

4.3. With regard to innovative products and treatments for “reduction in consumption of tobacco,”

a. How can the reduction best be measured?

b. If the reduction is associated with a certain goal or benefit:

i. What evidence is available to indicate that the reduction in consumption will bring about that goal or achieve that benefit?

ii. What degree and duration of reduction are necessary to achieve that goal or benefit?

4.4. With regard to innovative products and treatments for “reduction in the harm associated with continued tobacco use”:

a. How should the “harm” be identified and measured?

b. Is there a range of harms that might be addressed, and if so, which are the most important to address?

4.5. With regard to innovative products and treatments making claims in any of the three categories identified in section 918(b), what barriers exist to development and marketing approval?

4.6 In regulating the innovative products and treatments referenced in section 918(b), how can FDA and other HHS Agencies act to ensure that the three effects mentioned in section 918(b)—total abstinence from tobacco use, reductions in consumption of tobacco, and reductions in the harm associated with continued tobacco use—are achieved as broader outcomes, in a manner that best protects and promotes the public health?

4.7. How can these broader outcomes be taken into account in FDA’s premarket evaluation of new product candidates?

III. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-served basis. Individuals who wish to present at the public hearing must register by December 6, 2012, and provide complete contact information, including name, title, affiliation, address, email, and phone number. Those without email access may register by contacting Ayanna Augustus (see **FOR FURTHER INFORMATION CONTACT**). FDA has included questions for comment in section II of this document. You should identify the number of each question you wish to address in your presentation, so that FDA can consider that in organizing the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and

request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times, and make available an agenda at <http://www.fda.gov/Drugs/NewsEvents/ucm324938.htm> approximately 1 week prior to the public hearing. Once FDA notifies registered presenters of their scheduled times, presenters should submit to FDA an electronic copy of their presentation to Section918PublicMeeting@fda.hhs.gov by December 10, 2012.

If you need special accommodations because of a disability, please contact Ayanna Augustus (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

A live Web cast of this public hearing may be seen at <https://collaboration.fda.gov/Section918> on the day of the public hearing. A video record of the public hearing will be available at the same Web address for 1 year.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by senior management and technical experts from various offices within FDA.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI of this document). To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic or written comments to the Division of Dockets Management (see **ADDRESSES**). It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

Transcripts of the public hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at <http://www.regulations.gov> approximately 30 days after the public hearing. A transcript will also be made available in either hard copy or on CD-ROM, upon submission of a Freedom of Information request. Written requests should be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: November 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28835 Filed 11–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF STATE

22 CFR Part 121

RIN 1400–AD25

[Public Notice: 8091]

Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Category XI and Definition for “Equipment”

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: As part of the President’s Export Control Reform effort, the Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to revise Category XI (military electronics) of the U.S. Munitions List (USML) to describe more precisely the articles warranting control on the USML and to provide a definition for “equipment.” 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: The Department of State will accept comments on this proposed rule until January 28, 2013.

ADDRESSES: Interested parties may submit comments within 60 days of the date of publication by one of the following methods:

- *Email:*

DDTCResponseTeam@state.gov with the subject line, "ITAR Amendment—Category XI and 'Equipment.'"

- *Internet:* At *www.regulations.gov*, search for this notice by using this rule's RIN (1400-AD25).

Comments received after that date will be considered if feasible, but consideration cannot be assured. Those submitting comments should not include any personally identifying information they do not desire to be made public or information for which a claim of confidentiality is asserted because those comments and/or transmittal emails will be made available for public inspection and copying after the close of the comment period via the Directorate of Defense Trade Controls Web site at *www.pmdtc.state.gov*. Parties who wish to comment anonymously may do so by submitting their comments via *www.regulations.gov*, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself. Comments submitted via *www.regulations.gov* are immediately available for public inspection.

FOR FURTHER INFORMATION CONTACT: Ms. Candace M. J. Goforth, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663-2792; email *DDTCResponseTeam@state.gov*. ATTN: Regulatory Change, USML Category XI and "Equipment."

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.

