

# Rules and Regulations

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 892

[Docket No. FDA-2005-N-0346] (formerly 2005N-0467)

#### Medical Devices; Radiology Devices; Reclassification of Bone Sonometers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of July 17, 2008 (73 FR 40967). The final rule reclassified bone sonometer devices from class III into class II, subject to special controls. The document contained an inadvertent error regarding the impact of the final rule on small businesses. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Domini Cassis, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2342.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E8-16354, appearing on page 40969 in the **Federal Register** of Thursday, July 17, 2008, there was an error regarding the impact of the final rule on small businesses. Specifically, language certifying that the final rule meets the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612) was inadvertently omitted during document preparation. Accordingly, the following correction is made:

1. On page 40969, in the middle column, under section "VI. Analysis of Impacts," in the second full paragraph, the third sentence is revised to read: "The agency certifies that the final rule

will not have a significant economic impact on a substantial number of small entities."

Dated: August 8, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-18792 Filed 8-13-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF STATE

### 22 CFR Part 121

[Public Notice 6316]

RIN 1400-AC47

#### Amendment to the International Traffic in Arms Regulations: The United States Munitions List Category VIII

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending the text of the International Traffic in Arms Regulations (ITAR), Part 121 to add language clarifying how the criteria of Section 17(c) of the Export Administration Act of 1979 ("EAA") are implemented in accordance with the Department of State's obligations under the Arms Export Control Act ("AECA"), and restating the Department's longstanding policy and practice of implementing the criteria of this provision.

**DATES:** *Effective Date:* This rule is effective August 14, 2008.

**FOR FURTHER INFORMATION CONTACT:** Director Ann Ganzer, Office Defense Trade Controls Policy, Department of State, Telephone (202) 663-2792 or Fax (202) 261-8199; e-mail [DDTCResponseTeam@state.gov](mailto:DDTCResponseTeam@state.gov). ATTN: Regulatory Change, ITAR Part 121.

**SUPPLEMENTARY INFORMATION:** On April 11, 2008, the Department published a Notice of Proposed Rulemaking (NPRM) to add language clarifying how the criteria of Section 17(c) of the Export Administration Act of 1979 are implemented in accordance with the Arms Export Control Act by amending Category VIII \*(b), (h), and the Note. Further background is provided with the NPRM at 73 FR 19778.

This rule reinstates the Section 17(c) reference in the ITAR to assist exporters in understanding the scope and application of the Section 17(c) criteria

to parts and components for civil aircraft. It also clarifies that any part or component that (a) is standard equipment; (b) is covered by a civil aircraft type certificate (including amended type certificates and supplemental type certificates) issued by the Federal Aviation Administration for civil, non-military aircraft (this expressly excludes military aircraft certified as restricted and any type certification of Military Commercial Derivative Aircraft, defined by FAA Order 8110.101 effective date September 7, 2007 as "civil aircraft procured or acquired by the military"); and (c) is an integral part of such civil aircraft, is subject to the jurisdiction of the Export Administrative Regulations (EAR). Where such part or component is not Significant Military Equipment ("SME"), no Commodity Jurisdiction (CJ) determination is required to determine whether the item meets these criteria for exclusion under the United States Munitions List (USML), unless doubt exists as to whether these criteria have been met. However, where the part or component is SME, a CJ determination is always required, except where a SME part or component was integral to civil aircraft prior to the effective date of this rule.

Additionally, this proposed rule adds language in a new Note after Category VIII(h) to provide guidelines concerning the parts or components meeting these criteria. The change to Category VIII\*(b) also identifies and designates certain sensitive military items, heretofore controlled under Category VIII(h), as SME. Previous and current authorizations concerning the manufacturer of these items will not require notification in accordance with § 124.11, and will not require a "Nontransfer and Use Certificate" DSP-83, unless they are amended, modified, or renewed.

This requirement for a CJ determination by the Department of State helps ensure the U.S. Government is made aware of, and can reach an informed decision regarding, any sensitive military item proposed for standardization in the commercial aircraft industry before the item or technology is actually applied to a commercial aircraft program, whether such item is integral to the aircraft, and, if so, whether the development, production, and use of the technology

associated with the item should nevertheless be controlled on the USML. It will also ensure the Department of State fulfills the requirements of section 38(f) of the Arms Export Control Act.

This regulation is intended to clarify the control of aircraft parts and components, and does not remove any items from the USML, nor does it change any CJ determinations. Should there be an apparent conflict between this regulation and a CJ determination issued prior to this date, the holder of the determination should seek reconsideration, citing this **Federal Register** Notice and 22 CFR 121.1(c) Category VIII Note of this subchapter.

