.105 Initial determination.

■ 6. In newly redesignated § 791.105:
 ■ a. Amend paragraph (a) introductory text by removing “§ 7.104” and adding “§ 791.104” in its place and removing “§ 7.103(c)” and adding “§ 791.103(c)” in its place;
 ■ b. Amend paragraph (b) introductory text by removing “§ 7.104” and adding “§ 791.104” in its place and removing the two instances of “§ 7.103(c)” and adding “§ 791.103(c)” in their place.

§ 791.107 Procedures governing response and mitigation.

■ 7. In newly redesignated § 791.107:
 ■ a. Amend the introductory text by removing “§ 7.105” and adding “§ 791.105” in its place;
 ■ b. Amend paragraph (d) by removing “§ 7.109” and adding “§ 791.109” in its place; and
 ■ c. Amend paragraph (f) by removing “section 7.108 of this rule” and adding “§ 791.108” in its place.

§ 791.108 Second interagency consultation.

■ 8. In newly redesignated § 791.108:
 ■ a. Amend paragraph (a) by removing “§ 7.107” and adding “§ 791.107” in its

place and removing “§ 7.103(c)” and adding “§ 791.103(c)” in its place;
 ■ b. Amend paragraph (b) by removing “§ 7.107” and adding “§ 791.107” in its place and by adding “of this section” after “with paragraph (a)”; and
 ■ c. Amend paragraph (d) by removing “§ 7.109” and adding “§ 791.109” in its place.

§ 791.109 Final determination.

■ 9. In newly redesignated § 791.109, amend paragraph (b) by removing “§ 7.103” and adding “§ 791.103” in its place.

■ 10. Under the authority of section 301 of Title 5, United States Code, (5 U.S.C. 301) and Chapter 40 of Title 15 of the United States Code (15 U.S.C. 1501 *et seq.*), add subchapter E, consisting of parts 790 through 799, to read as follows:

Subchapter E—Information and Communications Technology and Services Regulations

PART 790 [RESERVED]

PART 791—SECURING THE INFORMATION AND COMMUNICATIONS TECHNOLOGY AND SERVICES SUPPLY CHAIN.

PARTS 792–799 [RESERVED]

■ 11. Transfer part 791 to subchapter E.

Elizabeth Cannon,

Executive Director for the Office of Information and Communications Technology and Services.

[FR Doc. 2024–15258 Filed 7–17–24; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 744 and 772

[Docket No. 240712–0190]

RIN 0694–A106

Standards-Related Activities and the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Interim final rule with request for comments.

SUMMARY: In this interim final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the scope and the terms used in the EAR to describe “standards-related activities” that are subject to the EAR. BIS is making these revisions to ensure that

export controls and associated compliance concerns do not impede the participation and leadership of U.S. companies in legitimate standards-related activities.

DATES:

Effective date: This rule is effective July 18, 2024.

Comment date: Comments must be received by BIS no later than September 16, 2024.

ADDRESSES: You may submit comments, identified by docket number BIS–2020–0017 or RIN 0694–AI06, through the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments. You can find this interim final rule by searching for its *regulations.gov* docket number, which is BIS–2020–0017.

All filers using the portal should use the name of the person or entity submitting comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and also provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” The “BC” and “P” should be followed by the name of the person or entity submitting the comments. Any submissions with file names that do not begin with a “BC” or “P” will be assumed to be public and will be made publicly available through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Susan Kramer, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce. Phone: (202) 482–2440; Email: Susan.Kramer@bis.doc.gov.

SUPPLEMENTARY INFORMATION:**A. Background**

Participation and leadership in standards development is crucial to protecting and enhancing U.S. national and economic security and has been instrumental to the global technological

leadership of the United States. Standards development underpins U.S. economic prosperity and fortifies U.S. leadership in critical and emerging technologies. The U.S. standards development system is unique because it is built upon a wide variety of processes that are open, voluntary, decentralized, and led by the private sector. These processes feature openness to participation by materially interested stakeholders and consensus-based decision making. Finalized standards are primarily published by private sector standards organizations, not the U.S. Government.

On May 4, 2023, the Biden-Harris Administration announced the “United States Government National Standards Strategy for Critical and Emerging Technology” (USG NSSCET). The USG NSSCET is intended to support and complement existing private sector-led activities and plans, including the American National Standards Institute (ANSI) United States Standards Strategy (USSS), with a focus on critical and emerging technology(ies) (CET). Consistent with the USG NSSCET strategy, the Commerce Department is committed to engaging “with a broad range of private sector, academic and other key stakeholders, including foreign partners, to address gaps and bolster U.S. participation in [CET] standards development activities.” As outlined in the USG NSSCET, the U.S. Government is prioritizing efforts for CET standards development in identified areas that are essential to U.S. national security and competitiveness in critical industries including biotechnologies; positioning, navigation and timing services; communications and networking technologies; and quantum information technologies among others. The USG NSSCET outlines four objectives (investment, participation, workforce, and integrity and inclusivity) and eight corresponding lines of effort to ensure that the United States remains a global leader in developing merit-based standards that embrace transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and broad participation. More information regarding the USG NSSCET can be found here: <https://www.whitehouse.gov/wp-content/uploads/2023/05/US-Gov-National-Standards-Strategy-2023.pdf>.

