

*Related Definitions:* N/A

*Items:*

a. Tooling, templates, jigs, mandrels, molds, dies, fixtures, alignment mechanisms, and test “equipment” not enumerated or otherwise described in USML Category XVIII and not elsewhere specified on the USML that are “specially designed” for the “development,” “production,” repair, overhaul, or refurbishing of commodities controlled by USML Category XVIII.

b. through w. [Reserved]

x. “Parts,” “components,” “accessories,” and “attachments” “specially designed” for a commodity subject to control under paragraph .a of this ECCN and not enumerated or otherwise described in USML Category XVIII and not elsewhere specified on the USML.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6—Sensors and Lasers,” add a new ECCN 6D619 between ECCNs 6D201 and 6D991 to read as follows:

**6D619 “Software” “specially designed” for the “development,” “production,” operation or maintenance of commodities controlled by 6B619.**

**License Requirements**

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

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

**License Exceptions**

*CIV:* N/A

*TSR:* N/A

**Special Conditions for STA**

*STA:* Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 6D619.

**List of Items Controlled**

*Related Controls:* “Software” directly related to articles enumerated or otherwise described in USML Category XVIII is subject to the ITAR (See 22 CFR 121.1, Category XVIII(f)).

*Related Definitions:* N/A

*Items:*

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

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6—Sensors and Lasers,” add ECCN 6E619 between ECCNs 6E202 and 6E990 to read as follows:

**6E619 “Technology” “required” for the “development,” “production,” operation, installation, maintenance, repair, overhaul or refurbishing of**

**commodities controlled by 6B619 or “software” controlled by 6D619.**

**License Requirements**

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

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

**License Exceptions**

*CIV:* N/A

*TSR:* N/A

**Special Conditions for STA**

*STA:* Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 6E619.

**List of Items Controlled**

*Related Controls:* Technical data directly related to articles enumerated or otherwise described in USML Category XVIII are subject to the ITAR (See 22 CFR 121.1, Category XVIII(f)).

*Related Definitions:* N/A

*Items:*

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

**Kevin J. Wolf,**

*Assistant Secretary for Export Administration.*

[FR Doc. 2016–17506 Filed 7–27–16; 8:45 am]

**BILLING CODE 3510–33–P**

**DEPARTMENT OF STATE**

**22 CFR Part 121**

**[Public Notice: 9466]**

**RIN 1400–AD03**

**Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** As part of the President’s Export Control Reform effort, the Department of State amends the International Traffic in Arms Regulations (ITAR) to revise Categories XIV (toxicological agents, including chemical agents, biological agents, and associated equipment) and XVIII (directed energy weapons) of the U.S. Munitions List (USML) to describe more precisely the articles warranting control on the USML. The revisions contained in this rule are part of the Department of State’s retrospective plan under E.O.

13563, completed on August 17, 2011. The Department of State’s full plan can be accessed at <http://www.state.gov/documents/organization/181028.pdf>.

**DATES:** This Final rule is effective on December 31, 2016.

**FOR FURTHER INFORMATION CONTACT:** Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–2792; email [DDTCPublicComments@state.gov](mailto:DDTCPublicComments@state.gov). ATTN: ITAR Amendment—USML Categories XIV and XVIII.

**SUPPLEMENTARY INFORMATION:** The Directorate of Defense Trade Controls (DDTC), U.S. Department of State, administers the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). The items subject to the jurisdiction of the ITAR, *i.e.*, “defense articles,” are identified on the ITAR’s U.S. Munitions List (USML) (22 CFR 121.1). With few exceptions, items not subject to the export control jurisdiction of the ITAR are subject to the jurisdiction of the Export Administration Regulations (“EAR,” 15 CFR parts 730–774, which includes the Commerce Control List (CCL) in Supplement No. 1 to Part 774), administered by the Bureau of Industry and Security (BIS), U.S. Department of Commerce. Both the ITAR and the EAR impose license requirements on exports and reexports. Items not subject to the ITAR or to the exclusive licensing jurisdiction of any other set of regulations are subject to the EAR.

All references to the USML in this rule are to the list of defense articles controlled for the purpose of export or temporary import pursuant to the ITAR, and not to the defense articles on the USML that are controlled by the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATFE) for the purpose of permanent import under its regulations. See 27 CFR part 447. Pursuant to section 38(a)(1) of the Arms Export Control Act (AECA), all defense articles controlled for export or import are part of the USML under the AECA. The list of defense articles controlled by ATFE for the purpose of permanent import is the U.S. Munitions Import List (USMIL). The transfer of defense articles from the ITAR’s USML to the EAR’s CCL does not affect the list of defense articles controlled on the USMIL.

**Revision of Category XIV**

This final rule revises USML Category XIV, covering toxicological agents, including chemical agents, biological agents, and associated equipment. The revisions are undertaken in order to more accurately describe the articles

within the subject categories, and to establish a “bright line” between the USML and the CCL for the control of these articles. The Department published a proposed rule for these revisions on June 17, 2015 (80 FR 34572).

This final rule adopts for those pathogens and toxins that meet specific capabilities listed in paragraph (b) the “Tier 1” pathogens and toxins established in the Department of Health and Human Services and the United States Department of Agriculture select agents and toxins regulations (42 CFR part 73 and 9 CFR part 121). The Tier 1 pathogens and toxins that do not meet these capabilities remain controlled in Export Control Classification Number (ECCN) 1C351 on the CCL.

Additionally, this rule, in concert with the analogous rule published by the Department of Commerce, moves riot control agents to the export jurisdiction of the Department of Commerce, as well as the articles covered previously in paragraphs (j), (k), and (l), which include test facilities, equipment for the destruction of chemical and biological agents, and tooling for production of articles in paragraph (f), respectively.

Other changes include the addition of paragraph (a)(5) to control chemical warfare agents “adapted for use in war” and not elsewhere enumerated, as well as the removal of paragraphs (f)(3) and (f)(6) and movement to the CCL of equipment for the sample collection and decontamination or remediation of chemical agents and biological agents. Paragraph (f)(5) for collective protection was removed and partially combined in paragraph (f)(4) or the CCL. Paragraph (g) enumerates antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts exclusively funded by a Department of Defense contract for detection of the biological agents listed in paragraph (b)(1)(ii).

The Department notes that the controls in paragraph (f)(2) that include the phrase “developed under a Department of Defense contract or other funding authorization” do not apply when the Department of Defense acts solely as a servicing agency for a contract on behalf of another agency of the U.S. government. Moreover, “other funding authorization” refers to other funding authorization from the Department of Defense.

