

manufacturer, this AD does not include that requirement.

(1) Before further flight: Replace the hydraulic accumulator with a new or serviceable accumulator.

(2) Before further flight: Do a detailed inspection for signs of failure (leaking or cracking) of the hydraulic accumulator, and replace any failed accumulator before further flight. If there is no sign of failure, repeat the inspection thereafter at the applicable interval in paragraph (g)(2)(i) or (g)(2)(ii) of this AD. Within 75 days after the effective date of this AD, replace the affected hydraulic accumulator with a new or serviceable accumulator. Doing the replacement terminates the repetitive inspections.

(i) At intervals not to exceed 48 hours.

(ii) Before further flight following a report of hydraulic fumes in the cabin air supply, or after a hydraulic fluid low-level warning; and thereafter at intervals not to exceed 48 hours.

(h) For airplanes on which more than one affected accumulator is identified during the inspection required by paragraph (f) of this AD: Within 12 days after the effective date of this AD, replace any affected accumulator in accordance with paragraph (g)(1) of this AD, so that no more than one accumulator with an affected S/N remains on the airplane; and inspect any remaining accumulator at the applicable interval in paragraph (g)(2) of this AD.

Note 1: BAE Systems (Operations) Limited Service Bulletin ISB.29-A046, dated March 14, 2006, refers to APPH Service Bulletin AIR91666-29-02, dated March 2006, as an additional source of service information for determining if an accumulator is a serviceable accumulator. The procedures include disassembling the accumulator cylinder, and testing it for cracking.

Note 2: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

Parts Installation

(i) Except as provided by paragraph (g)(2) of this AD: As of the effective date of this AD, no hydraulic accumulator having P/N AIR91666-0, -1, or -2 that has an S/N identified in paragraph C. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.29-A046, dated March 14, 2006, may be installed on any airplane except for accumulators on which the actions specified in the Accomplishment Instructions of APPH Service Bulletin AIR91666-29-02, dated March 2006, have been done.

Special Flight Permit Limited

(j) Using special flight permits (14 CFR 21.197 and 21.199) before all affected hydraulic actuators are replaced on the

airplane is allowed only if the airplane has not flown more than 5 flight cycles since the last inspection done in accordance with paragraph (g)(2) or (h) of this AD, as applicable; and if the flight can be accomplished in one flight cycle with the airplane unpressurized.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(l) European Aviation Safety Agency (EASA) emergency airworthiness directive 2006-0061-E [Corrected], dated March 17, 2006, also addresses the subject of this AD.

Material Incorporated by Reference

(m) You must use BAE Systems (Operations) Limited Inspection Service Bulletin ISB.29-A046, dated March 14, 2006, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL-401, Nassif Building, Washington, DC; or the Internet at <http://dms.dot.gov>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on October 31, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6-18965 Filed 11-9-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2006-25337; Directorate Identifier 2006-NM-138-AD; Amendment 39-14825; AD 2006-23-13]

RIN 2120-AA64

Airworthiness Directives; BAE Systems (Operations) Limited Model BAe 146 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all BAE Systems (Operations) Limited Model BAe 146 airplanes. This AD requires inspecting the three-phase circuit breakers and three-phase circuit breaker panels for discrepancies; and fixing any discrepancy and replacing unserviceable units with new units, if necessary. This AD results from reports of three-phase circuit breakers overheating on in-service airplanes. We are issuing this AD to prevent failure of a three-phase circuit breaker. Such failure could prevent an electrical load from being isolated from its electrical supply, which could result in smoke or fire in the flight deck.

DATES: This AD becomes effective December 18, 2006.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of December 18, 2006.

ADDRESSES: You may examine the AD docket on the Internet at <http://dms.dot.gov> or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC.

Contact British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1175; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at <http://dms.dot.gov> or in person at the

Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647-5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to all BAE Systems (Operations) Limited Model BAe 146 airplanes. That NPRM was published in the **Federal Register** on July 13, 2006 (71 FR 39595). That NPRM proposed to require inspecting the three-phase circuit breakers and three-phase circuit breaker panels for discrepancies; and fixing any discrepancy and replacing unserviceable units with new units, if necessary.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Request To Consider Electronic Test in Place of Visual Inspection

The commenter, a private citizen who is also an airplane mechanic, believes that a physical inspection will not adequately determine an operational deficiency. The commenter recommends adding a periodic electrical test of the affected circuit breakers. In support of his recommendation, the commenter describes his experience as a helicopter operator, and states that he built a bench check unit that could verify an operational deficiency of circuit breakers.

We disagree with requiring an electrical test in place of a detailed (physical) inspection of the circuit breakers. Both the original equipment manufacturer and the European Aviation Safety Agency (EASA), which is the airworthiness authority for the European Union, have determined that a detailed inspection is adequate to ensure safety. The commenter did not provide factual or statistical data to show that damaged circuit breakers could remain on the airplane even though the detailed inspection shows no damage. However, the commenter presents some interesting information that we will share with the EASA. We have not changed the AD in this regard.