Since 2019, BIS has made a number of revisions to the EAR (15 CFR parts 730–774) that have affected U.S. participation and leadership in standards-related activities. Most recently, BIS published an interim final rule, “Authorization of Certain “Items”

to Entities on the Entity List in the Context of Specific Standards Activities” (see 87 FR 55241 (September 9, 2022)) (the September 2022 rule), that amended the EAR to authorize the release of specified items subject to the EAR when such release is for a “standards-related activity” as defined in the EAR (a term in double quotes indicates the term is defined in part 772 (Definition of Terms) of the EAR). Additional information about that process, the listing of Huawei Technologies Co., Ltd and its non-U.S. affiliates (collectively “Huawei”), and associated licensing requirements can be found at 84 FR 22961 (May 21, 2019) (background section providing a brief overview of how entities are added to the Entity List); see also 87 FR at 55241 (background section describing licensing requirements for Huawei as a result of being added to the Entity List).

The revisions promulgated in the September 2022 rule sought to ensure that export controls do not impede the participation and leadership of U.S. companies in standards-related activities. As noted in that rule, any impediment to U.S. participation in standards development forums is a national security threat to the United States because it not only limits U.S. leadership in standards development, but other countries are already racing to replace U.S. participation with their own leadership and standards. In many cases, a decrease in U.S. participation not only undermines U.S. national security and foreign policy interests but also contributes to a potential future global standards environment that works to oppose U.S. interests.

BIS Regulatory Actions and Standards

BIS has been actively involved on issues related to standards and export controls since the addition of Huawei to supplement no. 4 to part 744 (Entity List) of the EAR on May 16, 2019 (See 84 FR 22961 (May 21, 2019)). The addition of Huawei to the Entity List imposed a license requirement on all exports, reexports and transfers (in-country) to Huawei and its listed affiliates. Since that action and subsequent additions of other Huawei affiliates to the Entity List, BIS has engaged with industry as well as the interagency on export controls and standards-related activities and has published two interim final rules specific to how the EAR treat standards-related activities.

(a) TGL and the June 2020 IFR

First, to avoid disruption to existing U.S. and global telecommunications networks, on May 22, 2019, BIS issued

a Temporary General License (TGL) to authorize certain activities with Huawei, including, among other things, U.S. industry's participation as necessary for the development of 5G standards by a duly recognized standards body when Huawei was also participating in the standards-related activities (see 84 FR 23468 (May 22, 2019)). The TGL was subsequently extended through August 13, 2020. As the TGL was set to expire, BIS published an interim final rule with a request for comment, "Release of 'Technology' to Certain Entities on the Entity List in the Context of Standards Organizations" (see 85 FR 36719, June 18, 2020) (the June 2020 rule), that amended the EAR to authorize the release of certain technology to Huawei and its affiliates on the Entity List.

The June 2020 rule defined "standards" and "standards organizations" on the basis of the Office of Management and Budget Circular A-119 (OMB A-119) definitions and authorized limited releases of low-level "technology" and "software" to Huawei in the context of "standards" in a "standards organization." In public comments received in response to the June 2020 rule, U.S. industry raised concerns that the definitions and provisions promulgated in the June 2020 rule were chilling U.S. industry's participation in standards development.

Standards development in the United States, unlike in other countries, is driven by the private sector (e.g., industry, academia, etc.), which is an important factor that has fueled effective U.S. leadership in standards development. The U.S. Government takes a consultative role in this process through the work of the Department of Commerce's National Institute of Standards and Technology (NIST). Although the countries from which standards proposals originate are identified during standards development and setting activities, company affiliations are generally not known and are not a requirement for membership or participation.

Certain export control-related factors in the standards-making process, including but not limited to BIS's increased use of end-use and end-user controls, led to an environment of uncertainty for U.S. companies. They stopped sharing information and data in international standards bodies and in legitimate standards development activities because of, e.g., the participation of entities listed on the Entity List (other than Huawei) in standards bodies and standards development activities. Standards bodies began to view the United States

as a less than ideal place to hold standards meetings and discussions, as U.S. export controls introduced an element of non-openness which is contrary to the spirit and definition of standards organization espoused by OMB A-119. As a result, U.S. leadership in international standards development was at risk in key industries. The lack of U.S. participation in standards that form the foundation of future industrial and commercial development worldwide directly and negatively impacts U.S. national security, and limits U.S. global commercial influence. This encourages foreign actors to develop and promote their own standards across the global community at the expense of the United States. Additionally, U.S. non-participation in the development of standards affects U.S. companies as they must manufacture items that meet foreign standards.

(b) September 2022 IFR

In response to the public comments received on the June 2020 rule and following renewed consultation among government agencies, BIS published the September 2022 rule amending the EAR to authorize the release of specified items subject to the EAR without a license to entities added to the Entity List pursuant to § 744.11 in the narrow circumstance when that release occurs in the context of a "standards-related activity," as defined in the September 2022 rule. Specifically, BIS clarified the scope and application of standards activities covered by the authorization by removing the defined terms for "standards" and "standards organization" from the EAR and adding a new definition for "standards-related activity" that more accurately reflects the standards-setting landscape. BIS authorized the release of "software" controlled for anti-terrorism (AT) reasons only and items designated EAR99 (i.e., items subject to the EAR but not identified on the Commerce Control List (supplement no. 1 to part 774) (CCL)) in the scope of the authorization and included the release of specific "software" and "technology" only for the "development," "production," and "use" of cryptographic functionality in the authorization. The rule also required that the items were authorized for release only if there was an intent to "publish" the resulting standard. Additionally, the language regarding "standards-related activity" was removed from the License Requirement column in the Entity List and added to §§ 744.11 and 744.16 of the EAR. The September 2022 rule thus revised the scope of the standards authorization to

apply to entities on the Entity List with license requirement solely referencing § 744.11 and not other end use and end user license requirements in other sections of parts 744 (Control Policy: End-User and End-Use Based) and 746 (Embargoes and Other Special Controls) of the EAR.