The Department notes that the controls in paragraphs (g)(1) and (h) that include the phrase “exclusively funded by a Department of Defense contract” do not apply when the Department of Defense acts solely as a servicing agency for a contract on behalf of another

agency of the U.S. government, or, for example, in cases where the Department of Defense provides initial funding for the development of an item but another agency of the U.S. government provides funding to further develop or adapt the item.

Paragraph (h) enumerates certain vaccines funded exclusively by the Department of Defense, as well as certain vaccines controlled in (h)(4) that are specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in (b). Thus, the scope of vaccines controlled in (h)(4) is circumscribed by the nature of funding and the satisfaction of the term “specially designed” as that term is defined in ITAR § 120.41. In evaluating the scope of this control, please note that the Department offers a decision tool to aid exporters in determining whether a defense article meets the definition of “specially designed.” This tool is available at [http://www.pmddtc.state.gov/licensing/dt\\_SpeciallyDesigned.htm](http://www.pmddtc.state.gov/licensing/dt_SpeciallyDesigned.htm).

Paragraph (i) is updated to provide better clarity on the scope of the control by including examples of Department of Defense tools that are used to determine or estimate potential effects of chemical or biological weapons strikes and incidents in order to plan to mitigate their impacts.

A new paragraph (x) has been added to USML Category XIV, allowing ITAR licensing on behalf of the Department of Commerce for commodities, software, and technology subject to the EAR, provided those commodities, software, and technology are to be used in or with defense articles controlled in USML Category XIV and are described in the purchase documentation submitted with the application. The intent of paragraph (x) is not to impose ITAR jurisdiction on commodities, software, and technology subject to EAR controls. Items described in paragraph (x) remain subject to the jurisdiction of the EAR. The Department added the paragraph as a regulatory reference point in response to industry requests to be able to use a Department of State license to export shipments that have a mix of ITAR controlled items and EAR controlled items for use in or with items described in that category.

Finally, this rule establishes USML control in subparagraph (f)(2) of certain chemical or biological agent equipment only when it contains reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense contract or other funding authorization.

One commenter questioned whether the use of the words “to include” in proposed paragraph (a) was meant to indicate an all-inclusive list or only examples of controlled agents. The Department has modified paragraph (a) to replace “to include” with the all-inclusive “as follows” in light of this comment, and in order to align this language with the comparable language that appears in paragraph (b).

A commenting party suggested that the removal of former subparagraph (n)(2) would inhibit university research with respect to agents controlled by paragraph (a). The Department disagreed with this comment because former subparagraph (n)(2) applied only to agents controlled in paragraph (b).

Several commenters expressed confusion with respect to subparagraph (b)(1), arguing that, for example, the list in subparagraph (b)(1)(ii) was incomplete, or represented a migration to ITAR control of agents or research formerly subject to the EAR. The Department clarifies that all of the biological agents subject to control under revised paragraph (b) were also subject to ITAR control under former paragraph (b), which generally controlled those biological agents or biologically derived substances that were specifically developed, configured, adapted, or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment, or damage crops.

By contrast, subparagraph (b)(1) of revised Category XIV controls only those agents that meet the criteria of both subparagraphs (b)(1)(i) and (b)(1)(ii). To be controlled, the agent must be one of the specific listed microorganisms or toxins, or their non-naturally occurring genetic elements, *and* it must have been modified in a manner that is known or reasonably expected to result in an increase of at least one of two specific criteria. Subparagraph (b)(2) controls only biological agents that meet the criteria of subparagraph (b)(2)(i) *and* do so in a manner that is known or reasonably expected to result in an increase of at least one of three specific criteria in (b)(2)(ii). Subparagraphs (b)(1) and (b)(2) represent a narrowing of the universe of agents subject to control under the paragraph (b), and a more specific means of control than the broad, generic language of former paragraph (b).

One commenting party recommended an exclusion in paragraph (b) for research funded by the National Institutes of Health, the Centers for Disease Control and Prevention, or the U.S. Department of Agriculture. Given the refined and narrowed scope of

control in paragraph (b) as described above, which focuses on specific and weaponized biological agents, the Department disagreed with this suggestion because it is overly broad.

Four commenting parties argued that regulation of biological agents in paragraph (b) is not necessary in the manner proposed because of the existence of the Federal Select Agent Program and the Dual Use Research of Concern policy. The Department disagreed with these comments because the referenced program and policy are not munitions export control regimes and do not share the national security and foreign policy objectives of the ITAR. As stated above, the articles described in revised paragraph (b) were subject to the ITAR under the previous Category XIV and do not include any biological agents that were not previously subject to the ITAR; as such, there is no expansion of control beyond what existed previously, and the relationship between these agents and the Federal Select Agent Program or Dual Use Research of Concern policy is unchanged.

One commenting party observed that subparagraph (b)(1)(ii) of the proposed rule adopted the Tier 1 list of select agents meeting certain criteria, but did not incorporate the exclusions of the Federal Select Agent Program. Revised Category XIV is not intended to intersect with the Federal Select Agent Program. The ITAR and Federal Select Agent Program do not share identical objectives; accordingly, it would be inappropriate to provide common exclusions for largely unrelated regulatory concerns.

Four commenters requested the reinstatement of former subparagraph (n)(2), which provided an exclusion for agents otherwise controlled in paragraph (b) that had been modified for civil applications. The Department disagreed with these comments because, as noted above, paragraph (b) has been reduced in scope significantly to control only weaponized strains of specified agents. By contrast, former paragraph (b) required the subparagraph (n)(2) exclusion because it was otherwise overly broad. Since the revised paragraph (b) does not capture modifications that would be undertaken for civil applications that do not merit control, the subparagraph (n)(2) exclusion is no longer appropriate.

One commenting party stated that former paragraph (b) was in essence an empty box because the export licensing of biological agents as munitions would violate the Biological Weapons Convention (BWC). The Department disagreed with this comment because

such treatment of biological agents does not violate the BWC when used in the development of countermeasures, which serve “prophylactic” or “protective” purposes explicitly permitted by the BWC. Moreover, prevention of the acquisition of weaponized biological agents for impermissible purposes, as is achieved through regulation of such agents under the ITAR, is consistent with the objectives of the BWC.

