List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–11–09 Airbus Industrie: Amendment 39–12252. Docket 2001–NM–135–AD.

Applicability: Model A330 and A340 series airplanes, certificated in any category, equipped with a trimmable horizontal stabilizer actuator (THSA) part number 47172, and on which Airbus Modification 45299 has been performed.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of 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 degraded operation of the THSA due to the entrance of water into the ball nut, and consequent reduced controllability of the airplane, accomplish the following:

Repetitive Inspections

(a) Within 150 flight hours from the effective date of this AD, perform a detailed visual inspection to detect discrepancies in the THSA (including distortion of the transfer tubes, disconnection of the tubes, and distortion of the collar of the ball nut), in accordance with All Operators Telex (AOT) A330–27A3088 (for Model A330 series airplanes) or A340–27A4093 (for Model A340 series airplanes), both dated April 5, 2001, as applicable. If any discrepancy, as defined in paragraph 4–2–2/Rejection Criteria of the applicable AOT, is detected, prior to further flight, replace the THSA with a serviceable one, per the applicable AOT.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(b) At intervals not to exceed 150 flight hours, repeat the inspection mandated in paragraph (a) of this AD.

Report of Inspection Findings

(c) Submit a report of inspection findings (both positive and negative) to Airbus; at the applicable time specified in paragraph (c)(1) or (c)(2) of this AD. The report must include the inspection results, a description of any discrepancies found, the airplane serial number, and the number of landings and flight hours on the airplane. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For airplanes on which the inspection is accomplished after the effective date of this AD: Submit the report within 10 days after performing the inspection required by paragraph (a) or (b) of this AD.

(2) For airplanes on which the inspection has been accomplished prior to the effective date of this AD: Submit the report within 10 days after the effective date of this AD.

Alternative Methods of Compliance

(d) 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, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 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.

Incorporation by Reference

(f) The inspections and replacement shall be done in accordance with Airbus All Operators Telex A330–27A3088, dated April 5, 2001; or Airbus All Operators Telex A340–27A4093, dated April 5, 2001; as applicable. 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 Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. 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.

Note 4: The subject of this AD is addressed in French airworthiness directives 2001–141(B) and 2001–140(B), both dated April 18, 2001.

Effective Date

(g) This amendment becomes effective on June 26, 2001.

Issued in Renton, Washington, on May 25, 2001.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–13996 Filed 6–8–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 61, 63, 65, 108, 121 and 135

[Docket No. FAA–2000–7497; Amendment No. 61–107, 63–30, 65–41, 108–18, 121–280 and 135–79]

RIN 2120–AH01

Advanced Qualification Program; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final rule, published in the **Federal Register** on October 10, 2000 (65 FR 60334). That final rule established a new termination date for Special Federal Aviation Regulation (SFAR) No. 58 (55 FR 40275; October 2, 1990), which provided the approval of an alternate method (known as ''Advanced Qualification Program'' or ''AQP'') for qualifying, training and certifying, and otherwise ensuring the competeny of crewmembers, aircraft dispatchers, other operations personnel, instructors, and evaluators who are required to be trained or qualified under 14 CFR parts 121 and 135.

FOR FURTHER INFORMATION CONTACT: Thomas M. Longridge, (703) 661–0260.

Correction of Publication

In the final rule FR Doc. 00–25951, beginning on page 60334 in the **Federal Register** issue of October 10, 2000, make the following corrections:

1. On page 60334, in column 1, in the heading section, beginning on line 7,

correct ''Amendment No. 61–107, 63–30, 65–41, 108–18, 121–280 and 135–78'' to read ''Amendment Nos. 61–107, 63–30, 65–41, 108–18, 121–280 and 135–79''.

Issued in Washington, DC on June 6, 2001.

Donald Byrne,

Assistant Chief Counsel, Regulations Division.

[FR Doc. 01–14656 Filed 6–8–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121 and 135

[Docket No. FAA–2000–7119; Amendment No. 121–281 and 135–80]

RIN 2120–AG89

Emergency Medical Equipment; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final rule, published in the **Federal Register** on April 12, 2001 (66 FR 19028). That final rule responds to the Aviation Medical Assistance Act of 1998 by requiring that air carrier operators carry automated external defibrillators on large, passenger-carrying aircraft and augment currently required emergency medical kits.

FOR FURTHER INFORMATION CONTACT: Judi citrenbaum, (202) 267–9689.

Correction of Publication

In the final rule FR Doc. 01–8923, beginning on page 19028 in the **Federal Register** issue of April 12, 2001, make the following corrections:

1. On page 19028, in column 1, in the heading section, beginning on line 5, correct ''Amendment No. 121–280 and 135–78'' to read ''Amendment Nos. 121–281 and 135–80''.

Issued in Washington, DC, on June 6, 2001.

Donald Byrne,

Assistant Chief Counsel, Regulations Division.

[FR Doc. 01–14657 Filed 6–8–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 607, 610, 640, 660, and 809

[Docket No. 98N–0581]

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the general biological product standards applicable to human blood and blood components by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements, by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for supplemental (i.e., additional, more specific) testing approved for such use by FDA when a donation is found to be reactive for any of the required screening tests for evidence of infection due to communicable disease agents. The agency also is requiring manufacturers of certain test kits to use reference panels, when available, to verify the acceptable sensitivity and specificity of each lot. This final rule is intended to help protect the safety and ensure the quality of the Nation's blood supply, to enhance the safety of medical devices containing blood or blood components, to provide FDA with clear enforcement authority, and to promote consistency in the industry. Elsewhere in this issue of the **Federal Register**, FDA is publishing a rule requiring blood and plasma establishments to notify donors, including autologous donors, whenever the donor is deferred or determined not to be suitable for current or future donations of blood and blood components.

DATES: This rule is effective December 10, 2001.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Requirements for testing blood donors for hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (anti-HIV) are currently codified in part 610 (21 CFR part 610), and requirements for performing a serological test for syphilis are codified in part 640 (21 CFR part 640). The agency has issued various guidance documents to registered blood and plasma establishments providing recommendations for testing for antibody to hepatitis B core antigen (anti-HBc), antibody to human T-lymphotropic virus types I and II (anti-HTLV I/II), antibody to hepatitis C virus (anti-HCV), and HIV–1 p 24 antigen. The purposes of the guidance documents are to assist blood and plasma establishments in protecting the safety of the blood supply and to establish policies with the intent of promoting consistency in the industry. These guidance documents represent the agency's current thinking on the appropriate testing of human blood donors for evidence of infection due to various communicable disease agents. Through inspection, we (FDA) determined that blood and plasma establishments generally have been following these recommendations. However, there have been instances where there have been variations in testing and in the determination of suitability of the blood based on the testing results. Accordingly, we proposed a regulation requiring testing consistent with our current recommendations and industry practice.

In the **Federal Register** of August 19, 1999 (64 FR 45340), we published a proposed rule to revise the testing requirements codified in part 610. The proposed rule would require:

- Each donation of human blood or blood component, including autologous donations, to be tested for evidence of infection due to HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II;
- Each donation that tests reactive for any of the required screening tests for evidence of infection due to communicable disease agents, to be further tested using a supplemental (additional, more specific) test that has been approved for such use by FDA;
- The required testing to be performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or meeting equivalent requirements as described by Health Care Financing Administration (HCFA), and registered with FDA in accordance with part 607 (21 CFR part 607);
- Deferral from future donations of donors who test reactive;
- Criteria for release or shipment of human blood or blood components prior to completion of testing under limited circumstances;