Prior to the June 2020 rule, the majority of entities on the Entity list had, and continue to have, a license requirement that refers to § 744.11. Since the publication of the June 2020 rule, however, BIS has published a number of rules that have expanded end-use and end-user controls. As a result, since the publication of the June 2020 rule, over 400 additional entities have been added to the Entity List with a license requirement that references a provision other than § 744.11. In recognition of these circumstances, in the September 2022 rule, BIS requested comments on whether excluding these other end-use and end-user provisions of the EAR from the authorization would negatively impact and prevent U.S. industry from actively participating and leading in "standards-related activities," or if export controls and compliance concerns would continue to limit U.S. leadership and participation in standards-related activities, thereby negatively impacting U.S. commercial and national security interests.

B. Changes to Licensing Requirements in the Context of Specific Standards Activities

Based on public comments received from the September 2022 rule (as summarized in Section D), as well as continued discussions with other U.S. Government agencies and industry, BIS is amending the EAR to ensure that export controls and associated compliance concerns do not continue to impede or jeopardize U.S. participation and leadership in legitimate standards-related activities. The national security threat that results from ceding, and in some cases ceasing, U.S. participation and leadership in standards development and promulgation far outweighs the risks related to the limited release of the authorized low-level technology and software to parties on the Entity List when released in the context of a "standards-related activity." BIS has concluded that excluding end-use and end-user controls from the authorization has had and will continue to have unintended negative consequences on the U.S. national security interests by curtailing U.S. involvement in legitimate standards-related activities.

As further detailed in the White House report on USG NSSCET

discussing the key objective of U.S. participation, the U.S. Government is taking action to “remove and prevent barriers to private sector participation in standards development.” Standards activities and development will continue to drive technological and industrial growth with or without input from U.S. companies. For U.S. industry to keep its leadership role and continued participation in standards development, especially in critical and emerging technologies identified in the USG NSSCET, the U.S. Government must address this issue comprehensively. As public comments to prior efforts to control exports related to standards development have shown, not addressing U.S. industry’s uncertainty regarding the end-use and end-user controls in the EAR is counterproductive and endangers U.S. commercial and strategic interests over the long term. To address these concerns and to further streamline and clarify controls over technology and software subject to the EAR as related to standards-related activities, BIS is making the following revisions to the EAR:

1. Moving the authorization for “standards-related activity” that was added to § 744.11 in the September 2022 rule to § 734.10. BIS is also making necessary conforming changes to § 744.16 and the introductory paragraph to supplement no. 4 to Part 744. This final rule does not change existing provisions in these sections regarding patents and whether they are subject to the EAR.

2. Revising the existing definition of ‘standards-related activity’ and adding the revised definition to § 734.10. This rule clarifies that a “standards-related activity” includes activities conducted with the intent to “publish” a standard as well as those conducted for an already “published” standard. BIS revises the definition of “standards-related activity” to remove the phrase “with which compliance is not mandatory.” In addition, in Part 772, BIS is revising the definition for “standards-related activity” to reference § 734.10.

When “technology” or “software” is released for a “standards-related activity,” the same item scope promulgated in the September 2022 continues to apply, *i.e.*, specific “technology” or “software” is not subject to the EAR if the item is designated EAR99, controlled on the CCL for anti-terrorism (AT) reasons only, or the release is of specified “software” and “technology” when specifically for the “development,”

“production,” and “use” of cryptographic functionality.

C. Request for Additional Public Comments for This Interim Final Rule

Instructions for submission of comments, including comments that contain business confidential information, are found in the **ADDRESSES** section of this interim final rule. BIS is requesting comment on whether the revisions promulgated in this interim final rule effectively promote Objective 2 of the USG NSSCET by removing and preventing barriers to private sector participation in standards development.

D. Summary and Response to Comments Received Regarding the September 2022 Standards Interim Final Rule

The summary and responses to the nine relevant comments that BIS received from the September 2022 interim final rule have been separated into seven topic areas. For topics in which the comments expressed the same or very similar viewpoints, BIS has addressed them by topic area rather than by individual comment. For topic areas in which the commenters expressed unique viewpoints, thoughts, or ideas, BIS has addressed the individual comments. The majority of comments have been addressed by the revisions to the EAR promulgated in this rule. BIS greatly appreciates the public comments received and encourages continued engagement and feedback.

Topic Area 1: Limits on standards-related activities due to export controls creates economic and national security risks for the United States.

Five commenters noted that any chilling of U.S. participation and leadership in standards development creates new security risks and vulnerabilities that threaten U.S. economic and national security interests. For example, one commenter stated that when its organization is restricted from engaging in information-sharing activities because those activities are not covered under the definition of “standards-related activities,” its organization loses the opportunity to receive valuable and potentially time-sensitive information about cyber incidents, threats, and vulnerabilities as well as the ability to further discuss those issues among the organization’s members and identify needed and appropriate resolutions.