A commenter expressed the view that based on proposed paragraph (b), an expression vector that produces Ebola virus envelope protein for use in pseudotyping minimal lentiviral vectors, even though harmless in itself, might be subject to ITAR control because the envelope is a pathogenicity factor to Ebola virus, even in the absence of Ebola virus. The Department disagrees with this comment because the described item would not be controlled by paragraph (b) unless it satisfied the criteria of subparagraph (b)(1)(i), particularly taken together with Note 2 to paragraph (b).

One commenter suggested that the list of biological agents in paragraph (b)(1)(ii) fails to take into account the danger and exposure risk presented by each toxin. The Department notes, as stated above, that the list in subparagraph (b)(1)(ii) does not stand alone as a list of agents subject to control. To be subject to the ITAR, an agent listed in subparagraph (b)(1)(ii) must also meet the criteria of subparagraph (b)(1)(i).

Four commenting parties indicated that the properties referenced in subparagraph (b)(1)(i) and (b)(2)(ii) are not properties for which researchers would typically test, and that the proposed language might result in mandatory testing for these properties to avoid inadvertent violations. The Department revised the language in these subparagraphs to limit the analysis of modifications to those that are known to or are reasonably expected to result in an increase in the subject properties.

Two commenters suggested that the research subject to control in subparagraph (b)(1) should focus on the intent or purpose of the research. The Department disagreed with this comment in light of the revisions made to subparagraphs (b)(1)(i) and (b)(2)(ii) in response to public comments, and also in order to avoid the introduction of an intent or end use-based control, which has been a longstanding objective of the ECR initiative.

Three commenting parties observed that the use of “e.g.” in subparagraph (b)(1)(i)(A) suggests that the parenthetical examples of persistence in

a field environment is not complete. The Department changed “e.g.” to “i.e.,” and updated the parenthetical list accordingly.

One commenter requested a definition of “persistence in a field environment” in subparagraph (b)(2)(i)(A) to avoid ambiguity. The Department refined the subparagraph to provide more comprehensive criteria.

Three commenters noted that ECCN 1C352 has been combined with ECCN 1C351, and that any references to the former should be deleted from Category XIV. The Department agrees with these comments.

Two commenting parties submitted comments that suggested a misunderstanding that references in subparagraph (b)(2) to ECCNs 1C351, 1C353, and 1C354 would move agents controlled under those ECCNs to the jurisdiction of the Department of State. No biological agents are moved from the CCL to the USML as a result of this rulemaking, nor was such movement suggested in the proposed rule. The ECCNs are referenced merely in order to better define the articles subject to control, to which the criteria of both subparagraphs (b)(2)(i) and (b)(2)(ii) must apply.

Two commenting parties observed that the use of “e.g.” in subparagraph (b)(2)(i)(A) suggests that the parenthetical examples of persistence in a field environment is not complete. The Department changed “e.g.” to “i.e.,” and updated the parenthetical list accordingly.

Similarly, two commenting parties observed that the use of “e.g.” in subparagraph (b)(2)(ii)(B) indicates that the list of possible dispersal characteristics is not complete. In this case, the Department confirms that the parenthetical list is intended to be exemplary in nature.

One commenter stated that Note 2 to paragraph (b)’s limitation to wild type agents is still unnecessarily restrictive with respect to the agents listed in subparagraph (b)(1)(ii). The Department disagreed with this comment because, as indicated previously, to be subject to the ITAR an agent listed in subparagraph (b)(2)(ii) must also meet the criteria of subparagraph (b)(2)(i).

A commenter remarked that the controls described in the proposed rule would establish ITAR control over technical data and research and development activities related to, *inter alia*, biological agents described in paragraph (b). Bearing in mind the fact that all agents controlled under revised paragraph (b) were subject to control under former paragraph (b), the Department believes that control over

such information and activities is appropriate given the narrowed scope of revised paragraph (b) to specific weaponized biological agents.

A commenting party identified typographical errors in subparagraphs (c)(4) and (c)(5). The Department made the appropriate corrections.

Two commenters requested clarification regarding the phrase "Department of Defense contract or funding authorization," as it appears in subparagraphs (f)(1)(ii), (f)(2), and (f)(2)(ii). The Department clarifies that the quoted language captures a range of possible Department of Defense funding authorization mechanisms that extend beyond contracts, such as grants. While these subparagraphs do not require exclusive funding by the Department of Defense to cause the articles to become subject to ITAR control, and there is no *de minimis* funding level that triggers control, the use of "specially designed" in certain of these subparagraphs limits the scope of control, in addition to other specific criteria set forth in the subparagraphs.

A commenting party questioned the intent and meaning of Note 3 to paragraph (f)(2). The Department deleted the note.

Two commenting parties recommended a revision to subparagraph (f)(2)(i) to control only relevant equipment for chemical or biological agents specified in the Department of Defense contract or other funding authorization as intended for control under USML Category XIV, or to clarify the funding mechanism that specifies the chemical or biological agent and thus triggers the provision. The Department disagreed with the former comment because it would introduce a discretionary contract mechanism that could allow for the subjective application or removal of ITAR control, but modified the subparagraph to better define the scope of control. The modifications clarify the link between the funding mechanisms referenced in subparagraph (f)(2) and (f)(2)(ii).

One commenting party recommended the movement to the EAR of all articles controlled in subparagraph (f)(4), or the removal of the Significant Military Equipment (SME) designation at a minimum. The Department disagreed with this comment because the commenter did not provide a sufficient rationale to compel removal from the USML or the SME designation for these articles.

A comment recommended that subparagraph (f)(4)(iii) be revised to remove the trade name ASZM-TEDA and instead specify the parameters or

criteria that merit control for activated carbon products. The Department revised the subparagraph to reference the specification that merits control.

Two commenters observed that paragraph (f)(4)(iv) would not distinguish between military and non-military protective apparel, but would rely on a "breakthrough test" that could capture garments designed to National Fire Protection Association standards or designed to integrate with civil gas masks if they met breakthrough levels. The Department has refined subparagraph (f)(4)(iv) to the same paragraph to more precisely describe the articles that warrant control and incorporated the elements described in the prior Note into the control parameters.

One commenting party recommended that Chemical Agent Resistant Coatings (CARC) be moved from subparagraph (f)(7) to the EAR. The Department updated the subparagraph to control the appropriate specification, but disagreed with the remainder of the comment in order to maintain ITAR control over coatings that have been qualified to military specifications.

A commenter suggested the replacement of the word "qualified" in subparagraph (f)(7) with the phrase "meet the requirements of." The Department disagreed with this comment because the phrasing used is intended to mean that the article has in fact been qualified by the Department of Defense to the relevant standard.

