

the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent arcing between exposed conductors, which could result in burning of the adjacent electrical bundles, failure of essential electrical systems, and consequent fire hazard for passengers and crewmembers, accomplish the following:

(a) Within 30 days after the effective date of this AD, perform a detailed visual inspection for damage or chafing of the electrical wiring bundles located forward of the P37 panel adjacent to the AE0218 disconnect panel, and for adequate clearance between the wire bundles and adjacent forward galley air chiller, in accordance with Boeing Message Number M-7200-98-00140, dated January 11, 1998.

Note 2: Boeing Message Number M-7200-98-00140, dated January 11, 1998, also references Boeing Standard Wiring Practices Manual D6-54446, as an additional source of service information.

(1) If no damage or chafing is detected and adequate clearance exists, accomplish either paragraph (a)(1)(i) or (a)(1)(ii) of this AD.

(i) Repeat the visual inspection required by paragraph (a) of this AD, thereafter, each time the forward galley air chiller is removed and reinstalled. Or

(ii) Prior to further flight, install protective tape or sleeve over the wire bundles, in accordance with Section 20-00-11 of the Boeing Standard Wiring Practices Manual. Operators shall use one of the following materials to protect the bundles: RT876 (sleeve), TFX-2X standard wall thickness (sleeve), P-440 (tape), Scotch 70 (tape), or CHR-A-2005 (tape).

(2) If no damage or chafing is detected and inadequate clearance exists, prior to further flight, modify the routing of the wire bundles in accordance with the Boeing message, and install protective tape or sleeve over the wire bundles in accordance with Section 20-00-11 of the Boeing Standard Wiring Practices Manual. Operators shall use one of the following materials to protect the bundles: RT876 (sleeve), TFX-2X standard wall thickness (sleeve), P-440 (tape), Scotch 70 (tape), or CHR-A-2005 (tape).

(3) If damage or chafing is detected and adequate clearance exists, prior to further flight, repair the wire bundles in accordance with Boeing message, and accomplish either paragraph (a)(3)(i) or (a)(3)(ii) of this AD.

(i) Repeat the visual inspection required by paragraph (a) of this AD, thereafter, each time the forward galley chiller is removed and reinstalled. Or

(ii) Prior to further flight, install protective tape or sleeve over the wire bundles in accordance with Section 20-00-11 of the Boeing Standard Wiring Practices Manual. Operators shall use one of the following materials to protect the bundles: RT876 (sleeve), TFX-2X standard wall thickness (sleeve), P-440 (tape), Scotch 70 (tape), or CHR-A-2005 (tape).

(4) If damage or chafing is detected and inadequate clearance exists, prior to further

flight, repair and modify the routing of the wire bundles in accordance with the Boeing message, and install protective tape or sleeve over the wire bundles in accordance with Section 20-00-11 of the Boeing Standard Wiring Practices Manual. Operators shall use one of the following materials to protect the bundles: RT876 (sleeve), TFX-2X standard wall thickness (sleeve), P-440 (tape), Scotch 70 (tape), or CHR-A-2005 (tape).

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The inspections and modification shall be done in accordance with Boeing Message Number M-7200-98-00140, dated January 11, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on April 21, 1998.

Issued in Renton, Washington, on March 27, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 118

[T.D. 98-29]

RIN 1515-AC07

Centralized Examination Stations

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations regarding the establishment and scope of operation of

Centralized Examination Stations (CESs). To reflect Customs interest in maximizing compliance with export control laws and regulations without unduly impeding the movement of outbound merchandise, the definition of a CES is expanded to allow merchandise intended to be exported as well as imported merchandise to be handled by a CES. The amendment allows outbound cargo to be inspected at CESs at ports other than the shipment's designated port of exit. Further, to make the CES application procedure more amenable to local conditions, this amendment provides CES applicants with more flexibility regarding the time frame to conform a facility to meet Customs security or other physical or equipment requirements. Lastly, this amendment removes one of the criteria on the application to operate a CES because Customs believes it is too subjective. These changes are made in order to keep the CES program responsive to both Customs and the trade community's demands for the facilitated examinations of trade merchandise.

DATES: Effective: May 6, 1998.

FOR FURTHER INFORMATION CONTACT:

For Policy Inquiries: Steven T. Soggin, Office of Field Operations, (202) 927-0765;

For Legal Inquiries: Jerry Laderberg, Office of Regulations and Rulings, Entry Procedures and Carriers Branch, (202) 927-2269.

