Background

The DOD contracts for passenger and air cargo movements from air carriers certificated by the FAA. The DOD is congressionally mandated to conduct capability evaluations of contracted carriers. These evaluations ensure each carrier is able to satisfy the unique requirements of military contracts and to adhere to the DOD Commercial Air Carrier Quality and Safety Requirements. These evaluations apply only to carriers under contract with the DOD or carriers wanting to enter into contracts with the DOD.

DOD commercial air carrier evaluators require uninterrupted access to the flight deck to perform their reviews. For many years, DOD commercial air carrier evaluators relied on the FAA, the air carrier, and the pilot in command authorizing their access to conduct the air carrier evaluation mission. Language contained in 14 CFR parts 121 and 135 did not include DOD commercial air carrier evaluators among those individuals authorized access to the flight deck.

The absence of direct authority in the regulation listing and the lack of a well-known DOD evaluator credential significantly hindered the congressionally mandated DOD air carrier evaluations.

The amendments in the final rule make clear the authority of DOD commercial air carrier evaluators to conduct cockpit evaluations by including them in the regulation text. These changes, with the creation of the S&A Form 110B evaluator credential, have alleviated the problems DOD commercial air carrier evaluators have faced in the field.

Discussion of Comments

The FAA received comments from a private citizen and a commercial air carrier. The content of the two letters was identical. These comments are addressed below.

The commenters stated that allowing cockpit access to the DOD evaluators was not ''prudent or necessary'' and the potential existed for DOD evaluators to abuse the process by wanting ''free rides.''

FAA response: The FAA does not agree with the commenters. The DOD is required by law to conduct carrier evaluations including cockpit observations. The DOD coordinates these observations in advance with the air carrier. Flight crews are made aware of the presence of the DOD evaluator before the flight. Surprise evaluations are not part of this program and DOD evaluators must show proper documentation, including their S&A Form 110B credential and military orders, to gain access to the aircraft. Additionally, these evaluations only occur on air carriers participating, or applying to participate, in the DOD program. The process currently in place safeguards the security of the aircraft and does not allow for ''free ride'' abuse by the evaluators.

The FAA received comments regarding the possible falsification of the new credential being issued to DOD evaluators and the potential for increased costs to the air carrier by having to verify the evaluator's documentation.

FAA response: The FAA does not agree that the credential is easily falsified. The new credential issued to DOD air carrier evaluators has the same security features as the credentials carried by FAA inspectors and are difficult to falsify. In addition, DOD evaluators must present military orders with their S&A Form 110B credential. Verifying the credential and military order should not take any more time than in the past, and we expect the costs to be minimal. Again, these evaluations only occur on air carriers participating, or applying to participate, in the DOD program.

Conclusion

After consideration of the comments submitted in response to the final rule, the FAA has determined that no further rulemaking action is necessary. The final rule, ''DOD Commercial Air Carrier Evaluators'' remains in effect as adopted.

Issued in Washington, DC, on December 15, 2004.

Marion C. Blakey,

Administrator.

[FR Doc. 04–27896 Filed 12–22–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 041123328–4328–01]

RIN 0694–AD16

Revision of Export Control Classification Number (ECCN) 2B351 To Conform With the Australia Group (AG) ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology''

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is publishing this final rule to amend the Export Administration Regulations (EAR) by revising the Commerce Control List (CCL) entry that describes controls on certain toxic gas monitoring systems to conform with the Australia Group (AG) ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology.'' Specifically, this final rule removes a technical note that contained an overly broad description of the types of toxic gas monitoring systems and detectors subject to chemical/biological (CB) controls under the EAR. The note covered a number of toxic gas monitoring systems and detectors not included on the AG control list. By removing the technical note, this final rule eliminates the CB license requirement for these toxic gas monitoring systems and detectors. Toxic gas monitoring systems and detectors that are included on the AG control list continue to require a license, for CB reasons, to certain destinations.

DATES: This rule is effective December 23, 2004.