One commenting party recommended the removal of the SME designation for subparagraph (f)(7). The Department disagreed with this comment because the commenter did not provide a sufficient rationale for removal of the designation.

Three commenting parties suggested that subparagraph (g)(1) should control relevant articles based on parameters or criteria other than the funding source. The Department notes that subparagraph (g)(1) controls only those relevant articles that are exclusively funded by the Department of Defense, for detection of the biological agents listed in subparagraph (b)(1)(ii). The Department believes that this is an appropriately tailored subparagraph, particularly in light of the requirement that Department of Defense funding be exclusive.

One commenter presented a similar comment with respect to the analogous exclusive funding provision in subparagraph (h). Again, the Department disagrees with this comment because the exclusive funding requirement narrows the range of

controlled vaccines to an appropriate scope.

A commenting party suggested that the use of specially designed in paragraph (h) undermines the notion of control due to funding source, as certain vaccines could be released through ITAR § 120.41(b). The Department disagrees with this comment because it is not likely that ITAR § 120.41(b) would allow for the release of vaccines that were exclusively funded by the Department of Defense to protect against biological agents controlled under paragraph (b).

A commenter requested clarification as to whether subparagraph (h)(4) is subject to the requirement that the vaccine be funded exclusively by a Department of Defense contract or other funding authorization. Since this exclusive funding requirement appears in subparagraph (h), the Department confirms that this is the case.

#### Revision of Category XVIII

This final rule revises USML Category XVIII, covering directed energy weapons. As with USML Category XIV, the revisions are undertaken in order to more accurately describe the articles within the subject categories, and to establish a "bright line" between the USML and the CCL for the control of these articles. This final rule revises paragraph (a) to control only those articles that, other than as a result of incidental, accidental, or collateral effect, achieve the effects described in the paragraph by way of non-acoustic techniques.

The articles controlled previously in paragraphs (c) and (d) are moved to the export control jurisdiction of the Department of Commerce.

The remaining paragraphs in this category underwent conforming changes to bring their structures into alignment with the analogous provisions found in other revised USML categories.

A commenting party suggested that the reference in proposed paragraph (a) to the "primary purpose" of system or equipment at issue was unclear. The Department revised the paragraph to remove this language and clarify the intended scope of control.

Two commenting parties recommended revisions to the structure of paragraph (a). The Department revised the paragraph text to enhance clarity and readability.

A commenter noted that "flash blindness," as used in proposed paragraph (a), has no commonly understood meaning. The Department revised the subject language to clarify the intended scope of control.

One commenting party recommended the addition of a note to paragraph (a) to confirm that the paragraph does not control articles subject to control under subparagraphs XI(a)(4)(iii) or XII(b)(9). The Department disagrees with this comment because the USML Order of Review establishes that the paragraph that most specifically identifies a given article will control that article; accordingly, it is not necessary to add clarifying notes of this nature.

A commenter observed that it was not clear what “associated systems or equipment” meant in proposed paragraph (e). The Department revised the paragraph to match the structure of analogous paragraphs found in other revised USML categories.

A commenting party recommended a note to paragraph (e) that would indicate that components, parts, accessories, attachments and associated systems or equipment specially designed for articles controlled under paragraph XVIII(e) are subject to the EAR. Noting that no such note has been applied to the analogous paragraphs in other revised USML categories, the Department disagrees with this comment because the inclusion of “specially designed” in paragraph (e) provides the intended scope of control for the articles at issue.

### Regulatory Findings

#### *Administrative Procedure Act*

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (Rulemaking) and 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department published this rule as a proposed rule (80 FR 34572) with a 60-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

#### *Regulatory Flexibility Act*

Since the Department is of the opinion that this rule is exempt from the rulemaking provisions of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

#### *Unfunded Mandates Reform Act of 1995*

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal

governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

#### *Executive Orders 12372 and 13132*

This amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this amendment.

#### *Executive Order 12866 and 13563*

Executive Orders 12866 and 13563 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, distributed impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

#### *Executive Order 12988*

The Department of State has reviewed the amendment in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

#### *Executive Order 13175*

The Department of State has determined that this rulemaking will

not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

#### *Paperwork Reduction Act*

Following is a listing of approved collections that will be affected by revision of the U.S. Munitions List (USML) and the Commerce Control List pursuant to the President’s Export Control Reform (ECR) initiative. This rule continues the implementation of ECR. The list of collections pertains to revision of the USML in its entirety, not only to the categories published in this rule. The Department is not proposing or making changes to these collections in this rule. The information collections impacted by the ECR initiative are as follows:

- (1) Statement of Registration, DS–2032, OMB No. 1405–0002.
- (2) Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data, DSP–5, OMB No. 1405–0003.
- (3) Application/License for Temporary Import of Unclassified Defense Articles, DSP–61, OMB No. 1405–0013.
- (4) Application/License for Temporary Export of Unclassified Defense Articles, DSP–73, OMB No. 1405–0023.
- (5) Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Technical Data, DSP–6, –62, –74, –119, OMB No. 1405–0092.
- (6) Request for Approval of Manufacturing License Agreements, Technical Assistance Agreements, and Other Agreements, DSP–5, OMB No. 1405–0093.
- (7) Maintenance of Records by Registrants, OMB No. 1405–0111.

#### **List of Subjects in 22 CFR Part 121**

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, title 22, chapter I, subchapter M, part 121 is amended as follows:

#### **PART 121—THE UNITED STATES MUNITIONS LIST**

■ 1. The authority citation for part 121 continues to read as follows:

**Authority:** Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat. 1920; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 2. Section 121.1 is amended by revising U.S. Munitions List Categories XIV and XVIII to read as follows:

**§ 121.1 The United States Munitions List.**

\* \* \* \* \*

**Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment**

\* (a) Chemical agents, as follows:

(1) Nerve agents, as follows:

(i) O-Alkyl (equal to or less than C<sub>10</sub>, including cycloalkyl) alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonofluoridates, such as: Sarin (GB); O-Isopropyl methylphosphonofluoridate (CAS 107-44-8) (CWC Schedule 1A); and Soman (GD); O-Pinacolyl methylphosphonofluoridate (CAS 96-64-0) (CWC Schedule 1A);

(ii) O-Alkyl (equal to or less than C<sub>10</sub>, including cycloalkyl) N,N-dialkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphoramidocyanidates, such as: Tabun (GA); O-Ethyl N, N-dimethylphosphoramidocyanidate (CAS 77-81-6) (CWC Schedule 1A); or