Another commenter stated that “it is important that there be a two-way communication regarding security vulnerabilities discovered in hardware and software items. If participation of

Entity List entities is restricted, then security vulnerabilities discovered by these entities, many of which are quite large, may be withheld as they develop their own competing standards after being locked out of access to participation.” The same commenter went on to state that “we believe that the revised EAR exemption, as amended by the IFR, continues to work against the stated intent of the IFR and against the national security interests of the United States by prohibiting the dissemination of technology and software subject to the EAR in the context [of] standards-related activity when these specified items are released by open membership organizations” that develop their standards via an open process available to any member.

Response: BIS understands, as commenters have stated, that limits on the sharing of information in a standards development environment have both economic and national security implications. The national security threat that results from ceding U.S. participation and leadership in standards development and promulgation far outweighs the risks related to the limited release of low-level technology and software to parties on the Entity List in the context of a “standards-related activity” that supports U.S. commercial and economic interests. Therefore, in this rule, BIS is amending part 734 of the EAR so that activities that meet the definition of “standards-related activity” are no longer subject to the EAR. Specifically, when released for a “standards-related activity,” “technology” or “software” is not subject to the EAR if it meets the item scope of 734.10(b)(1) and is released for a “published” standard and/or occurs with the intent that the resulting standard will be “published.”

The USG NSSCET specifically highlights U.S. leadership in standards development of critical technologies. The USG NSSCET Executive Summary explicitly states that: “strength in standards development has been instrumental to the United States’ global technological leadership. Standards development underpins economic prosperity across the country and fortifies U.S. leadership in the industries of the future at the same time. Bolstering U.S. engagement in standards for critical and emerging technology (CET) spaces will strengthen U.S. economic and national security.”

Additionally, the Export Control Reform Act of 2018 (ECRA; 50 U.S.C. 4801–4852) states under § 4811(3) that: “the national security of the United States requires that the United States maintain its leadership in the science,

technology, engineering, and manufacturing sectors, including foundational technology that is essential to innovation. Such leadership requires that United States persons are competitive in global markets.”

Both the USG NSSCET and ECRA support and endorse the revisions to the EAR to ensure that export controls and licensing requirements do not prove detrimental to or limit the ability of U.S. industry to participate in and lead international standards development across industries, especially in areas critical to United States industrial, commercial, and national security leadership.

Topic Area 2: U.S. export controls continue to hinder U.S. leadership and participation in international standards development.

Six commenters expressed concern that the export controls and license requirements related to the sharing of information in a standards-development forum, as implemented in the September 2022 rule, were continuing to hinder and chill U.S. companies’ participation in international standards development. Specifically, one commenter stated that “[o]pen standardization is critical to U.S. leadership across established and emerging technology areas and limiting [the] ability of SSO’s [standard setting organizations] would provide significant barriers to U.S. participation and leadership in standardization.” Another commenter noted that the current authorization is “[i]nsufficient to maintain U.S. leadership at organizations that work on standards” and that it does not adequately “support global cooperation on other critical activities conducted by standards organizations.” One commenter stated that unless BIS broadens the scope of the authorization, they anticipate that the organization’s legal department will not allow it to participate in any meetings at which Entity List parties could potentially be in attendance.

Four commenters noted that the export controls and license requirements that apply only to U.S. companies have the effect of walling off U.S. standards development from global development and allowing foreign actors to develop and promote their own standards across the global community at the expense of the United States. One of the commenters stated that controls that lead SSOs to limit U.S. entities’ participation in global standards development will “fragment the standardization ecosystem that has served U.S. interests well to date” Another commenter stated that compliant use of the limited

authorization “would impose a significant compliance burden as international standards organizations would need to restructure groups to isolate standards related activities from other activities and spend resources to monitor communications among members.” As noted above, another commenter said, “if participation of Entity List entities is restricted, then security vulnerabilities discovered by these entities, many of which are quite large, may be withheld as they develop their own competing standards after being locked out of access to participation.” Finally, a commenter noted that artificial limits on sharing of information favors compliance by larger commercial enterprises at the expense of smaller parties, including other standards organizations that do not have the same resources as large commercial operations.

Response: BIS agrees that the September 2022 authorization is not broad enough to allow U.S. companies to participate freely in standards development due to uncertainty regarding whether the information they are sharing is subject to the EAR and, if so, whether EAR license requirements apply. BIS recognizes the importance of protecting sensitive and leading-edge U.S. technology but understands the national security implications of limiting U.S. participation and leadership in international standards development. BIS appreciates that the U.S. Government needs to apply U.S. export controls in a way that supports and encourages U.S. technological leadership in standards development, particularly in light of efforts by adversarial countries to coordinate, subsidize, and promote activities in international standards bodies for the benefit of their own enterprises and industry leadership. BIS also recognizes that an environment of competing national standards or the exclusion of U.S. companies in international standards development is not advantageous to U.S. commercial or national security interests. Therefore, in this final rule, BIS has made “standards-related activities” not subject to the EAR as long as the “release” of the “software” or “technology” during these activities meets the criteria contained in revised § 734.10 of the EAR. This treatment of “standards-related activity” as defined in § 734.10 will support U.S. companies’ efforts to create and maintain a leadership position in the global standards community in all industries.

BIS further agrees that fragmentation in the standards development environment could provide foreign

actors and organizations with an opening to develop their own unique and separate international standards, without U.S. industry input or participation, and at the expense of U.S. commercial and national security interests. This fragmentation leads to significant disadvantages for U.S. industry by providing foreign actors with the opportunity to specify their own indigenous benchmarks that U.S. companies must adhere to or lose market share. U.S. non-participation in the foreign development of such standards also affects U.S. companies’ bottom line as they must revise their manufacturing processes to meet the foreign standards. This final rule alleviates such concerns by providing U.S. companies the ability to freely participate in all standards-development forums by making the release of software or technology in such forums not subject to the EAR, provided the releases meet the criteria of new § 734.10(b) of the EAR. It also obviates the need for U.S. companies to wall off their input into global standards development.