Export Control Reform Update

The Departments of State and Commerce described in their respective Advanced Notices of Proposed Rulemaking (ANPRM) in December 2010 the Administration's plan to make the USML and the CCL positive, tiered, and aligned so that eventually they can be combined into a single control list (*see* "Commerce Control List: Revising Descriptions of Items and Foreign Availability," 75 FR 76664 (December 9, 2010) and "Revisions to the United States Munitions List," 75 FR 76935 (December 10, 2010)). The notices also called for the establishment of a "bright line" between the USML and the CCL to reduce government and industry uncertainty regarding export jurisdiction by clarifying whether particular items are subject to the jurisdiction of the ITAR or the EAR. While these remain the Administration's ultimate Export Control Reform objectives, their concurrent implementation would be problematic in the near term. In order to more quickly reach the national security objectives of greater interoperability with U.S. allies, enhancing the defense industrial base, and permitting the U.S. Government to focus its resources on controlling and monitoring the export and reexport of more significant items to destinations, end-uses, and end-users of greater concern than NATO allies and other multi-regime partners, the Administration has decided, as an interim step, to propose and implement revisions to both the USML and the CCL that are more positive, but not yet tiered.

Specifically, based in part on a review of the comments received in response to the December 2010 notices, the Administration has determined that fundamentally altering the structure of the USML by tiering and aligning it on a category-by-category basis would significantly disrupt the export control compliance systems and procedures of exporters and reexporters. For example, until the entire USML was revised and became final, some USML categories would follow the legacy numbering and control structures while the newly revised categories would follow a completely different numbering structure. In order to allow for the national security benefits to flow from re-aligning the jurisdictional status of defense articles that no longer warrant control on the USML on a category-by-category basis while minimizing the impact on exporters' internal control

and jurisdictional and classification marking systems, the Administration plans to proceed with building positive lists now and afterward return to structural changes.

Revision of Category XI

This proposed rule revises USML Category XI, covering military electronics, to advance the national security objectives set forth above and to more accurately describe the articles within the category, in order to establish a "bright line" between the USML and the CCL for the control of these articles.

Paragraphs (a)(1) (covering underwater hardware, equipment, and systems), (a)(3) (covering radar systems and equipment), (a)(4) (covering electronic combat equipment), and (a)(5) (covering C³, C⁴, C⁴ISR, and identification systems and equipment), are amended to more specifically enumerate the articles controlled therein.

Paragraph (a)(6), which currently controls military computers, is removed, and the articles controlled therein are transferred to the jurisdiction of the Department of Commerce under new ECCN 3A611.

Paragraph (a)(8) is added to cover unattended ground sensors.

Paragraph (a)(9) is added to cover electronic sensor systems for anti-submarine warfare or mine warfare.

Paragraph (a)(10) is added to cover electronic sensor systems for concealed weapons.

Paragraph (a)(11) is added to cover test sets "specially designed" and programmed for testing counter radio controlled improvised explosive device electronic warfare systems.

Paragraph (a)(12) is added to cover equipment to process or analyze Category XI defense articles.

Paragraph (b) (covering electronic systems or equipment for search, reconnaissance, collection, monitoring, direction finding, display, analysis, or production of information from the electromagnetic spectrum and electronic systems or equipment that counteracts electronic surveillance) is amended to provide consistency with Wassenaar Munitions List controls while retaining the same catch-all coverage of the current paragraph (b).

A significant aspect of this more positive, but not yet tiered, proposed USML category is that it does not contain controls on all generic parts, components, accessories, and attachments that are specifically designed or modified for a defense article, regardless of their significance to maintaining a military advantage for the United States. Rather, it contains, with

a few exceptions, a positive list of specific types of parts, components, accessories, and attachments that continue to warrant control on the USML. The exceptions pertain to those parts, components, accessories, and attachments identified as “specially designed.”

Paragraph (d) is amended to remove reference to Significant Military Equipment.

Section 121.8 is amended by including a definition for “equipment” in new paragraph (h).

Finally, articles common to the Missile Technology Control Regime (MTCR) Annex and the USML are to be identified on the USML with the parenthetical “(MT)” at the end of each section containing such articles. A separate proposed rule will address the sections in the ITAR that include MTCR definitions.