SUPPLEMENTARY INFORMATION:

Background

In 1993, Customs amended the Customs Regulations to provide for the establishment, operation, and termination of Centralized Examination Stations (CESs). A CES is a privately-operated facility, not in the charge of a Customs officer, at which imported merchandise is made available to Customs officers for physical examination. Because merchandise intended to be *exported* is subject to examination, Customs wanted CESs to be authorized to provide inspectional facilities for this merchandise as well. Accordingly, on August 19, 1997, Customs published a Notice of Proposed Rulemaking in the **Federal Register** (62 FR 44102) that proposed to amend the Customs Regulations regarding the establishment and scope of operation of CESs.

In order to reflect Customs' interest in maximizing compliance with export control laws and regulations without unduly impeding the movement of outbound merchandise, the Notice proposed to expand the definition of a

CES to allow merchandise intended to be exported as well as imported merchandise to be handled by a CES. Further, the document proposed to allow for the inspection of outbound cargo at CESs at ports other than the shipments' designated ports of exit. To make the CES application procedure more amenable to local conditions, the document proposed more flexibility regarding the time frame for an applicant to conform a facility to meet Customs security or other physical or equipment requirements. Lastly, Customs proposed to amend one of the criteria on the application to operate a CES because of Customs' belief that it is too subjective. These changes were proposed in order to keep the CES program responsive to both Customs' and the trade community's demands for the facilitated examinations of trade merchandise. These proposed changes to the regulations affected §§ 118.0, 118.22, and 118.23 of the Customs Regulations (19 CFR 118.0, 118.22, and 118.23). The document solicited comments concerning these changes.

The comment period closed on October 20, 1996. Six comments were received. The comments and Customs responses to them follow.

Discussion of Comments

The comments received were from a major manufacturing corporation involved with importing/exporting its products; a trade association representing 1,000 member firms engaged in all aspects of international trade; an exporter of merchandise; a manufacturer that exports its product; a CES operator; and an association representing insurance and surety companies.

Comment: Four commenters opposed the use of CESs for outbound inspections because they stated that expansion of the CES program to exports will mean that the burdens (needless delays and cost overruns) routinely experienced on the import side with CESs will also occur with examination of exports. These commenters argue that similar processing delays could result in missing the time for lading the merchandise to be exported, which may result in the loss of export sales, leading to a negative impact on the country's balance of trade.

Customs response: Customs disagrees. Inspection time involved with export examinations is considerably less than the inspection time involved with import examinations due to less paperwork being required. Further, the proposed amendments were designed to keep CESs responsive to the trade

community's demands for facilitating examinations. Since the number of export shipments is expected to increase 6% per year, reaching a total value of \$1.2 trillion by the year 2003, Customs believes that centralizing outbound examinations will facilitate inspections. As Customs will be able to conduct the outbound examination before merchandise is loaded for transport to a port of exit, unnecessary delays of shipments will be prevented by sparing exporters the expense and delay involved in unloading shipments at dispersed ports of exit for inspection.

Comment: One commenter stated that the proposed amendment to the Customs custodial bond provision of § 118.4(g) is unnecessary. The commenter stated that the obligation envisioned by the new language, that CES operators will accept and keep safe all merchandise delivered to the CES for examination, currently exists and that unless the amendment serves some significant, but unstated, need, it should be deleted from the final rule.

Customs response: Customs disagrees with the proposition that the proposed amendment is not necessary because it speaks to an existing obligation. The proposed amendment to § 118.4(g) clarifies Customs policy that a CES operator will accept all merchandise delivered to the CES for examination, thus, eliminating any assumption that CES operators have discretion whether to accept merchandise delivered to the facility for Customs examination. Accordingly, Customs believes that the proposed amendment to § 118.4(g) is necessary.

Conclusion

After analysis and review of the comments and further consideration by Customs, Customs has determined to adopt the final rule as it was proposed.

Regulatory Flexibility Act

Pursuant to provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendments will not have a significant economic impact on a substantial number of small entities, because the amendments would operate to confer new benefits on potential CES operations, by allowing them to perform more services. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

This document does not meet the criteria for a "significant regulatory action" as defined in E.O. 12866.