Topic Area 3: Revise the definition of “standards-related activity.”

BIS received comments requesting that the agency revise, expand, and clarify the definition of “standards-related activity.”

Four commenters suggested that BIS should expand the definition of “standards-related activity.” One commenter stated that the definition should include but not be limited to “the sharing of technical assistance and exchange of information within conformity assessment procedures, with the intent that the resulting standard will be “published” in order to clarify that sharing and exchanging technical information is within the scope of the authorization. Another commenter suggested that the definition is too narrow and should be expanded to “activities outside of “standards-related activities”” so as to include “many vital functions of international standards organizations that are necessary and incidental to standards related activity but may be conducted outside the context of standards development, such as fostering the exchange of information on developing industry trends and discussions of emerging issues among members.” Another commenter suggested expanding the definition “to include information sharing activities by members of standards organizations on emerging issues and developments.” The last commenter on this topic proposed allowing a standards-related activity to occur if conducted in a Voluntary Consensus Standards Body

(VCSB), as defined by OMB Circular A-119. In the September 2022 rule, BIS removed the “standards organization” definition and replaced it with a “standards-related activity authorization.” According to the commenter, however, the VCSB definition does not require that standards be “published.”

Five commenters requested that BIS remove the word mandatory from the definition of “standards-related activity” in part 772 of the EAR. Essentially all of the commenters stated that in the context of standards development, whether or not a standard will be voluntary or mandatory makes no difference to the stakeholders involved in the development of the standard. Additionally, some voluntary standards become mandatory when adopted through national (domestic) regulations, such as international aircraft standards promulgated by the International Civil Aviation Organization (ICAO).

Five commenters stated that the current wording of the authorization implied that standards-related activities were covered by the authorization only before or during publication of the standard. These commenters asked for clarification that such activities continued to be covered by the authorization after publication of the standards. One commenter noted that conformance testing is a vital component in the commercialization of standards compliant products and that the “vast majority of such activities only usefully occur after a standard has been published and compliant products have been produced.” Another commenter noted that “BIS already provides examples of activities that occur in connection with already published standards (promulgating, revising, amending, reissuing, interpreting, implementing . . .)” but that such actions do not occur for a standard that does not yet exist. These commenters gave examples of three SSOs engaged in cellular, wireless, and other devices that routinely engage in standards-related activities for already published standards, such as conformity assessments. Two commenters requested clarification on whether organizations that are not VCSBs that “require a party to be a member of an organization to receive standards in their final form” would qualify for the authorization.

One commenter suggested that BIS extend the current authorization to additional standards activities that occur before the standard is published. According to this commenter, in information and communications

technology (ICT) “compliance testing also includes pre-product release activities intended to help products reliably interoperate with other products implementing the same standards. The need for such activities arises from the fact that ICT standards frequently do not provide sufficient detail to ensure complete interoperability without additional tinkering.” This commenter suggests that the additional tinkering is often done via a “plugfest” which is “an activity that allows competing vendors to meet and test their products against each other, often anonymous to each other, to work out the final technical changes necessary to allow consumers and business purchasers to achieve the type of ‘plug and play’ ease of use they require. Because plugfests are usually conducted before products reach the marketplace, and often before their existence or specifications have been publicly disclosed, they are non-public and conducted on a confidential basis. Typically, the technical information exchanged one on one between two vendors includes only that information that is necessary to allow each vendor to work out the cause of a lack of compatibility.”

Response: BIS agrees with most of these comments. In new § 734.10(b), BIS revises and clarifies the scope of what is authorized when released for a “standards-related activity.” When released for a “standards-related activity,” “technology” or “software” is not subject to the EAR once it meets at least one condition in both § 734.10(b)(1) and (2). The scope of the “technology” or “software” covered by the authorization has not been revised and is now listed in § 734.10(b)(1). The conditions in § 734.10(b)(2) clarify that activities that occur after the publication of a standard are included in the definition of “standards-related activity”—i.e., a “standards-related activity” occurring specific to an already “published” standard is included in the authorization. BIS also removed the phrase “with which compliance is not mandatory” from the definition of “standards-related activity.”

BIS is not expanding the definition of “standards-related activity” to include activities that are conducted in a VCSB as the expansion is unwarranted. Based on public comment and engagement with other agencies, BIS has determined that the relevant activities of a VCSB are already captured in the definition of “standards-related activity” or, as in the example provided by the commenter, not subject to the EAR (see discussion in Topic Area 4). BIS welcomes public

comments on whether there are additional VCSB activities that are excluded from the current definition of “standards-related activity” and remain subject to the EAR.

Topic Area 4: Expand the definition of “published in § 734.7 of the EAR.”

Comment: Six commenters suggested that the definition of “published” be expanded to cover standards development activities. One commenter suggested that the EAR’s definition of “published” should be expanded to include the “sharing of technical assistance and exchange of information within conformity assessment procedures.”

Response: The definition of “standards-development activity” in part 772 already explicitly includes the exchange of technical data in the conformity process provided it is for the purpose of standards-development activities. Therefore, no further revisions are warranted to the definition of “published” to reference the exchange of technical data.