(iii) O-Alkyl (H or equal to or less than C<sub>10</sub>, including cycloalkyl) S-2-dialkyl (Methyl, Ethyl, n-Propyl or Isopropyl) aminoethyl alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonothiolates and corresponding alkylated and protonated salts, such as VX: O-Ethyl S-2-diisopropylaminoethyl methyl phosphonothiolate (CAS 50782-69-9) (CWC Schedule 1A);

(2) Amiton: O,O-Diethyl S-[2(diethylamino)ethyl] phosphorothiolate and corresponding alkylated or protonated salts (CAS 78-53-5) (CWC Schedule 2A);

(3) Vesicant agents, as follows:

(i) Sulfur mustards, such as: 2-Chloroethylchloromethylsulfide (CAS 2625-76-5) (CWC Schedule 1A); Bis(2-chloroethyl)sulfide (HD) (CAS 505-60-2) (CWC Schedule 1A); Bis(2-chloroethylthio)methane (CAS 63839-13-6) (CWC Schedule 1A); 1,2-bis (2-chloroethylthio)ethane (CAS 3563-36-8) (CWC Schedule 1A); 1,3-bis (2-chloroethylthio)-n-propane (CAS 63905-10-2) (CWC Schedule 1A); 1,4-bis (2-chloroethylthio)-n-butane (CWC Schedule 1A); 1,5-bis (2-chloroethylthio)-n-pentane (CWC Schedule 1A); Bis (2-chloroethylthiomethyl)ether (CWC Schedule 1A); Bis (2-chloroethylthioethyl)ether (CAS 63918-89-8) (CWC Schedule 1A);

(ii) Lewisites, such as: 2-chlorovinylchloroarsine (CAS 541-25-3) (CWC Schedule 1A); Tris (2-chlorovinyl) arsine (CAS 40334-70-1) (CWC Schedule 1A); Bis (2-chlorovinyl)

chloroarsine (CAS 40334-69-8) (CWC Schedule 1A);

(iii) Nitrogen mustards, or their protonated salts, as follows:

(A) HN1: Bis (2-chloroethyl) ethylamine (CAS 538-07-8) (CWC Schedule 1A);

(B) HN2: Bis (2-chloroethyl) methylamine (CAS 51-75-2) (CWC Schedule 1A);

(C) HN3: Tris (2-chloroethyl) amine (CAS 555-77-1) (CWC Schedule 1A); or

(D) Other nitrogen mustards, or their salts, having a propyl, isopropyl, butyl, isobutyl, or tertiary butyl group on the bis(2-chloroethyl) amine base;

**Note 1 to paragraph (a)(3)(iii):** Pharmaceutical formulations containing nitrogen mustards or certain reference standards for these formulations are not considered to be chemical agents and are subject to the EAR when: (1) The pharmaceutical is in the form of a final medical product; or (2) the reference standard contains salts of HN2 [bis(2-chloroethyl) methylamine], the quantity to be shipped is 150 milligrams or less, and individual shipments do not exceed twelve per calendar year per end user.

**Note 2 to paragraph (a)(3)(iii):** A “final medical product,” as used in this paragraph, is a pharmaceutical formulation that is (1) designed for testing and administration in the treatment of human medical conditions, (2) prepackaged for distribution as a clinical or medical product, and (3) approved for marketing by the Food and Drug Administration or has a valid investigational new drug application (IND) in effect, in accordance with 21 CFR part 312.

(iv) Ethyldichloroarsine (ED) (CAS 598-14-1); or

(v) Methylchloroarsine (MD) (CAS 593-89-5);

(4) Incapacitating agents, such as:

(i) 3-Quinuclidinyl benzilate (BZ) (CAS 6581-06-2) (CWC Schedule 2A);

(ii) Diphenylchloroarsine (DA) (CAS 712-48-1); or

(iii) Diphenylcyanoarsine (DC) (CAS 23525-22-6);

(5) Chemical warfare agents not enumerated above adapted for use in war to produce casualties in humans or animals, degrade equipment, or damage crops or the environment. (See the CCL at ECCNs 1C350, 1C355, and 1C395 for control of certain chemicals not adapted for use in war.)

**Note to paragraph (a)(5):** “Adapted for use in war” means any modification or selection (such as altering purity, shelf life, dissemination characteristics, or resistance to ultraviolet radiation) designed to increase the effectiveness in producing casualties in humans or animals, degrading equipment, or damaging crops or the environment.

**Note 1 to paragraph (a):** Paragraph (a) of this category does not include the following:

Cyanogen chloride, Hydrocyanic acid, Chlorine, Carbonyl chloride (Phosgene), Ethyl bromoacetate, Xylyl bromide, Benzyl bromide, Benzyl iodide, Chloro acetone, Chloropicrin (trichloronitromethane), Fluorine, and Liquid pepper.

**Note 2 to paragraph (a):** Regarding U.S. obligations under the Chemical Weapons Convention (CWC), refer to Chemical Weapons Convention Regulations (CWCRC) (15 CFR parts 710 through 721). As appropriate, the CWC schedule is provided to assist the exporter.

\* (b) Biological agents and biologically derived substances and genetic elements thereof as follows:

(1) Genetically modified biological agents:

(i) Having non-naturally occurring genetic modifications that are known to or are reasonably expected to result in an increase in any of the following:

(A) Persistence in a field environment (*i.e.*, resistance to oxygen, UV damage, temperature extremes, arid conditions, or decontamination processes); or

(B) The ability to defeat or overcome standard detection methods, personnel protection, natural or acquired host immunity, host immune response, or response to standard medical countermeasures; and

(ii) Being any micro-organisms/toxins or their non-naturally occurring genetic elements as listed below:

- (A) *Bacillus anthracis*;  
 (B) *Botulinum neurotoxin* producing species of *Clostridium*;  
 (C) *Burkholderia mallei*;  
 (D) *Burkholderia pseudomallei*;  
 (E) Ebola virus;  
 (F) Foot-and-mouth disease virus;  
 (G) *Francisella tularensis*;  
 (H) Marburg virus;  
 (I) Variola major virus (Smallpox virus);  
 (J) Variola minor virus (Alastrim);  
 (K) *Yersinia pestis*; or  
 (L) Rinderpest virus.