Definition for Specially Designed

Although one of the goals of the export control reform initiative is to describe USML controls without using design intent criteria, a few of the controls in the proposed revision nonetheless use the term “specially designed.” It is, therefore, necessary for the Department to define the term. Three proposed definitions have been published to date. For the purpose of evaluation of this proposed rule, reviewers should use the definition provided by the Department of State in the June 19, 2012, proposed rule (77 FR 36428).

Request for Comments

As the U.S. Government works through the proposed revisions to the USML, some solutions have been adopted that were determined to be the best of available options. With the thought that multiple perspectives would be beneficial to the USML revision process, the Department welcomes the assistance of users of the lists and requests input on the following:

(1) A key goal of this rulemaking is to ensure the USML and the CCL together control all the items that meet Wassenaar Arrangement commitments embodied in Munitions List Category 11 (WA-ML11). To that end, the public is asked to identify any potential lack of coverage brought about by the proposed rules for Category XI contained in this notice and the new Category 3 ECCNs published separately by the Department of Commerce when reviewed together.

(2) The key goal of this rulemaking is to establish a “bright line” between the USML and the CCL for the control of these materials. The public is asked to

provide specific examples of military electronics whose jurisdiction would be in doubt based on this revision.

(3) The current USML Category XI(c) does not control electronic parts, components, accessories, and attachments “in normal commercial use.” Although the proposed revisions to the USML do not preclude the possibility that electronic and other items in normal commercial use would or should be ITAR-controlled because, e.g., they provide the United States with a critical military or intelligence advantage, the U.S. Government does not want to inadvertently control items on the ITAR that are in normal commercial use. The public is thus asked to provide specific examples of electronics, if any, that would be controlled by the revised Category XI that are now in normal commercial use.

Regulatory Analysis and Notices

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 (APA). Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department is publishing this rule 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. As noted above, and also without prejudice to the Department position that this rulemaking is not subject to the APA, the Department previously published a related Advance Notice of Proposed Rulemaking (RIN 1400-AC78) on December 10, 2010 (75 FR 76935), and accepted comments for 60 days.

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 proposed 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 proposed 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 proposed 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 proposed 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 proposed amendment.

Executive Orders 12866 and 13563

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, 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 proposed 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

Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB control number. This proposed rule would affect the following approved collections: (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) Nontransfer and Use Certificate, DSP-83, OMB No. 1405-0021; (5) Application/License for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Classified Technical Data, DSP-85, OMB No. 1405-0022; (6) Application/License for Temporary Export of Unclassified Defense Articles, DSP-73, OMB No. 1405-0023; (7) Statement of Political Contributions, Fees, or Commissions in Connection with the Sale of Defense Articles or Services, OMB No. 1405-0025; (8) Authority to Export Defense Articles and Services Sold Under the Foreign Military Sales (FMS) Program, DSP-94, OMB No. 1405-0051; (9) 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; (10) Request for Approval of Manufacturing License Agreements, Technical Assistance Agreements, and Other Agreements, DSP-5, OMB No. 1405-0093; (11) Maintenance of Records by Registrants, OMB No. 1405-0111; (12) Annual Brokering Report, DS-4142, OMB No. 1405-0141; (13) Brokering Prior Approval (License), DS-4143, OMB No. 1405-0142; (14) Projected Sale of Major Weapons in Support of Section 25(a)(1) of the Arms Export Control Act, DS-4048, OMB No. 1405-0156; (15) Export Declaration of Defense Technical Data or Services, DS-4071, OMB No. 1405-0157; (16) Request for Commodity Jurisdiction Determination, DS-4076, OMB No. 1405-0163; (17) Request to Change End-User, End-Use, and/or Destination of Hardware, DS-6004, OMB No. 1405-0173; (18) Request for Advisory Opinion, DS-6001, OMB No.

1405-0174; (19) Voluntary Disclosure, OMB No. 1405-0179; and (20) Technology Security/Clearance Plans, Screening Records, and Non-Disclosure Agreements Pursuant to 22 CFR 126.18, OMB No. 1405-0195. The Department of State believes there will be minimal changes to these collections. The Department of State believes the combined effect of all rules to be published moving commodities from the USML to the EAR as part of the Administration's Export Control Reform would decrease the number of license applications by approximately 30,000 annually. The Department of State is looking for comments on the potential reduction in burden.

List of Subjects in Part 121

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 121 is proposed to be 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); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; Pub. L. 105-261, 112 Stat. 1920.