ADDRESSES: You may submit comments, identified by RIN 0694–AD16, by any of the following methods:

- E-mail: *wfisher@bis.doc.gov.* Include ''RIN 0694–AD16'' in the subject line of the message.
- Fax: (202) 482–3355. Please alert the Regulatory Policy Division, by calling (202) 482–2440, if you are faxing comments.
- Mail or Hand Delivery/Courier: Willard Fisher, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th St. & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, ATTN: RIN 0694–AD16.

FOR FURTHER INFORMATION CONTACT: Mark Sagrans, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–7900.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) by revising Export Control Classification Number (ECCN) 2B351 on the Commerce Control List (CCL) (Supplement No. 1 to Part 774 of the EAR) to conform with the Australia Group (AG) ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology.''

The AG is a multilateral forum, consisting of 38 participating countries, that maintains export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

Specifically, this rule revises ECCN 2B351 by removing the Technical Note at the end of the entry. BIS is removing this Technical Note because it is not included in the AG ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology'' and its inclusion in ECCN 2B351 resulted in controls on certain toxic gas monitoring systems and devices not designed for the detection of chemical warfare agents or precursors. The wording of the Technical Note indicated that the toxic gas monitoring systems controlled under ECCN 2B351.a included systems (such as environmental air pollution detectors, anesthetic gas monitors for patients, and sulfur hexafluoride detectors) that have a detection capability for chemicals, which contain phosphorus, sulfur, fluorine or chlorine, but are not controlled under ECCN 1C350.

As a result of the removal of the Technical Note by this final rule, ECCN 2B351.a no longer controls toxic gas monitoring systems that have a detection capability for chemicals (other than chemical warfare agents), which contain phosphorus, sulfur, fluorine or chlorine, but are not controlled under ECCN 1C350. A license no longer is required, for chemical/biological (CB) reasons, to export or reexport such systems; however, such systems may require a license for reasons specified elsewhere in the EAR (*e.g.,* the end-user/end-use restrictions described in Part 744 of the EAR or the restrictions described in Part 746 of the EAR that apply to embargoed countries). Systems designed for continuous operation that are capable of detecting chemical warfare agents or any of the chemicals controlled under ECCN 1C350 (including those containing phosphorus, sulfur, fluorine or chlorine), at concentrations of less than 0.3 mg/m^3, continue to be controlled under ECCN 2B351.a and continue to require a license, for CB reasons, to destinations listed in Country Group D:3 (as specified in Supplement No. 1 to Part 740 of the EAR).

Although the Export Administration Act expired on August 20, 2001, Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), as extended by the Notice of August 6, 2004 (69 FR 48763, August 10, 2004), continues the Regulations in effect under the International Emergency Economic Powers Act .

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694–0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to David Rostker, Office of Management and Budget (OMB), by e-mail to *David_Rostker@omb.eop.gov,* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044.

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

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

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

List of Subjects in 15 CFR Part 774

Exports, Foreign trade, Reporting and recordkeeping requirements.

■ Accordingly, Part 774 of the Export Administration Regulations (15 CFR Parts 730–799) is amended as follows:

PART 774—[AMENDED]

■ 1. The authority citation for 15 CFR Part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 68 FR 47833 (August 10, 2004).

Supplement No. 1 to Part 774 [Amended]

■ 2. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2B351 is revised to read as follows:

2B351 Toxic gas monitoring systems that operate on-line and dedicated detectors therefor.

License Requirements

Reason for Control: CB, AT.

Control(s)	Country chart
CB applies to entire entry	CB Column 3.
AT applies to entire entry	AT Column 1.

License Exceptions

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Unit: Equipment in number.

Related Controls: See ECCNs 1A004 and 1A995 for detection equipment that is not covered by this entry.

Related Definitions: For the purposes of this entry, the term ''continuous operation'' describes the capability of the equipment to operate on line without human intervention. The intent of this entry is to control toxic gas monitoring systems capable of collection and detection of samples in environments such as chemical plants, rather than those used for batch-mode operation in laboratories.