(2) Biological agent or biologically derived substances controlled in ECCNs 1C351, 1C353, or 1C354:

(i) Physically modified, formulated, or produced as any of the following:

(A) 1–10 micron particle size;  
 (B) Particle-absorbed or combined with nano-particles;

(C) Having coatings/surfactants, or  
 (D) By microencapsulation; and

(ii) Meeting the criteria of paragraph (b)(2)(i) of this category in a manner that is known to or is reasonably expected to result in an increase in any of the following:

(A) Persistence in a field environment (*i.e.*, resistant to oxygen, UV damage, temperature extremes, arid conditions, or decontamination processes);

(B) Dispersal characteristics (*e.g.*, reduced susceptibility to shear forces, optimized electrostatic charges); or

(C) The ability to defeat or overcome: standard detection methods, personnel protection, natural or acquired host immunity, or response to standard medical countermeasures.

**Note 1 to paragraph (b):** Non-naturally occurring means that the modification has not already been observed in nature, was not discovered from samples obtained from nature, and was developed with human intervention.

**Note 2 to paragraph (b):** This paragraph does not control biological agents or biologically derived substances when these agents or substances have been demonstrated to be attenuated relative to natural pathogenic isolates and are incapable of causing disease or intoxication of ordinarily affected and relevant species (e.g., humans, livestock, crop plants) due to the attenuation of virulence or pathogenic factors. This paragraph also does not control genetic elements, nucleic acids, or nucleic acid sequences (whether recombinant or synthetic) that are unable to produce or direct the biosynthesis of infectious or functional forms of the biological agents or biologically derived substances that are capable of causing disease or intoxication of ordinarily affected and relevant species.

**Note 3 to paragraph (b):** Biological agents or biologically derived substances that meet both paragraphs (b)(1) and (b)(2) of this category are controlled in paragraph (b)(1).

\* (c) Chemical agent binary precursors and key precursors, as follows:

(1) Alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonyl difluorides, such as: DF: Methyl Phosphonyldifluoride (CAS 676-99-3) (CWC Schedule 1B); Methylphosphinyldifluoride (CAS 753-59-3) (CWC Schedule 2B);

(2) O-Alkyl (H or equal to or less than C<sub>10</sub>, including cycloalkyl) O-2-dialkyl (methyl, ethyl, n-Propyl or isopropyl) aminoethyl alkyl (methyl, ethyl, n-propyl or isopropyl) phosphonite and corresponding alkylated and protonated salts, such as QL: O-Ethyl-2-di-isopropylaminoethyl methylphosphonite (CAS 57856-11-8) (CWC Schedule 1B);

(3) Chlorosarin: O-Isopropyl methylphosphonochloridate (CAS 1445-76-7) (CWC Schedule 1B);

(4) Chlorosoman: O-Pinacolyl methylphosphonochloridate (CAS 7040-57-5) (CWC Schedule 1B); or

(5) Methylphosphonyl dichloride (CAS 676-97-1) (CWC Schedule 2B); Methylphosphinyldichloride (CAS 676-83-5) (CWC Schedule 2B).

(d) [Reserved]

(e) Defoliants, as follows:

(1) 2,4,5-trichlorophenoxyacetic acid (CAS 93-76-5) mixed with 2,4-dichlorophenoxyacetic acid (CAS 94-75-7) (Agent Orange (CAS 39277-47-9)); or

(2) Butyl 2-chloro-4-fluorophenoxyacetate (LNF).

\* (f) Parts, components, accessories, attachments, associated equipment, materials, and systems, as follows:

(1) Any equipment for the dissemination, dispersion, or testing of articles controlled in paragraphs (a), (b), (c), or (e) of this category, as follows:

(i) Any equipment "specially designed" for the dissemination and dispersion of articles controlled in paragraphs (a), (b), (c), or (e) of this category; or

(ii) Any equipment "specially designed" for testing the articles controlled in paragraphs (a), (b), (c), (e), or (f)(4) of this category and developed under a Department of Defense contract or other funding authorization.

(2) Any equipment, containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense contract or other funding authorization, for the detection, identification, warning, or monitoring of:

(i) Articles controlled in paragraphs (a) or (b) of this category; or

(ii) Chemical agents or biological agents specified in the Department of Defense contract or other funding authorization.

**Note 1 to paragraph (f)(2):** This paragraph does not control articles that are (a) determined to be subject to the EAR via a commodity jurisdiction determination (see § 120.4 of this subchapter), or (b) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

**Note 2 to paragraph (f)(2):** Note 1 does not apply to defense articles enumerated on the USML.

(3) [Reserved]

(4) For individual protection or collective protection against the articles controlled in paragraphs (a) and (b) of this category, as follows:

(i) M53 Chemical Biological Protective Mask or M50 Joint Service General Purpose Mask (JSGPM);

(ii) Filter cartridges containing sorbents controlled in paragraph (f)(4)(iii) or (n) of this category;

(iii) Carbon meeting MIL-DTL-32101 specifications (e.g., ASZM-TEDA carbon); or

(iv) Ensembles, garments, suits, jackets, pants, boots, or socks for individual protection, and liners for collective protection that allow no more than 1% breakthrough of GD or no more than 2% breakthrough of any other chemical controlled in paragraph (a) of this category, when evaluated by

executing the applicable standard method(s) of testing described in the current version of Test Operating Protocols (TOPs) 08-2-201 or 08-2-501 and using the defined Department of Defense-specific requirements;

(5)-(6) [Reserved]

(7) Chemical Agent Resistant Coatings that have been qualified to military specifications (MIL-PRF-32348, MIL-DTL-64159, MIL-C-46168, or MIL-DTL-53039); or

(8) Any part, component, accessory, attachment, equipment, or system that:

(i) Is classified;

(ii) Is manufactured using classified production data; or

(iii) Is being developed using classified information.

**Note to paragraph (f)(8):** "Classified" means classified pursuant to Executive Order 13526, or predecessor order, and a security classification guide developed pursuant thereto or equivalent, or to the corresponding classification rules of another government.