Request To Change Incorporation of Certain Information

The Modification and Replacement Parts Association (MARPA) states that, typically, airworthiness directives are based on service information originating with the type certificate holder or its suppliers. MARPA adds that manufacturer service documents are privately authored instruments generally having copyright protection against duplication and distribution. MARPA notes that when a service document is incorporation by reference into a public document, such as an airworthiness directive, it loses its private, protected status and becomes a public document. MARPA adds that, if a service document is used as a mandatory element of compliance, it should not simply be referenced, but should be incorporated into the regulatory document; by definition, public laws must be public, which means they cannot rely upon private writings. MARPA is concerned that the failure to incorporate essential service information could result in a court decision invalidating the AD.

MARPA adds that incorporated by reference service documents should be made available to the public by publication in the Document Management System (DMS), keyed to the action that incorporates them. MARPA notes that the stated purpose of the incorporated by reference method is brevity, to keep from expanding the **Federal Register** needlessly by publishing documents already in the hands of the affected individuals; traditionally, "affected individuals" means aircraft owners and operators, who are generally provided service information by the manufacturer. MARPA adds that a new class of affected individuals has emerged, since the majority of aircraft maintenance is now performed by specialty shops instead of aircraft owners and operators. MARPA notes that this new class includes maintenance and repair organizations, component servicing and repair shops, parts purveyors and distributors, and organizations manufacturing or servicing alternatively certified parts under § 21.303 ("Parts manufacturer approval") of the Federal Aviation Regulations (14 CFR part 21). MARPA adds that the concept of brevity is now nearly archaic as documents exist more frequently in electronic format than on paper. Therefore, MARPA asks that the service documents deemed essential to the accomplishment of the NPRM be incorporated by reference into the regulatory instrument, and published in the DMS.

We do not agree that documents should be incorporated by reference during the NPRM phase of rulemaking. The Office of the Federal Register (OFR) requires that documents that are necessary to accomplish the requirements of the AD be incorporated by reference during the final rule phase of rulemaking. This final rule incorporates by reference the document necessary for the accomplishment of the requirements mandated by this AD. Further, we point out that while documents that are incorporated by reference do become public information, they do not lose their copyright protection. For that reason, we advise the public to contact the manufacturer to obtain copies of the referenced service information.

Additionally, we do not publish service documents in DMS. We are currently reviewing our practice of publishing proprietary service information. Once we have thoroughly examined all aspects of this issue, and have made a final determination, we will consider whether our current practice needs to be revised. However, we consider that to delay this AD action for that reason would be inappropriate, since we have determined that an unsafe condition exists and that the requirements in this AD must be accomplished to ensure continued safety. Therefore, we have not changed the AD in this regard.

Clarification of Costs of Compliance

We have clarified the Costs of Compliance section in this AD to reflect a revised number of U.S.-registered airplanes.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

This AD affects about 16 airplanes of U.S. registry. The inspection takes about 5 work hours per airplane, at an average labor rate of \$80 per work hour. Based on these figures, the estimated cost of the AD for U.S. operators is \$6,400, or \$400 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006-23-13 BAE Systems (Operations) Limited (Formerly British Aerospace

Regional Aircraft): Amendment 39-14825. Docket No. FAA-2006-25337; Directorate Identifier 2006-NM-138-AD.

Effective Date

(a) This AD becomes effective December 18, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all BAE Systems (Operations) Limited Model BAe 146-100A, -200A, and -300A series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from reports of three-phase circuit breakers overheating on in-service airplanes. We are issuing this AD to prevent failure of a three-phase circuit breaker. Such failure could prevent an electrical load from being isolated from its electrical supply, which could result in smoke or fire in the flight deck.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Detailed Inspection and Corrective Actions

(f) Within 12 months after the effective date of this AD, do a detailed inspection of the three-phase circuit breakers and three-phase circuit breaker panels for discrepancies (including but not limited to physical damage, cracks, deterioration, corrosion, discoloration, contamination by foreign objects, and missing or improperly installed terminal connections or attachments), in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.24-141, dated August 15, 2005. If any discrepancy is found, before further flight, fix the discrepancy and replace unserviceable units with new units, as applicable, in accordance with the inspection service bulletin.

Note 1: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

No Reporting

(g) Although the inspection service bulletin referenced in this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(i) The European Aviation Safety Agency airworthiness directive 2006-0132, dated May 18, 2006, also addresses the subject of this AD.

Material Incorporated by Reference

(j) You must use BAE Systems (Operations) Limited Inspection Service Bulletin ISB.24-141, dated August 15, 2005, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL-401, Nassif Building, Washington, DC; on the Internet at <http://dms.dot.gov>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on October 31, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6-18966 Filed 11-9-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. 1992N-0297 (formerly 92N-0297)]

RIN 0905-AC81

Distribution of Blood Derivatives by Registered Blood Establishments That Qualify as Health Care Entities; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Delay of Applicability Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of applicability date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until December 1, 2008, the applicability date of a certain