2. Section 121.1 is amended by revising U.S. Munitions List Category XI to read as follows:

§ 121.1 General. The United States Munitions List.

* * * * *

Category XI—Military Electronics

(a) Electronic equipment not included in Category XII of the U.S. Munitions list, as follows:

(1) Underwater hardware, equipment, or systems, as follows:

(i) Active or passive acoustic array sensing systems or equipment that survey or detect, and track, localize (*i.e.*, determine range and bearing), classify, or identify surface vessels, submarines, other undersea vehicles, torpedoes, or mines having any of the following:

(A) Multi-aspect capability;
(B) Operating frequency less than 20 kHz;

(C) Bandwidth greater than 10 kHz; or
(D) Capable of real-time processing;

(ii) Underwater single acoustic sensor system that distinguishes tonals and locates the origin of the sound;

(iii) Non-acoustic systems that survey or detect, and track, localize, classify, or identify surface vessels, submarines, other undersea vehicles, torpedoes, or mines;

Note to paragraph (a)(1)(iii): Equipment controlled in CCL ECCN 5A001.b.1 is not included.

(iv) Acoustic modems, networks, and communications equipment with adaptive compensation or employing Low Probability of Intercept (LPI);

Note 1 to paragraph (a)(1)(iv): Adaptive compensation is the capability of an underwater modem to assess the water conditions to select the best algorithm to receive and transmit data.

Note 2 to paragraph (a)(1)(iv): The term "Low Probability of Intercept" used in this paragraph and elsewhere in this category is defined as a class of measures that disguise, delay, or prevent the interception of acoustic or electromagnetic signals. LPI techniques can involve permutations of power management, energy management, frequency variability, out-of-receiver-frequency band, low-side lobe antenna, complex waveforms, and complex scanning. LPI is also referred to as Low Probability of Intercept, Low Probability of Detection, and Low Probability of Identification.

(v) LF/VLF electronic modems, routers, interfaces and communications equipment "specially designed" for submarine communications; or

(vi) Autonomous processing/control systems and equipment that enable cooperative sensing and engagement by fixed (bottom mounted/seabed) or mobile Autonomous Underwater Vehicles (AUVs);

(2) Underwater acoustic countermeasures or counter-countermeasures systems or equipment;

(3) Radar systems and equipment, as follows:

(i) Airborne radar that track targets;
(ii) Synthetic aperture radar (SAR) incorporating image resolution less than (better than) 0.3 meter, or incorporating Coherent Change Detection (CCD) with geo-registration accuracy less than (better than) 0.3 meter;

(iii) Inverse Synthetic Aperture Radar (ISAR);

(iv) Radar that geo-locates with a target location error 50 (TLE50) less than or equal to 10 meters;

(v) Any ocean surface surveillance radar with either a product of transmit peak power times antenna gain divided by minimum detectable signal of >165 dB, or a capability to distinguish a target of <10 dBsm from sea clutter with a false alarm rate of 10^{-6} or better in sea state 3 or higher, or both;

(vi) Sea surveillance/navigation radar with free space detection of 1 square meter radar cross section (RCS) target at 20 nautical miles (nmi) or greater range;

(vii) Land or perimeter surveillance radar with free space detection of 1 square meter RCS target at 5.4 nmi or greater range and has a revisit rate of faster than once every sixty seconds;

(viii) Air surveillance radar with free space detection of 1 sq m RCS target at 85 nmi or greater range or free space detection of 1 sq m RCS target at an altitude of 65,000 feet and an elevation angle greater than 20 degrees;

(ix) Air surveillance radar with multiple elevation beams, phase or amplitude monopulse estimation, or 3D height-finding;

(x) Air surveillance radar with a beam solid angle less than or equal to 16 degrees² that performs free space tracking of 1 sq m RCS target at a range greater or equal to 25 nmi with revisit rate greater or equal to 1/3 hertz;

(xi) Instrumentation radar for anechoic test facility or outdoor range to track targets, or provide measure of RCS of static target less than or equal to -10dBsm, or RCS of dynamic target;

(xii) Radar incorporating pulsed operation with electronics steering of transmit beam in elevation and azimuth;

(xiii) Radar with mode(s) for ballistic tracking or ballistic extrapolation to source of launch or impact point of articles controlled in USML Categories III or IV;

(xiv) Active protection radar and missile warning radar with mode(s) implemented for detection of incoming munitions;

(xv) Over the horizon high frequency sky-wave (ionosphere) radar;

(xvi) Radar that detects a moving object through a physical obstruction at distance greater than 0.2 meters from the obstruction;

(xvii) Radar having moving target indicator (MTI) or pulse-Doppler processing where any single Doppler filter provides a normalized clutter attenuation of greater than 50dB;

Note to paragraph (a)(3)(xvii): "Normalized clutter attenuation" is defined as the reduction in the power level of received distributed clutter when normalized to the thermal noise level.

(xviii) Radar having electronic protection (EP) or electronic counter-countermeasures (ECCM) other than manual gain control, automatic gain control, radio frequency selection, constant false alarm rate, and pulse repetition interval jitter;

(xix) Radar employing electronic attack (EA) mode(s) using the radar transmitter and antenna;

(xx) Radar employing electronic support (ES) mode(s) (*i.e.*, the ability to use a radar system for ES purposes in one or more of the following: As a high-gain receiver, as a wide-bandwidth receiver, as a multi-beam receiver, or as part of a multi-point system);

(xxi) Radar employing non-cooperative target recognition (NCTR)

(*i.e.*, the ability to recognize a specific platform type without cooperative action of the target platform);

(xxii) Radar employing automatic target recognition (ATR) (*i.e.*, recognition of generic target type using structural features of the target) with system resolution better than (less than) 0.3 meters;

(xxiii) Radar that sends interceptor guidance commands or provides illumination keyed to an interceptor seeker;

(xxiv) Radar employing waveform generation for low probability of intercept (LPI) other than frequency modulated continuous wave (FMCW) with linear ramp modulation;

(xxv) Radar that sends and receives communications;

(xxvi) Radar that tracks or discriminates ballistic missile warhead from debris or countermeasures;

(xxvii) Bi-static/multi-static radar that exploits greater than 125 kHz bandwidth and is lower than 2 GHz center frequency to passively detect or track using RF transmissions (*e.g.*, commercial radio or television stations);

(xxviii) Radar target generators, projectors, or simulators "specially designed" for radars controlled by this category; or

(xxix) Radar and laser radar systems "specially designed" for defense articles in (a)(1) of Category IV and (a)(5) and (a)(6) of Category VIII (MT);

Note to paragraph (a)(3): This category does not control secondary surveillance radar (SSR) or precision approach radar (PAR) equipment conforming to ICAO standards and employing electronically steerable linear (1-dimensional) arrays or mechanically positioned passive antennae.

(4) Electronic combat equipment, as follows:

(i) Electronic support (ES) systems and equipment that search for, intercept, and identify, or locate sources of intentional or unintentional electromagnetic energy for the purpose of immediate threat detection, recognition, targeting, planning, or conduct of future operations;

Note to paragraph (a)(4)(i): Electronic Support functions consist of tactical situational awareness, automatic cueing, targeting, electronic order of battle planning, electronic intelligence (ELINT), communication intelligence (COMINT), signals intelligence (SIGINT).

(ii) Systems and equipment that detect and automatically discriminate acoustic energy emanating from weapons fire (*e.g.*, gunfire, artillery, rocket propelled grenades, or other projectiles), determining location or direction of weapons fire in less than

two seconds from receipt of event signal, and able to operate on-the-move (*e.g.*, operating on personnel, land vehicles, sea vessels, or aircraft while in motion); or

(iii) Systems and equipment "specially designed" to introduce extraneous or erroneous signals into radar, infrared based seekers, electro-optic based seekers, radio communication receivers, navigation receivers, or that otherwise hinder the reception, operation, or effectiveness of adversary electronics (*e.g.*, active or passive electronic attack, electronic countermeasure, electronic counter-countermeasure equipment, jamming, and counter jamming equipment);

(5) Command, control, and communications (C³), command, control, communications, and computers (C⁴), command, control, communications, computers, intelligence, surveillance, and reconnaissance (C⁴ISR), and identification systems or equipment, as follows:

(i) C³, C⁴, and C⁴ISR systems "specially designed" to integrate, incorporate, network, or employ defense articles controlled in this subchapter;

(ii) Identification friend or foe (IFF) systems or equipment incorporating U.S. government Modes 4 or 5;

(iii) Systems or equipment that implement active or passive electronic counter-countermeasures (ECCM) used to counter acts of communication disruption (*e.g.*, radios that incorporate HAVE QUICK I/II, SINCGARS, SATURN);

(iv) Systems or equipment implementing techniques to suppress compromising emanations of information bearing signals "specially designed" or certified to meet U.S. Government NSTISSAM TEMPEST 1-92 standards or CNSSAM TEMPEST 01-02; or

(v) Systems or equipment that transmit voice or data signals "specially designed" to elude electromagnetic detection;

(6) [Reserved]

(7) Developmental electronic devices, systems, or equipment funded by the Department of Defense;

Note 1 to paragraph (a)(7): Paragraph XI(a)(7) does not control developmental electronic devices, systems, or equipment (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 as being developed for both civil and military applications.

Note 2 to paragraph (a)(7): Note 1 does not apply to defense articles enumerated on the

USML, whether in production or development.

(8) Unattended ground sensor (UGS) systems or equipment having all of the following:

- (i) Automatic target detection;
- (ii) Automatic target tracking, classification, recognition, or identification;
- (iii) Self-forming or self-healing networks; and
- (iv) Self-localization for geo-locating targets;

(9) Electronic sensor systems or equipment for non-acoustic anti-submarine warfare (ASW) or mine warfare (e.g., magnetic anomaly detectors (MAD), electric-field, and electromagnetic induction);

(10) Electronic sensor systems or equipment for detection of concealed weapons, having a standoff detection range of greater than 45 meters for personnel or detection of vehicle-carried weapons;

(11) Test sets "specially designed" and programmed for testing counter radio controlled improvised explosive device (C-RCIED) electronic warfare (CREW) systems;

(12) Equipment "specially designed" to process or analyze signals from defense articles controlled by this category; or

(13) Direction finding equipment for determining bearings to specific electromagnetic sources or terrain characteristics "specially designed" for defense articles in paragraph (a)(1) of Category IV and paragraphs (a)(5) and (a)(6) of Category VIII (MT).

(b) Electronic systems or equipment "specially designed" for the collection, surveillance, monitoring, or exploitation of the electromagnetic spectrum (regardless of transmission medium), for intelligence or security purposes or for counteracting such activities. This includes:

(1) Non-cooperative direction finding systems that have an angle of arrival (AOA) accuracy better than (less than) two degrees RMS and are not "specially designed" for navigation;

(2) Such systems or equipment that use burst techniques (e.g., time compression techniques);

(3) Systems and equipment "specially designed" for measurement and signature intelligence (MASINT);

(4) Technical surveillance counter-measure (TSCM) or electronic surveillance equipment and counter electronic surveillance equipment (including spectrum analyzers) for the RF/microwave spectrum that:

(i) Sweep or scan speed exceeding 250 MHz per second;

(ii) Have instantaneous bandwidth exceeding 110 MHz;

(iii) Have built-in signal analysis capability;

(iv) Have a volume of less than 1 cubic foot;

(v) Record time-domain or frequency-domain digital signals other than single trace spectral snapshots; and

(vi) Display time-vs-frequency domain (e.g., waterfall or rising raster).

(c) Parts, components, accessories, attachments, and associated equipment, as follows:

(1) Application specific integrated circuits (ASIC) for which the functionality is "specially designed" for defense articles in this subchapter;

(2) Printed circuit boards or patterned multichip modules for which the layout is "specially designed" for defense articles in this subchapter;

(3) Transmit/receive modules or transmit modules that have any two perpendicular sides, with either length d (in cm) equal to or less than 15 divided by the lowest operating frequency in GHz [$d \leq 15 \text{ cm} * \text{GHz} / f_{\text{GHz}}$], that incorporate a MMIC or discrete RF power transistor and a phase shifter or phasers;

(4) High-energy storage capacitors with a repetition rate of 6 discharges or more per minute that have any of the following:

(i) Volumetric energy density greater than or equal to 1.3 J/cc;