Comment: Another commenter suggested amending the text of § 734.7 of the EAR to replace the phrase “without restrictions upon its further dissemination” with the phrase “in hard copy or electronic form available from, or viewable at, one or more public websites.” The commenter makes this suggestion because “virtually all standards bear copyright notices, and many standards setting organizations (SSOs) add further legends highlighting that copying and further distribution of their standards are prohibited. Some vigorously defend their copyrights in court.” While it is true that many SSOs (and particularly consortia) give their standards away for free, most traditional SSOs derive a significant percentage of their revenues from the sale of their standards. Thus, in the view of this commenter, “requiring unlimited downstream distribution” as provided in existing § 734.7 “would violate the copyrights of SSOs.”

Response: BIS believes that the regulatory amendments to § 734.10 of the EAR promulgated in this rule obviate the need to amend § 734.7 of the EAR to account for standards that may be copyrighted. In this final rule, BIS has removed “standards-related activities” from being subject to the EAR, as long as the release of the “software” or “technology” meets the definition of a “standards-related activity” as defined in part 772 of the EAR, and meets the requirements for “release” in new § 734.10(b)(1) and the conditions of its “release” in new § 734.10(b)(2) of the EAR.

According to the criteria in new § 734.10(b)(2), the “standards-related activity” must be either for a “published” standard or occurs with the intent that the resulting standard will be “published.”

Comment: Another commenter asked for confirmation that “the references to ‘published’ standards in the definition are not limited to standards-related activities only by those involved in the standard’s development.” The commenter also asked for confirmation that a third-party entity that is not a member of the organization that published the standard (for example, a consortium or a certification authority) but engages in “standards-related activity” with that standard is consistent with the definition of “published” as used in the definition of “standards-related activity.”

Response: BIS confirms that this scenario is consistent with the definition of “standards-related activity” in § 734.10 and the definition of “published” in § 734.7 of the EAR. The changes in this rule remove standards-related activities from being subject to the EAR when the stated conditions are met; as long as the conditions in new § 734.10(b)(1) and (2) are met, then the activities would not be subject to the EAR.

Comments: One commenter stated that their organization’s “model of open membership dissemination does not publish in conformity with the strict publish definition used in the IFR” because although it makes standards readily available to the public, the interested member of the public must also be “willing to agree to the terms and conditions in its membership agreement and pay its dues.” The organization releases the resulting standards to all members without restriction. According to that commenter, “this model does not conform to the strict definition of ‘published’, so [the organization’s] standards-related activities do not qualify for the exemption under the terms of the IFR.”

Another commenter suggested that the definition of “published” be amended “to include dissemination to membership organization . . . that are open to the public without restriction, apart from confidentiality responsibilities, standard terms and conditions, a demonstrated interest in the design, development, manufacture or sale of products or services which utilize the standards at issue, and dues or membership fees.” An additional commenter requested clarification regarding the definition of “published” to make “clear whether BIS recognizes

that some standards organizations require a party to be a member of the organization to receive standards in their final form.”

Response: The relevant criteria in § 734.7 of the EAR that makes information not subject to the EAR is applicable when the information has been made available to the public without restrictions upon its further dissemination. This does not rely on cost or membership, provided that any member of the interested public could pay the associated membership dues and become a member if they so desired. Further, § 734.7(a)(1) states that unclassified “technology” or “software” is “published” and therefore not subject to the EAR, when it has been made available to the public without restrictions upon its further dissemination such as through “subscriptions available without restriction to any individual who desires to obtain or purchase the published information.”

Topic Area 5: Apply standards authorization to sections of EAR other than § 744.11.

Three commenters expressed concern that the September 2022 authorization continued to chill U.S. industry participation in international standards development because it applied only to releases of “software” and “technology” to entities that were added to the Entity List under § 744.11 of the EAR. These commenters noted that to allow the United States to freely participate in standards development forums, the authorization must be extended to all end users listed in part 744 of the EAR. One commenter stated the “Entity (L)ist is not all encompassing of potentially restricted parties, particularly within context of EAR Part 744. Parties having other [part 744] designations (such as military end-users (MEU) in § 744.21) may be present in such meetings or could otherwise receive the output documentation of such meetings.” Another commenter noted that the authorization “does not address territorial and end-use/end-user controls beyond the Entity List,” which have affected standards organizations and that deter U.S. companies from participating and requiring standards organization to restrict their participation. All three commenters requested the expansion of the authorization to the release of the same types of items enumerated in § 744.11(a)(1) to other part 744 end users.

Another commenter stated that modifications such as expansion or flexibility should be applied to the end-use and end-user controls to enable U.S.

industry to remain a thought-leader on standards-related activities. According to this commenter, the current authorization “requires the U.S. party to continually monitor membership of a standards organization to determine whether only parties on the Entity List are present or whether other restricted parties are potential recipients.” This requires U.S. parties to “over screen” and continuously perform and refresh their due diligence to ensure that a non-designated party has not been added to one of the restricted lists.

Two additional commenters expressed the same concern with regard to the amount of resources required to continuously monitor the end-use and end-user controls in part 744 of the EAR. These commenters suggested that the standards authorization be extended to other sections in part 744 but that this extension could be limited to countries listed in Country Group E (supplement no. 1 to part 740) of the EAR.

Another commenter noted that the current sanctions and resulting license requirements for Russia and Belarus extend to certain EAR99 and AT-only controlled items; therefore, these restrictions have an even larger effect on U.S. participation in standards development than Entity List designations. This commenter stated that as long as the standards-related authorization “does not apply to MEU or parties in Russia or Belarus, the international standards environment is likely to continue to fragment, which undermines U.S. leadership in these areas.” This commenter also recommended expanding the authorization to parties outside of Country Group E that are not on the Entity List “so that standards organizations (and U.S. membership) can fully benefit from the intent of the [authorization].”