The Proposed Rule had a comment period ending May 12, 2008. Twenty (20) parties filed comments by May 12th recommending changes. Having thoroughly reviewed and evaluated the comments and the recommended changes, the Department has determined that it will, and hereby does, adopt the Proposed Rule, with minor edits, and promulgates it as a Final Rule. The Department's evaluation of the written comments and recommendations follows.

#### Comment Analysis

Ten (10) commenting parties criticized the Department for making "specifically designed military hot section components and digital engine controls (e.g., Full Authority Digital Engine Controls (FADEC) and Digital Electronic Engine Controls (DEEC))" significant military equipment in paragraph \*(b) of Category VIII. The Department believes that the designation of these military hot section components and digital engine controls as significant military equipment is necessary to safeguard the national security of the United States, because these components and controls fulfill the definition of significant military equipment in 22 CFR 120.7 in that they have the "capacity for substantial military utility or capability." In addition, the significant military equipment designation of these components and controls is consistent with the exclusion of hot section technology from 22 CFR 124.2(c) and 126.5. The Department will not, as a matter of process, require DSP-83 nontransfer and use certificates for the export of spare parts for hot sections and digital engine controls previously authorized for export. The "grand-father clause" added to sub-paragraph (b) for military hot section components and digital engine controls manufactured to engineering drawings dated on or before January 1, 1970 was also intended to

address the concerns raised by the ten commenting parties.

Six (6) commenting parties recommended paragraph (h) of Category VIII(h) start with the phrase "Except as noted below." That phrase does not conform with the regulatory language used in other sub-paragraphs of the United States Munitions List categories that have associated notes paragraphs.

One (1) commenting party recommended the commodity jurisdiction requirement for significant military equipment be removed from the explanatory note. The inclusion of the commodity jurisdiction requirement for significant military equipment is needed to ensure the government has an opportunity to review proposals to use military equipment in a civil application and to avoid the removal of items from the United States Munitions List through company self-determinations. Before placing a defense article considered significant military equipment on a civil aircraft, a written commodity jurisdiction determination must be obtained.

Seven (7) commenting parties recommended the first sentence of the explanatory note add the EAR term "or item." The Department has chosen to use ITAR terms.

One (1) commenting party recommended the first sentence of the explanatory note use the phrase "component, part, accessory, and associated equipment" instead of "part or component." That recommendation was adopted.

Eleven (11) commenting parties recommended the first sentence of the explanatory note delete "exclusively." The suggestion was not adopted. The word is necessary, since the Department claims no jurisdiction over parts or components designed exclusively for civil, non-military aircraft. Such parts and components are subject to Department of Commerce jurisdiction.

Four (4) commenting parties recommended the "and" linking "civil, non-military aircraft" and "civil, non-military aircraft engines" in the first sentence of the explanatory note be changed to an "or." There was a concern about coverage of a part or component of a civil, non-military aircraft engine. The sentence in the final rule was changed to clarify that a part or component designed exclusively for civil, non-military aircraft and a part or component designed exclusively for a civil, non-military aircraft engine are both controlled by the Department of Commerce.

Two (2) commenting parties recommended part (b) of the second sentence of the explanatory note add

Parts Manufacturer Approval (PMA). As a PMA may be issued for an exclusively USML item, inclusion of PMA is not appropriate here.

Six (6) commenting parties recommended part (b) of the second sentence of the explanatory note be expanded to include foreign government civil aviation authorities. As Section 17(c) is limited to certifications issued by the Federal Aviation Administration, it is appropriate to limit the civil aircraft type certificate (including amended type certificates and supplemental type certificates) to those issued by the U.S. Federal Aviation Administration.

Six (6) commenting parties recommended part (b) of the second sentence of the explanatory note add "FAA Order 8110.10" after "Military Commercial Derivative Aircraft." That reference has been included in the supplementary information above.

Six (6) commenting parties recommended part (c) of the second sentence of the explanatory note change "control of the EAR" to "jurisdiction of the EAR." This change was adopted.

One (1) commenting party recommended explaining the Department of State's policy concerning its jurisdiction over an ITAR-controlled article that is incorporated into a civil item. With few exceptions specified in the ITAR (e.g. USML Category XIV(n)(4)(i)), a USML item does not change jurisdiction when it is incorporated into another item. As stated above, it is important for the government to review, via the Commodity Jurisdiction process, the proposed use of military items in commercial applications.

One (1) commenting party recommended the fourth sentence of the explanatory note change "part or component" to "components, parts, accessories, attachments, and associated equipment." This change was not adopted. An "accessory," an "attachment," and "associated equipment" are not considered standard equipment integral to the civil aircraft.

Four (4) commenting parties recommended the fourth sentence of the explanatory note change "a part" to "such a part" and delete "designated as SME in this category." The purpose of this sentence is to grandfather from obtaining a commodity jurisdiction determination a part or component designated as Significant Military Equipment (SME) in Category VIII that was standard equipment, integral to civil aircraft prior to the effective date of the final rule. The language of the proposed rule is clearer and has been retained.

Ten (10) commenting parties recommended the eighth sentence of the explanatory note add at the end of the sentence "of the item's form, fit, or function." This change was adopted.

Four (4) commenting parties recommended the ninth sentence of the explanatory note delete "radomes" and "low observable blades" and add "rotodomes" and "bomb bay doors." The Department accepted the substitution of rotodomes for radomes.

Fifteen (15) commenting parties recommended the tenth sentence of the explanatory note add "manufacturer's specification or standard" and add Technical Standard Order "TSO" in the parenthesis. As a TSO may be issued for an exclusively USML item, inclusion of TSOs is not appropriate here.

Eleven (11) commenting parties recommended the eleventh sentence of the explanatory note change "unpublished civil aviation industry specifications" to "unpublished (e.g., proprietary) manufacturer's specifications." Also, it was recommended to add "bolts" to the e.g. list. The Department believes that many of the concerns raised with regard to sentences ten and eleven are alleviated when the two sentences are read together. Parts and components meeting published industry or government specifications or established but unpublished (e.g., proprietary) industry standards are considered standard equipment. Also, the recommendation to add bolts was not adopted.

Eleven (11) commenting parties recommended the twelfth sentence of the explanatory note be deleted, noting that aircraft parts are routinely tested beyond the applicable specification for a variety of reasons, including marketing purposes or warranty obligations. This recommendation was not adopted. If a part is required to exceed established standards, such requirements call into question whether it is a "standard part."

Ten (10) commenting parties recommended the thirteenth sentence of the explanatory note delete "unless the item was designed or modified to meet that specification or standard." That change was adopted.

Fourteen (14) commenting parties recommended the fourteenth sentence of the explanatory note clarify the jurisdiction of exporting spare parts when the part or component is not installed in the aircraft at the time of export. The Department believes it is clear that parts and components that meet the section 17(c) criteria, when exported separately are subject to EAR jurisdiction.

Five (5) commenting parties recommended the fifteenth sentence of the explanatory note add "APUs, seats, and flaps" to the e.g. parenthesis. This change was not adopted. We believe the examples provided are sufficient, and note that not all APUs, seats, and flaps are subject to Department of Commerce jurisdiction.

One (1) commenting party objected to disqualifying "unique application parts or components not integral to the aircraft" in the sixteenth sentence of the explanatory note. Section 17(c) applies to standard parts and components integral to the aircraft. Parts that are not standard or are not integral to the aircraft are clearly not included in Section 17(c), and are therefore not included here.

#### *Regulatory Analysis and Notices*

##### Administrative Procedure Act

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures contained in 5 U.S.C. 553 and 554.

##### Regulatory Flexibility Act

Since this amendment involves a foreign affairs function of the United States, 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 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

This amendment is exempt from the review under Executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof.

##### Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

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

Arms and munitions, Exports, U.S. munitions list.

■ 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); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp, p. 79; 22 U.S.C. 2658; Pub L. 105-261, 112 Stat. 1920.

■ 2. In § 121.1, paragraph (c) Category VIII is amended by revising Category VIII paragraphs (b) and (h) to read as follows:

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

\* \* \* \* \*

##### **Category VIII—Aircraft and Associated Equipment**

\* \* \* \* \*

\*(b) Military aircraft engines, except reciprocating engines, specifically designed or modified for the aircraft in paragraph (a) of this category, and all specifically designed military hot section components (i.e., combustion chambers and liners; high pressure turbine blades, vanes, disks and related cooled structure; cooled low pressure turbine blades, vanes, disks and related cooled structure; cooled augmenters; and cooled nozzles) and digital engine controls (e.g., Full Authority Digital Engine Controls (FADEC) and Digital Electronic Engine Controls (DEEC)). However, if such military hot section components and digital engine controls are manufactured to engineering drawings dated on or before January 1, 1970, with no subsequent changes or

revisions to such drawings, they are controlled under Category VIII(h).

\* \* \* \* \*

(h) Components, parts, accessories, attachments, and associated equipment (including ground support equipment) specifically designed or modified for the articles in paragraphs (a) through (d) of this category, excluding aircraft tires and propellers used with reciprocating engines.

**Note:** The Export Administration Regulations (EAR) administered by the Department of Commerce control any component, part, accessory, attachment, and associated equipment (including propellers) designed exclusively for civil, non-military aircraft (see § 121.3 of this subchapter for the definition of military aircraft) and control any component, part, accessory, attachment, and associated equipment designed exclusively for civil, non-military aircraft engines. The International Traffic in Arms Regulations administered by the Department of State control any component, part, accessory, attachment, and associated equipment designed, developed, configured, adapted or modified for military aircraft, and control any component, part, accessory, attachment, and associated equipment designed, developed, configured, adapted or modified for military aircraft engines. For components and parts that do not meet the above criteria, including those that may be used on either civil or military aircraft, the following requirements apply. A non-SME component or part (as defined in §§ 121.8(b) and (d) of this subchapter) that is not controlled under another category of the USML, that: (a) Is standard equipment; (b) is covered by a civil aircraft type certificate (including amended type certificates and supplemental type certificates) issued by the Federal Aviation Administration for a civil, non-military aircraft (this expressly excludes military aircraft certified as restricted and any type certification of Military Commercial Derivative Aircraft); and (c) is an integral part of such civil aircraft, is subject to the jurisdiction of the EAR. In the case of any part or component designated as SME in this or any other USML category, a determination that such item may be excluded from USML coverage based on the three criteria above always requires a commodity jurisdiction determination by the Department of State under § 120.4 of this subchapter. The only exception to this requirement is where a part or component designated as SME in this category was integral to civil aircraft prior to August 14, 2008. For such part or component, U.S. exporters are not required to seek a commodity jurisdiction determination from State, unless doubt exists as to whether the item meets the three criteria above (See § 120.3 and § 120.4 of this subchapter). Also, U.S. exporters are not required to seek a commodity jurisdiction determination from State regarding any non-SME component or part (as defined in §§ 121.8(b) and (d) of this subchapter) that is not controlled under another category of the USML, unless doubt exists as to whether the item meets the three criteria above (See § 120.3 and § 120.4 of this

subchapter). These commodity jurisdiction determinations will ensure compliance with this section and the criteria of Section 17(c) of the Export Administration Act of 1979. In determining whether the three criteria above have been met, consider whether the same item is common to both civil and military applications without modification of the item's form, fit, or function. Some examples of parts or components that are not common to both civil and military applications are tail hooks, rotodomes, and low observable rotor blades. "Standard equipment" is defined as a part or component manufactured in compliance with an established and published industry specification or an established and published government specification (e.g., AN, MS, NAS, or SAE). Parts and components that are manufactured and tested to established but unpublished civil aviation industry specifications and standards are also "standard equipment," e.g., pumps, actuators, and generators. A part or component is not standard equipment if there are any performance, manufacturing or testing requirements beyond such specifications and standards. Simply testing a part or component to meet a military specification or standard for civil purposes does not in and of itself change the jurisdiction of such part or component. Integral is defined as a part or component that is installed in an aircraft. In determining whether a part or component may be considered as standard equipment and integral to a civil aircraft (e.g., latches, fasteners, grommets, and switches) it is important to carefully review all of the criteria noted above. For example, a part approved solely on a non-interference/provisions basis under a type certificate issued by the Federal Aviation Administration would not qualify. Similarly, unique application parts or components not integral to the aircraft would also not qualify.

\* \* \* \* \*

Dated: August 4, 2008.

**John C. Rood,**

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

[FR Doc. E8-18844 Filed 8-13-08; 8:45 am]

**BILLING CODE 4710-25-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1 and 602

[TD 9422]

RIN 1545-BE95

#### S Corporation Guidance Under AJCA of 2004 and GOZA of 2005

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations that provide guidance

regarding certain changes made to the rules governing S corporations under the American Jobs Creation Act of 2004 and the Gulf Opportunity Zone Act of 2005. The final regulations replace obsolete references in the current regulations and allow taxpayers to make proper use of the provisions that made changes to prior law. The final regulations include guidance on the S corporation family shareholder rules, the definitions of "powers of appointment" and "potential current beneficiaries" (PCBs) with regard to electing small business trusts (ESBTs), the allowance of suspended losses to the spouse or former spouse of an S corporation shareholder, and relief for inadvertently terminated or invalid qualified subchapter S subsidiary (QSub) elections. The final regulations affect S corporations and their shareholders.

**DATES: Effective Date:** These regulations are effective on *August 14, 2008*.

**Applicability Dates:** For dates of applicability, see §§ 1.1361-4(a)(9)(ii), 1.1361-6, 1.1362-4(g) and 1.1366-5.

**FOR FURTHER INFORMATION CONTACT:** Charles J. Langley, Jr., (202) 622-3060 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-2114.

The collection of information is required by § 1.1361-1(m)(2)(ii)(A) of these final regulations. This information is required to enable the IRS to verify whether the corporation is an eligible S corporation.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number.

Books or records relating to a collection of information must be retained as long as their contents might become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

##### Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) concerning S corporations under sections 1361, 1362, and 1366 of the Internal Revenue Code (Code). These