(ii) Mass energy density greater than or equal to 1.1 kJ/kg; or

(iii) Full energy life greater than or equal to 10,000 discharges;

(5) Radio frequency circulators of any dimension equal to or less than one quarter ($1/4$) wavelength of the highest operating frequency and isolation greater than 30dB;

(6) Polarimeter that detects and measures polarization of radio frequency signals within a single pulse;

(7) Digital radio frequency memory (DRFM) with RF instantaneous input bandwidth greater than 400 MHz, and 4 bit or higher resolution and "specially designed" parts and components therefor;

(8) Vacuum electronic devices, as follows:

(i) Multiple electron beam or sheet electron beam devices rated for operation at frequencies of 16 GHz or above, and with a saturated power output greater than 10,000 W (70 dBm) or a maximum average power output greater than 3,000 W (65 dBm); or

(ii) Cross-field amplifiers with a gain of 15 dB to 17 dB or a duty factor greater than 5%;

(9) Antenna, and "specially designed" parts and components therefor, that:

(i) Electronically steer angular beams and nulls with four or more elements;

(ii) Form adaptive null attenuation greater than 35 dB with convergence time less than 1 second;

(iii) Detect signals across multiple RF bands with matched left hand and right hand spiral antenna elements for determination of signal polarization; or

(iv) Determine signal angle of arrival less than two degrees (e.g., interferometer antenna);

(10) Radomes or electromagnetic antenna windows that:

(i) Incorporate radio frequency selective surfaces (MT);

(ii) Operate in multiple or more non-adjacent radar bands (MT);

(iii) Incorporate a structure that is "specially designed" to provide ballistic protection from bullets, shrapnel, or blast (MT);

(iv) Have a melting point greater than 1,300 °C and maintain a dielectric constant less than 6 at temperatures greater than 500 °C (MT);

(v) Are manufactured from ceramic materials with a dielectric constant less than 6 at any frequency from 100 MHz to 100 GHz (MT);

(vi) Maintain structural integrity at stagnation pressures greater than 6,000 pounds per square foot (MT);

(vii) Withstand combined thermal shock greater than $4.184 \times 10^6 \text{ J/m}^2$ accompanied by a peak overpressure of greater than 50 kPa (MT); or

(viii) Are configured to blend with the external geometry of end-items controlled in Category IV (MT);

(11) Underwater sensors (acoustic vector sensors, hydrophones, or transducers) or projectors "specially designed" for systems controlled by paragraphs (a)(1) and XI(a)(2) of this category, having any of the following:

(i) A transmitting frequency below 10 kHz;

(ii) Sound pressure level exceeding 224 dB (reference 1 μPa at 1 m) for equipment with an operating frequency in the band from 10 kHz to 24 kHz inclusive;

(iii) Sound pressure level exceeding 235 dB (reference 1 μPa at 1 m) for equipment with an operating frequency in the band between 24 kHz and 30 kHz;

(iv) Forming beams of less than 1° on any axis and having an operating frequency of less than 100 kHz;

(v) Designed to operate with an unambiguous display range exceeding 5,120 m; or

(vi) Designed to withstand pressure during normal operation at depths exceeding 1,000 m and having transducers with any of the following:

(A) Dynamic compensation for pressure; or

(B) Incorporating other than lead zirconate titanate as the transduction element;

(12) Parts or components containing piezoelectric materials which are "specially designed" for underwater hardware, equipment, or systems controlled by paragraph (c)(11) of this category;

(13) Tuners having an instantaneous bandwidth of 30 MHz or greater and a tuning speed of 300 microseconds or less to within 10 KHz of desired frequency;

(14) Electronic assemblies and components "specially designed" for missiles, rockets, or UAVs capable of achieving a range of at least 300 km and capable of operation at temperatures in excess of 125 °C (MT);

(15) "Specially designed" hybrid (combined analogue/digital) computers for modeling, simulation, or design integration of systems enumerated in paragraphs (a)(1), (d)(1), (d)(2), (h)(1), (h)(2), (h)(4), (h)(8), and (h)(9) of Category IV or paragraphs (a)(5) and (a)(6) of Category VIII (MT);

(16) Parts, components, or accessories "specially designed" to modify or customize the properties (e.g., operating frequencies, algorithms, waveforms, CODECs, or modulation/demodulation schemes) of a radio or information assurance/information security article controlled in this subchapter beyond what is specified in the public domain or the published product specifications; or

(17) Any part, component, accessory, attachment, equipment, or system that (MT for those articles designated as such):

- (i) Is classified;
- (ii) Contains classified software; or
- (iii) Is being developed using classified information.
- (iv) *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 or intergovernmental organization.

(d) Technical data (see § 120.10 of this subchapter) and defense services (see § 120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (c) of this category and classified technical data directly related to items controlled in CCL ECCN 9E620 and defense services using the classified technical data. (See § 125.4 of this subchapter for exemptions.) (MT for technical data and defense services related to articles designated as such.)

* * * * *

3. Section 121.8 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 121.8 End-items, components, accessories, attachments, parts, firmware, software, systems, and equipment.

* * * * *

(h) *Equipment* is a combination of parts, components, accessories, attachments, firmware, or software that operate together to perform a specialized function of an end-item or a system.

Dated: November 19, 2012.

Andrew J. Shapiro,

Assistant Secretary, Bureau of Political-Military Affairs, Department of State.

[FR Doc. 2012-28477 Filed 11-23-12; 11:15 am]

BILLING CODE 4710-25-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 226

Osage Negotiated Rulemaking Committee

AGENCY: Bureau of Indian Affairs, Interior

ACTION: Notice of public meeting cancellation

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, the U.S. Department of the Interior, Bureau of Indian Affairs, Osage Negotiated Rulemaking Committee has cancelled the December 13-14, 2012 meeting.

DATES: The meetings were originally scheduled for Thursday, December 13, 2012, and Friday, December 14, 2012, from 9 a.m. to 6 p.m. at the Wah Zha Zhi Cultural Center, 1449 W. Main, Pawhuska, Oklahoma 74056. A new meeting date and location will be announced later.

FOR FURTHER INFORMATION CONTACT: Mr. Eddie Streater, Designated Federal Officer, Bureau of Indian Affairs, Wewoka Agency, P.O. Box 1540, Seminole, OK 74818; telephone (405) 257-6250; fax (405) 257-3875; or email osageregneg@bia.gov. Additional Committee information can be found at: <http://www.bia.gov/osageregneg>.

SUPPLEMENTARY INFORMATION: On October 14, 2011, the United States and the Osage Nation (formerly known as the Osage Tribe) signed a Settlement Agreement to resolve litigation regarding alleged mismanagement of the Osage Nation's oil and gas mineral

estate, among other claims. As part of the Settlement Agreement, the parties agreed that it would be mutually beneficial "to address means of improving the trust management of the Osage Mineral Estate, the Osage Tribal Trust Account, and Other Osage Accounts." Settlement Agreement, Paragraph 1.i. The parties agreed that a review and revision of the existing regulations is warranted to better assist the Bureau of Indian Affairs (BIA) in managing the Osage Mineral Estate. The parties agreed to engage in a negotiated rulemaking for this purpose. Settlement Agreement, Paragraph 9.b. After the Committee submits its report, BIA will develop a proposed rule to be published in the **Federal Register**.

Dated: November 21, 2012.

Michael S. Black,

Director, Bureau of Indian Affairs.

[FR Doc. 2012-28806 Filed 11-27-12; 8:45 am]

BILLING CODE 4310-02-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2012-0938]

RIN 1625-AA87

Security Zone, Potomac and Anacostia Rivers; Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: This action is a supplemental notice of proposed rulemaking (SNPRM) to the Coast Guard's October 24, 2012, notice of proposed rulemaking (NPRM) that proposed to establish a security zone during activities associated with the Presidential Inauguration in Washington, DC from January 15, 2013 through January 24, 2013 (77 FR 64943). This supplemental proposal extends the southern boundary of the proposed security zone. This rule prohibits vessels and people from entering the security zone and requires vessels and persons in the security zone to depart the security zone, unless specifically exempt under the provisions in this rule or granted specific permission from the Coast Guard Captain of the Port Baltimore. This action is intended to temporarily restrict vessel traffic in portions of the Potomac and Anacostia Rivers during the event.

DATES: Comments and related material must be received by the Coast Guard on or before December 28, 2012.