Three commenters requested that the current standards authorization be expanded to all entities on the Entity List (supplement no. 4 to part 744). One commenter noted that such an expansion would be “critical to US leadership across established and emerging technology areas” and that limiting the authorization to only Entity List entities provides “significant barriers to U.S. participation and leadership in standardization, fragment[s] the standardization ecosystem that has served U.S. interests well to date and create[s] new security risks and vulnerabilities that threaten U.S. economic and national security interests.” Another commenter noted that unless BIS broadens the scope of the authorization, they anticipate that the organization’s legal department will

not allow it to participate in meetings that may include Entity List entities.

Response: The September 2022 rule expanded the scope of the authorization of releases of “software” and “technology” to all entities that were added to the Entity List under § 744.11 of the EAR.

This rule addresses the commenter’s other concerns by removing from EAR jurisdiction “technology” and “software” listed in new § 734.10(b)(1) when they meet at least one condition in new § 734.10(b)(2). This means that the “technology” and “software” will not be subject to the EAR when released for standards-related activities as that term is defined in part 772 of the EAR to all end users listed in part 744 of the EAR.

BIS notes that this change affects major industries in which global participation is crucial to create, maintain, and monitor international safety and operability standards. For example, as two commenters pointed out, the Russian Federal Air Transportation Agency (FATA) and the U.S. Federal Aviation Administration (FAA) both participate in the ICAO, an agency of the United Nations that coordinates the principles and techniques of international air navigation and sets worldwide standards for civil aviation safety. ICAO has members that are subject to unilateral U.S. export controls under part 744 of the EAR beyond the Entity List; however, U.S. participation in the forum is crucial in furtherance of U.S. support of civil air safety, security, efficiency, capacity, and environmental protection and so that the commercial interests of U.S. aircraft manufacturers and aviation equipment manufacturers are sufficiently presented in the discussions. Lack of U.S. participation would cede the development of international standards to foreign actors that may not only disregard U.S. commercial and national security interests but actively work to destabilize them.

This rule addresses these concerns by removing from EAR jurisdiction “technology” and “software” listed in new § 734.10(b)(1) when they meet at least one condition in new § 734.10(b)(2). This means that the specified “technology” and “software” will not be subject to the EAR when released for standards-related activities as that term is discussed in 734.

Topic Area 6: Current authorization and license requirements increase the compliance burden for U.S. companies.

Four commenters stated that the current authorization increases the export control compliance burden of

U.S. companies and standards organizations and their members. Two commenters stated this sentiment explicitly, with one commenter adding that “compliant use of the exemption IFR would impose a significant compliance burden as international standards organizations would need to restructure groups to isolate standards related activities from other activities and spend resources to monitor communications among members.” A third commenter stated that “analyzing and complying with uneven or inconsistent rules and exemptions requires additional resources that [their organization] could allocate to projects, training, or developing standards.” The requester asked that BIS keep in mind that it (and other standards organizations) do not have the same resources as large commercial operations.” However, another commenter stated that the changes promulgated in the September 2022 rule reduced the compliance burden on their organization.

Response: One organization’s compliance burden has been reduced under the existing regulations, and with the publication of this rule and the changed focus on the activities themselves, BIS fully expects that the compliance burden for the other organizations will also be reduced. This is because this rule removes from EAR jurisdiction “technology” and “software” listed in new § 734.10(b)(1) when they meet at least one condition in new § 734.10(b)(2). Accordingly, the listed “technology” and “software” will not be subject to the EAR when released for “standards-related activities” as that term is discussed in part 734 of the EAR.

Topic Area 7: Use clear language and clarification.

One commenter suggested that BIS use clear language and clarification in future regulations. Specifically, this commenter stated that “any efforts to simplify, clarify or limit [the technology] restrictions would be gratefully received by SSO’s, their decision makers, and their members.”

Response: BIS will continue to strive to use clear language and to use guidance, including a frequently asked questions (FAQ) document, to further clarify published regulations in accordance with the Plain Writing Act of 2010.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018

(ECRA) (codified, as amended, at 50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS’s principal authorities and serves as the authority under which BIS issues this rule.

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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This interim final rule has been designated as significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or 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 interim final rule involves the collection currently approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to change because this rule does not impose any additional license requirements. Current information regarding this collection of information—including all background materials—can be found at <https://www.reginfo.gov/public/do/PRAMain> by using the search function to enter either the title of the collection or the OMB Control Number.

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

4. Pursuant to section 1762 of ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements, including prior notice and the opportunity for public comment.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, are

not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 734

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

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 772

Exports.

Accordingly, parts 734, 744 and 772 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 734—SCOPE OF THE EXPORT ADMINISTRATION REGULATIONS

■ 1. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

■ 2. Amend § 734.3 by revising paragraph (b)(3)(iv) to read as follows:

§ 734.3 Items subject to the EAR.

* * * * *

- (b) * * *
- (3) * * *

(iv) Appear in patents or open (published) patent applications available from or at any patent office, unless covered by an invention secrecy order, or are otherwise patent information or are for a standards-related activity as described in § 734.10;

* * * * *

■ 3. Section 734.10 is revised to read as follows:

§ 734.10 Patents and standards-related activity.