Items:

a. Designed for continuous operation and usable for the detection of chemical warfare agents or chemicals controlled by 1C350 at concentrations of less than 0.3 mg/m^3; or

b. Designed for the detection of cholinesterase-inhibiting activity.

Dated: December 16, 2004.

Peter Lichtenbaum,

Assistant Secretary for Export Administration.

[FR Doc. 04–28104 Filed 12–22–04; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 2003F–0088]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations by establishing a new maximum permitted energy level of x rays for treating food of 7.5 million electron volts (MeV) provided that the x rays are generated from machine sources that use tantalum or gold as the target material, with no change in the maximum permitted dose levels or uses currently permitted by FDA's food additive regulations. This action is in response to a petition filed by Ion Beam Applications.

DATES: This rule is effective December 23, 2004. Submit written objections and request for a hearing by January 24, 2005. See Section VII of this document for information on the filing of objections.

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 2003F–0088, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2003F–0088 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of March 13, 2003 (68 FR 12087), FDA announced that a food additive petition (FAP 3M4745) had been filed by Ion Beam Applications (IBA), 6000 Poplar Ave., suite 426, Memphis, TN. Since the publication of this notice, IBA has been sold to PPM Ventures, which subsequently changed its name to Sterigenics International, Inc., 2015 Spring Rd., suite 650, Oak Brook, IL 60523. As a result, the rights to FAP 3M4745 have been transferred from IBA to Sterigenics International, Inc. The petition proposed that the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) be amended by increasing the maximum permitted energy level of x rays for treating food to 7.5 MeV from the currently permitted maximum level of 5 MeV. Higher x ray energy will result in an increased concentration of x rays in the forward direction and increased penetration of these x rays in materials. This increased emission efficiency (i.e., concentration of x rays produced in the forward direction) will result in reduced treatment time for food, and therefore, higher production rates and lower treatment costs. The increased penetration of 7.5 MeV versus 5 MeV x rays will allow for the irradiation of larger packages.

II. Evaluation of Safety

A source of radiation used to treat food meets the definition of a food additive under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)). Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations in 21 CFR 170.3(i) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

III. Evaluation of the Safety of the Petitioned Use of 7.5 MeV X Rays

A. Safety Concerns of Higher Energy X rays

The maximum energy limit of an x-ray machine is the maximum energy of the individual x-ray photons produced by that machine. When individual photons of x rays are absorbed by food, the absorbed energy causes atoms to be ionized until all the energy is converted into heat or chemical change. The amount of change in the food will depend on the total energy absorbed (i.e., dose). Because this petition seeks only to raise the maximum energy limit for x rays used for treating food, with no change in the maximum doses currently permitted by § 179.26, FDA concludes that the petition presents no new chemical issue, and that the only safety issue to be addressed is the potential for inducing radioactivity in the food.

Food, as well as other natural materials, displays low levels of naturally occurring radioactivity, such as that due to the presence of potassium-40 or carbon-14. To assess the safety of increasing the maximum energy of x rays to 7.5 MeV, the petitioner evaluated the potential for 7.5 MeV x rays to induce additional radioactivity in food. X rays with energies above an atom's threshold energy are capable of ejecting neutrons or protons from the nuclei of some atoms that have absorbed the x-ray energy. The threshold energy needed to cause the emission of a proton is higher than 7.5 MeV; therefore, the primary mechanism for inducing radioactivity in food by 7.5 MeV x rays will be from the loss of a neutron. This may in some cases result in the formation of radioactive nuclei. Radioactive nuclei are unstable and decay to a more stable form, spontaneously emitting particles and electromagnetic radiation in the form of gamma rays (i.e., high-energy photons). Often, this transition can occur very rapidly, such that an isotope produced in food from x rays will decay to a stable, nonradioactive state before leaving the irradiation facility. However, some radioactive isotopes could be sufficiently stable to be present in food