(g) Antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts (including their expression vectors, viruses, plasmids, or cultures of specific cells modified to produce them) as follows:

(1) When exclusively funded by a Department of Defense contract for detection of the biological agents at paragraph (b)(1)(ii) of this category even if naturally occurring;

(2) Joint Biological Agent Identification and Diagnostic System (JBAIDS) Freeze Dried reagents listed by JRPD-ASY-No and Description respectively as follows:

(i) JRPD-ASY-0016 Q-Fever IVD Kit;

(ii) JRPD-ASY-0100 Vaccinia (Orthopox);

(iii) JRPD-ASY-0106 Brucella melitensis (Brucellosis);

(iv) JRPD-ASY-0108 Rickettsia prowazekii (Rickettsia);

(v) JRPD-ASY-0109 Burkholderia ssp. (Burkholderia);

(vi) JRPD-ASY-0112 Eastern equine encephalitis (EEE);

(vii) JRPD-ASY-0113 Western equine encephalitis (WEE);

(viii) JRPD-ASY-0114 Venezuelan equine encephalitis (VEE);

(ix) JRPD-ASY-0122 Coxiella burnetii (Coxiella);

(x) JRPD-ASY-0136 Influenza A/H5 IVD Detection Kit;

(xi) JRPD-ASY-0137 Influenza A/B IVD Detection Kit; or

(xii) JRPD-ASY-0138 Influenza A Subtype IVD Detection Kit;

(3) Critical Reagent Polymerase (CRP) Chain Reactions (PCR) assay kits with Catalog-ID and Catalog-ID Product respectively as follows:



(i) PCR-BRU-1FB-B-K Brucella Target 1 FastBlock Master Mix Biotinylated;

(ii) PCR-BRU-1FB-K Brucella Target 1 FastBlock Master Mix;

(iii) PCR-BRU-1R-K Brucella Target 1 LightCycler/RAPID Master Mix;

(iv) PCR-BURK-2FB-B-K Burkholderia Target 2 FastBlock Master Mix Biotinylated;

(v) PCR-BURK-2FB-K Burkholderia Target 2 FastBlock Master Mix;

(vi) PCR-BURK-2R-K Burkholderia Target 2 LightCycler/RAPID Master Mix;

(vii) PCR-BURK-3FB-B-K Burkholderia Target 3 FastBlock Master Mix Biotinylated;

(viii) PCR-BURK-3FB-K Burkholderia Target 3 FastBlock Master Mix;

(ix) PCR-BURK-3R-K Burkholderia Target 3 LightCycler/RAPID Master Mix;

(x) PCR-COX-1FB-B-K Coxiella burnetii Target 1 FastBlock Master Mix Biotinylated;

(xi) PCR-COX-1R-K Coxiella burnetii Target 1 LightCycler/RAPID Master Mix;

(xii) PCR-COX-2R-K Coxiella burnetii Target 2 LightCycler/RAPID Master Mix;

(xiii) PCR-OP-1FB-B-K Orthopox Target 1 FastBlock Master Mix Biotinylated;

(xiv) PCR-OP-1FB-K Orthopox Target 1 FastBlock Master Mix;

(xv) PCR-OP-1R-K Orthopox Target 1 LightCycler/RAPID Master Mix;

(xvi) PCR-OP-2FB-B-K Orthopox Target 2 FastBlock Master Mix Biotinylated;

(xvii) PCR-OP-3R-K Orthopox Target 3 LightCycler/RAPID Master Mix;

(xviii) PCR-RAZOR-BT-X PCR-RAZOR-BT-X RAZOR CRP BioThreat-X Screening Pouch;

(xix) PCR-RIC-1FB-K Ricin Target 1 FastBlock Master Mix;

(xx) PCR-RIC-1R-K Ricin Target 1 LightCycler/RAPID Master Mix;

(xxi) PCR-RIC-2R-K Ricin Target 2 LightCycler/RAPID Master Mix; or

(xxii) PCR-VEE-1R-K Venezuelan equine encephalitis Target 1 LightCycler/RAPID Master Mix; or

(4) Critical Reagent Program Antibodies with Catalog ID and Product respectively as follows:

(i) AB-AG-RIC Aff. Goat anti-Ricin;

(ii) AB-ALVG-MAB Anti-Alphavirus Generic Mab;

(iii) AB-AR-SEB Aff. Rabbit anti-SEB;

(iv) AB-BRU-M-MAB1 Anti-Brucella melitensis Mab 1;

(v) AB-BRU-M-MAB2 Anti-Brucella melitensis Mab 2;

(vi) AB-BRU-M-MAB3 Anti-Brucella melitensis Mab 3;

(vii) AB-BRU-M-MAB4 Anti-Brucella melitensis Mab 4;

(viii) AB-CHOL-0139-MAB Anti-V.cholerae 0139 Mab;

(ix) AB-CHOL-01-MAB Anti-V.cholerae 01 Mab;

(x) AB-COX-MAB Anti-Coxiella Mab;

(xi) AB-EEE-MAB Anti-EEE Mab;

(xii) AB-G-BRU-A Goat anti-Brucella abortus;

(xiii) AB-G-BRU-M Goat anti-Brucella melitensis;

(xiv) AB-G-BRU-S Goat anti-Brucella suis;

(xv) AB-G-CHOL-01 Goat anti-V.cholerae 0:1;

(xvi) AB-G-COL-139 Goat anti-V.cholerae 0:139;

(xvii) AB-G-DENG Goat anti-Dengue;

(xviii) AB-G-RIC Goat anti-Ricin;

(xix) AB-G-SAL-T Goat anti-S. typhi;

(xx) AB-G-SEA Goat anti-SEA;

(xxi) AB-G-SEB Goat anti-SEB;

(xxii) AB-G-SEC Goat anti-SEC;

(xxiii) AB-G-SED Goat anti-SED;

(xxiv) AB-G-SEE Goat anti-SEE;

(xxv) AB-G-SHIG-D Goat anti-Shigella dysenteriae;

(xxvi) AB-R-BA-PA Rabbit anti-Protective Antigen;

(xxvii) AB-R-COX Rabbit anti-C. burnetii;

(xxviii) AB-RIC-MAB1 Anti-Ricin Mab 1;

(xxix) AB-RIC-MAB2 Anti-Ricin Mab 2;

(xxx) AB-RIC-MAB3 Anti-Ricin Mab 3;

(xxxi) AB-R-SEB Rabbit anti-SEB;

(xxxii) AB-R-VACC Rabbit anti-Vaccinia;

(xxxiii) AB-SEB-MAB Anti-SEB Mab;

(xxxiv) AB-SLT2-MAB Anti-Shigella-like t x2 Mab;

(xxxv) AB-T2T-MAB1 Anti-T2 Mab 1;

(xxxvi) AB-T2T-MAB2 Anti-T2 Toxin 2;

(xxxvii) AB-VACC-MAB1 Anti-Vaccinia Mab 1;

(xxxviii) AB-VACC-MAB2 Anti-Vaccinia Mab 2;

(xxxix) AB-VACC-MAB3 Anti-Vaccinia Mab 3;

(xl) AB-VACC-MAB4 Anti-Vaccinia Mab 4;

(xli) AB-VACC-MAB5 Anti-Vaccinia Mab 5;

(xlii) AB-VACC-MAB6 Anti-Vaccinia Mab 6;

(xliii) AB-VEE-MAB1 Anti-VEE Mab 1;

(xliv) AB-VEE-MAB2 Anti-VEE Mab 2;

(xlv) AB-VEE-MAB3 Anti-VEE Mab 3;

(xlvi) AB-VEE-MAB4 Anti-VEE Mab 4;

(xlvii) AB-VEE-MAB5 Anti-VEE Mab 5;

(xlviii) AB-VEE-MAB6 Anti-VEE Mab 6; or

(xlix) AB-WEE-MAB Anti-WEE Complex Mab.