(a) *Patents.* “Technology” is not subject to the EAR if it is contained in any of the following:

(1) A patent or an open (published) patent application available from or at any patent office;

(2) A published patent or patent application prepared wholly from foreign-origin “technology” where the application is being sent to the foreign inventor to be executed and returned to the United States for subsequent filing in the U.S. Patent and Trademark Office;

(3) A patent application, or an amendment, modification, supplement or division of an application, and authorized for filing in a foreign country in accordance with the regulations of the Patent and Trademark Office, 37 CFR part 5; or

(4) A patent application when sent to a foreign country before or within six months after the filing of a United States patent application for the purpose of obtaining the signature of an inventor who was in the United States when the invention was made or who is a co-inventor with a person residing in the United States.

(b) *Standards-related activity.* A standards-related activity includes the development, adoption, or application of a standard (*i.e.*, any document or other writing that provides, for common and repeated use, rules, guidelines, technical or other characteristics for products or related processes and production methods), including but not limited to conformity assessment procedures. A “standards-related activity” includes an action taken for the purpose of developing, promulgating, revising, amending, issuing or reissuing, interpreting, implementing or otherwise maintaining or applying such a standard. When released for a “standards-related activity,” “technology” or “software” is not subject to the EAR provided it meets at least one condition in both paragraphs (b)(1) and (2) of this section:

- (1) The “technology” or “software” is:
 - (i) Designated EAR99;
 - (ii) Controlled on the CCL for anti-terrorism reasons only; or
 - (iii) For the following ECCN “items” level paragraphs of “technology” or “software” specifically for the “development,” “production,” or “use” of cryptographic functionality once the release is for a “standards-related activity:” “software” that is classified under ECCN 5D002.b or 5D002.c.1 (for equipment specified in ECCN 5A002.a and 5A002.c only); “technology” that is classified under ECCN 5E002 (for equipment specified in ECCN 5A002.a, .b and .c); and “technology” for software controlled under ECCN 5D002.b or .c.1 (for equipment specified in ECCN 5A002.a and .c only) when the release is for a “standards-related activity;” and
- (2) The “standards-related activity:”
 - (i) Is for a “published” standard; or
 - (ii) Occurs with the intent that the resulting standard will be “published.”

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

■ 4. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; 3 CFR, 2022 Comp., p. 563; Notice of September 7, 2023, 88 FR 62439 (September 11, 2023); Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

■ 5. Section 744.11 is amended by revising paragraph (a) introductory text and removing and reserving paragraph (a)(1) to read as follows:

§ 744.11 License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States.

* * * * *

(a) *License requirement, availability of license exceptions, and license application review policy.* A license is required, to the extent specified on the Entity List, to export, reexport, or transfer (in-country) any item subject to the EAR when an entity that is listed on the Entity List is a party to the transaction as described in § 748.5(c) through (f) of the EAR unless otherwise authorized or excluded in this section. License exceptions may not be used unless authorized in the Entity List entry for the entity that is party to the transaction. Applications for licenses required by this section will be evaluated as stated in the Entity List entry for the entity that is party to the transaction, in addition to any other applicable review policy stated elsewhere in the EAR.

* * * * *

■ 6. Section 744.16 is amended by revising paragraph (a) to read as follows:

§ 744.16 ENTITY LIST

* * * * *

(a) *License requirements.* In addition to the license requirements for items specified on the CCL, you may not, without a license from BIS, export, reexport, or transfer (in-country) any items included in the License Requirement column of an entity’s entry on the Entity List (supplement no. 4 to this part) when that entity is a party to a transaction as described in § 748.5(c) through (f) of the EAR. The specific license requirement for each listed entity is identified in the license requirement column on the Entity List in supplement no. 4 to this part.

* * * * *

■ 7. Supplement no. 4 to part 744 is amended by revising the introductory text to read as follows:

Supplement No. 4 to Part 744—Entity List

This supplement lists certain entities subject to license requirements for specified items under this part 744 and part 746 of the EAR. License requirements for these entities include exports, reexports, and transfers (in-country) unless otherwise stated. A license is required, to the extent specified on the Entity List, to export, reexport, or transfer (in-country) any item subject to the EAR when an entity that is listed on the Entity List is a party to the transaction as described in § 748.5(c) through (f) of the EAR. This list of entities is revised and updated on a periodic basis in this Supplement by adding new or amended notifications and deleting notifications no longer in effect.

* * * * *

PART 772—DEFINITIONS OF TERMS

■ 8. The authority citation for 15 CFR part 772 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 9. Section 772.1 is amended by
■ a. Revising the definition of
“Standards-related activity.”

The revisions read as follows:

§ 772.1 Definitions of Terms as Used in the Export Administration Regulations (EAR).

* * * * *

Standards-related activity. See § 734.10 of the EAR.

* * * * *

Thea D. Rozman Kendler,
Assistant Secretary for Export Administration.

[FR Doc. 2024–15810 Filed 7–17–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 630

[Docket No. FDA–2022–D–0362]

Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final

guidance entitled “Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Guidance for Industry.” The guidance document addresses certain regulatory requirements for determining donor eligibility that apply to blood establishments that collect blood and blood components for transfusion or for further manufacturing use, including Source Plasma. In a final rule dated May 22, 2015, FDA amended the regulations applicable to blood establishments for determining donor eligibility and testing blood and blood components. The revised requirements were implemented in order to assure the safety of the blood supply and to protect donor health. This guidance finalizes the draft guidance entitled “Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry” issued on May 24, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on July 18, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets

Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2022–D–0362 for “Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management