List of Subjects in 19 CFR Part 118

Administrative practice and procedure, Customs duties and inspection, Examination stations, Exports, Imports, Licensing, Reporting and recordkeeping requirements.

Amendments to the Regulations

For the reasons stated above, part 118, Customs Regulations (19 CFR part 118), is amended as set forth below:

PART 118—CENTRALIZED EXAMINATION STATIONS

1. The authority citation for part 118 is revised to read as follows:

Authority: 19 U.S.C. 66, 1499, 1623, 1624; 22 U.S.C. 401; 31 U.S.C. 5317.

2. In § 118.1, the first sentence is amended by removing the word "imported", and a new sentence is added at the end to read as follows:

§ 118.1 Definition.

* * * To present outbound cargo for inspection at a CES at a port other than the shipment's designated port of exit, either proof of the shipper's consent to the inspection must be furnished or a complete set of transportation documents must accompany the shipment to evidence that exportation of the goods is imminent and that the goods are committed to export, thereby, making them subject to Customs examination.

3. In § 118.4, paragraph (g) is amended by adding a new second sentence to read as follows:

§ 118.4 Responsibilities of a CES operator.

* * * * *

(g) * * * The CES operator will accept and keep safe all merchandise delivered to the CES for examination.

* * *

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§ 118.11 [Amended]

4. In § 118.11, the second sentence in paragraph (b) is amended by removing the words "and the port director may allow, up to an additional 30 calendar days after tentative selection to conform the facility to such requirements, but in such a case the agreement referred to in § 118.3 of this part shall not be executed until those requirements are met" and adding, in their place, the words "time to conform the facility to such requirements. The agreement referred to in § 118.3 of this part shall not be executed, in any event, until the facility is conformed to meet the requirements"; and paragraph (g) is amended by removing the words "or a commitment to acquire that knowledge".

Approved: March 13, 1998.

Samuel H. Banks,

Acting Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 610, 640, and 1270

Foods and Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct certain errors that have become incorporated into the biologics regulations. This action is being taken to improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: April 6, 1998.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA has discovered that certain errors have become incorporated into the agency's codified regulations on biologics. FDA is correcting these errors. These corrections are nonsubstantive.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

Lists of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 1270

Communicable diseases, HIV/AIDS, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606, 610, 640, and 1270 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.121 [Amended]

2. Section 606.121 *Container label* is amended in paragraph (e)(1)(ii) by removing "expressd" and adding in its place "expressed".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

3. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.30 [Amended]

4. Section 610.30 *Test for Mycoplasma*, lines 12, 13, 31, and 33 are amended by removing the period after the capital "C" each time it occurs.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

5. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.2 [Amended]

6. Section 640.2 *General requirements* is amended in paragraph (e)(3) by removing the period after the capital "C".

§ 640.17 [Amended]

7. Section 640.17 *Modifications for specific products* is amended by removing the period after the capital "C".

§ 640.24 [Amended]

8. Section 640.24 *Processing* is amended in the first sentence in paragraph (b) by removing the phrase "between 20 to 24 °C" and adding in its place "between 20 and 24 °C".

§ 640.64 [Amended]

9. Section 640.64 *Collection of blood for Source Plasma* is amended in paragraph (c)(2) by adding a subscript "7" after the first "O" in "Citric acid".

§ 640.69 [Amended]

10. Section 640.69 *General requirements* is amended in paragraph (b) by removing the period after the capital "C".

§ 640.70 [Amended]

11. Section 640.70 *Labeling* is amended in paragraph (a)(3) by removing the period after the capital "C".

§ 640.74 [Amended]

12. Section 640.74 *Modification of Source Plasma* is amended in paragraph (b)(2) by removing the period after the capital "C".

§ 640.101 [Amended]

13. Section 640.101 *General requirements* is amended in paragraph (a) by removing the period after the capital "C".

§ 640.102 [Amended]

14. Section 640.102 *Manufacture of Immune Globulin (Human)* is amended in the second and third sentences in paragraph (c) and in the second sentence in paragraph (e) by removing the period after the capital "C" each time it occurs.

§ 640.104 [Amended]

15. Section 640.104 *Potency* is amended in paragraph (a) by removing the period after the capital "C".

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

16. The authority citation for 21 CFR part 1270 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1270.33 [Amended]

17. Section 1270.33 *Records, general requirements* is amended in paragraph (b)(1) by removing "or" and adding in its place "and".

Dated: March 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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