(h) Vaccines exclusively funded by a Department of Defense contract, as follows:

(1) Recombinant Botulinum Toxin A/B Vaccine;

(2) Recombinant Plague Vaccine;

(3) Trivalent Filovirus Vaccine; or

(4) Vaccines specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in paragraph (b) of this category.

**Note to paragraph (h):** See ECCN 1A607.k for military medical countermeasures such as autoinjectors, combopens, and creams.

(i) Modeling or simulation tools, including software controlled in paragraph (m) of this category, for chemical or biological weapons design, development, or employment developed or produced under a Department of Defense contract or other funding authorization (e.g., the Department of Defense's HPAC, SCIPUFF, and the Joint Effects Model (JEM)).

(j)-(l) [Reserved]

(m) Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (l) and (n) of this category. (See § 125.4 of this subchapter for exemptions.)

(n) Developmental countermeasures or sorbents funded by the Department of Defense via contract or other funding authorization;

**Note 1 to paragraph (n):** This paragraph does not control countermeasures or sorbents that are (a) in production, (b) determined to be subject to the EAR via a commodity jurisdiction determination (see § 120.4 of this subchapter), or (c) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

**Note 2 to paragraph (n):** Note 1 does not apply to defense articles enumerated on the USML, whether in production or development.

**Note 3 to paragraph (n):** This paragraph is applicable only to those contracts and funding authorizations that are dated July 28, 2017, or later.

(o)-(w) [Reserved]

(x) Commodities, software, and technology subject to the EAR (see § 120.42 of this subchapter) used in or with defense articles controlled in this category.

**Note to paragraph (x):** Use of this paragraph is limited to license applications for defense articles controlled in this category where the purchase documentation includes



commodities, software, or technology subject to the EAR (see § 123.1(b) of this subchapter).

\* \* \* \* \*

### Category XVIII—Directed Energy Weapons

\* (a) Directed energy weapons as follows:

(1) Systems or equipment that, other than as a result of incidental, accidental, or collateral effect:

(i) Degrade, destroy or cause mission-abort of a target;

(ii) Disturb, disable, or damage electronic circuitry, sensors or explosive devices remotely;

(iii) Deny area access;

(iv) Cause lethal effects; or

(v) Cause ocular disruption or blindness; and

(2) Use any non-acoustic technique such as lasers (including continuous wave or pulsed lasers), particle beams, particle accelerators that project a charged or neutral particle beam, high power radio-frequency (RF), or high pulsed power or high average power radio frequency beam transmitters.

\* (b) Systems or equipment specially designed to detect, identify, or provide defense against articles specified in paragraph (a) of this category.

(c)–(d) [Reserved]

(e) Components, parts, accessories, attachments, systems or associated equipment specially designed for any of the articles in paragraphs (a) or (b) of this category.

(f) Developmental directed energy weapons funded by the Department of Defense via contract or other funding authorization, and specially designed parts and components therefor;

**Note 1 to paragraph (f):** This paragraph does not control directed energy weapons (a) in production, (b) determined to be subject to the EAR via a commodity jurisdiction determination (see § 120.4 of this subchapter), or (c) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

**Note 2 to paragraph (f):** Note 1 does not apply to defense articles enumerated on the USML, whether in production or development.

**Note 3 to paragraph (f):** This paragraph is applicable only to those contracts and funding authorizations that are dated July 28, 2017, or later.

(g) Technical data (see § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (e) of this category;

(x) Commodities, software, and technology subject to the EAR (see

§ 120.42 of this subchapter) used in or with defense articles controlled in this category.

**Note to paragraph (x):** Use of this paragraph is limited to license applications for defense articles controlled in this category where the purchase documentation includes commodities, software, or technology subject to the EAR (see § 123.1(b) of this subchapter).

**Rose E. Gottemoeller,**

*Under Secretary, Arms Control and International Security, Department of State.*

[FR Doc. 2016–17505 Filed 7–27–16; 8:45 am]

**BILLING CODE 4710–25–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 33

[EPA–HQ–OA–2006–0278; FRL–9946–27–OA]

RIN 2090–AA40

### Participation by Disadvantaged Business Enterprises in Procurements Under EPA Financial Assistance Agreements

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final rule.

**SUMMARY:** Environmental Protection Agency (EPA) is taking direct final action on revisions to the EPA’s Disadvantaged Business Enterprise (DBE) program. We are approving these revisions to improve the practical utility of the program, minimize burden, and clarify requirements that have been the subject of questions from recipients of EPA financial assistance and from disadvantaged business enterprises. These revisions are in accordance with the requirements of the Federal laws that govern the EPA DBE program.

**DATES:** This rule is effective on October 26, 2016 without further notice, unless EPA receives adverse comment by August 29, 2016. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–OA–2006–0278, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other

information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

### FOR FURTHER INFORMATION CONTACT:

Teree Henderson, Office of the Administrator, Office of Small Business Programs (mail code: 1230A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–566–2222; fax number: 202–566–0548; email address: [henderson.teree@epa.gov](mailto:henderson.teree@epa.gov).

### SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

BCRLF Brownfields Cleanup Revolving Loan Fund  
 CWSRF Clean Water State Revolving Fund  
 DWSRF Drinking Water State Revolving Fund  
 EDWOSB Economically Disadvantaged Woman Owned Small Business Program  
 DOT Department of Transportation  
 SBA Small Business Administration  
 DBE Disadvantaged Business Enterprise  
 MBE Minority Business Enterprise  
 WBE Women’s Business Enterprise  
 EPA Environmental Protection Agency  
 OSBP Office of Small Business Programs  
 SBVPS Small Business Vendor Profile System

### I. Why is EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comments. The actions are intended to improve the practical utility of the program, minimize burden, and clarify requirements that have been the subject of questions from recipients of EPA financial assistance and from disadvantaged business enterprises. However, in the “Proposed Rules” section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to amend these regulations, if EPA receives significant adverse comments on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting