

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2010-0801; Directorate Identifier 2010-NM-054-AD; Amendment 39-16595; AD 2011-03-11]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A300 B4-600 and A300 B4-600R Series Airplanes, Model A300 F4-605R Airplanes, and Model A300 C4-605R Variant F Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

A recent Wide spread Fatigue Damage (WFD) calculation on A300-600 aeroplanes has shown that a reinforcement of the upper fuselage circumferential joint at FR (frame) 58 is necessary to enable the aeroplane to reach the Extended Service Goal (ESG).

The failure of the circumferential joint of the upper fuselage could affect the structural integrity of the aeroplane.

* * * * *

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective March 14, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 14, 2011.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2125; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on August 23, 2010 (75 FR 51705). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

A recent Wide spread Fatigue Damage (WFD) calculation on A300-600 aeroplanes has shown that a reinforcement of the upper fuselage circumferential joint at FR (frame) 58 is necessary to enable the aeroplane to reach the Extended Service Goal (ESG).

The failure of the circumferential joint of the upper fuselage could affect the structural integrity of the aeroplane.

For the reasons described above, this AD requires the reinforcement of the affected fuselage frame butt joint.

You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received.

Request To Revise Paragraph (g) of the NPRM

FedEx Express (FedEx) requested that we add the following sentence to paragraph (g) of the NPRM:

“Accomplish modification in accordance with the thresholds specified in [Airbus Mandatory] Service Bulletin A300-53-6146, Revision 01, [dated June 26, 2009,] paragraph E(2), Accomplishment Timescale.” FedEx stated that the threshold table in that service bulletin recommends the number of flight cycles for each model after which the modification should be embodied; if the modification is embodied before the recommended threshold, additional inspections are required according to Airbus instructions. FedEx further stated that the NPRM stipulates accomplishment before 42,500 flight cycles and FedEx agrees that following the Airbus recommendation for the thresholds will avoid extensive inspections similar to the Airworthiness Limitations Items (ALI) Tasks 53.16.04-01-1 and 53.16.22-01-1.

We do not agree to add the quoted sentence to the AD because, by doing the requirements of this AD at or before the compliance time specified in this AD, no further inspections are required by this AD. However, we have added a new Note 1 that states “In case of earlier accomplishment of Airbus Mandatory Service Bulletin A300-53-6146, Revision 01, dated June 26, 2009, before

the recommended thresholds contained in the Threshold Table in paragraph 1.E.(2) of Airbus Mandatory Service Bulletin A300-53-6146, Revision 01, dated June 26, 2009, are reached, the operator should contact Airbus to define an additional non-mandatory appropriate inspection program.” We have reidentified subsequent notes accordingly.

Further, we have determined that accomplishing the actions required by this AD terminates ALI Tasks 53.16.04-01-1 and 53.16.22-01-1. Therefore, we have added a new paragraph (h) to this AD to clarify that doing the requirements of this AD terminates ALI Tasks 53.16.04-01-1 and 53.16.22-01-1. We have reidentified subsequent paragraphs accordingly.

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable.

In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a Note within the AD.

Costs of Compliance

We estimate that this AD will affect about 124 products of U.S. registry. We also estimate that it will take about 347 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Required parts will cost about \$5,670 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of

this AD to the U.S. operators to be \$4,360,460 or \$35,165 per product.

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 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 this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the 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.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

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 FAA amends § 39.13 by adding the following new AD:

2011-03-11 Airbus: Amendment 39-16595. Docket No. FAA-2010-0801; Directorate Identifier 2010-NM-054-AD.

Effective Date

- (a) This airworthiness directive (AD) becomes effective March 14, 2011.

Affected ADs

- (b) None.

Applicability

(c) This AD applies to Airbus Model A300 B4-601, B4-603, B4-620, and B4-622 airplanes; Model A300 B4-605R and B4-622R airplanes; Model A300 F4-605R airplanes on which modification 12699 has not been accomplished; and Model A300 C4-605R Variant F airplanes; certificated in any category; all serial numbers.

Subject

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: A recent Wide spread Fatigue Damage (WFD) calculation on A300-600 aeroplanes has shown that a reinforcement of the upper fuselage circumferential joint at FR (frame) 58 is necessary to enable the aeroplane to reach the Extended Service Goal (ESG).

The failure of the circumferential joint of the upper fuselage could affect the structural integrity of the aeroplane.

* * * * *

Compliance

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

Actions

(g) Before the accumulation of 42,500 total flight cycles, or within 2,000 flight cycles after the effective date of this AD, whichever occurs later, reinforce the fuselage butt joint at FR 58 in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300-53-6146,

Revision 01, including Appendix 1, dated June 26, 2009.

(h) Accomplishment of the requirements of paragraph (g) of this AD terminates Airworthiness Limitations Items (ALI) Tasks 53.16.04-01-1 and 53.16.22-01-1 for these airplanes.

Note 1: In case of earlier accomplishment of Airbus Mandatory Service Bulletin A300-53-6146, Revision 01, dated June 26, 2009, before the recommended thresholds contained in the Threshold Table in paragraph 1.E.(2) of Airbus Mandatory Service Bulletin A300-53-6146, Revision 01, dated June 26, 2009, are reached, the operator should contact Airbus to define an additional appropriate inspection program.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows:
No differences.

Other FAA AD Provisions

(i) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2125; fax (425) 227-1149. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(j) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2010-0007, dated January 7, 2010; and Airbus Mandatory Service Bulletin A300-53-6146, Revision 01, including Appendix 1, dated June 26, 2009; for related information.

Material Incorporated by Reference

(k) You must use Airbus Mandatory Service Bulletin A300-53-6146, Revision 01, including Appendix 1, dated June 26, 2009, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail account.airworth-eas@airbus.com; Internet <http://www.airbus.com>.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at 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 January 25, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 2011-2433 Filed 2-4-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2010-D-0645]

Medical Devices; General and Plastic Surgery Devices; Classification of Contact Cooling System for Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the contact cooling system for aesthetic use into class II (special controls). The special control that will apply to the device is the guidance document entitled “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use.” The Agency is classifying the device into class II (special controls) in order to provide reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device type.

DATES: *Effective Date:* March 9, 2011.

FOR FURTHER INFORMATION CONTACT:

Richard Felten, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1436, Silver Spring, MD 20993, 301-796-6392.

SUPPLEMENTARY INFORMATION:

I. What is the background of this rulemaking?

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and the Food and Drug Administration Modernization Act (Pub. L. 107-250) established a comprehensive system for regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

FDA refers to devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as postamendments devices. Postamendments devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or class II in accordance with section 513(f)(2) of the FD&C Act; or FDA issues an order finding the device to be substantially equivalent, under section 513(i) to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device that has not previously been classified into class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA will, within 60 days of receiving this request,

classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 7, 2009, classifying the Zeltiq Lipolysis System for Aesthetic Use into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On October 13, 2009, Zeltiq™ Aesthetic, Inc., submitted a petition requesting classification of the lipolysis system for aesthetic use under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the contact cooling system for aesthetic use can be classified into class II with the establishment of special controls. FDA believes these special controls will provide assurance of the safety and effectiveness of the device.

The device was assigned the generic name “Cooling System for Aesthetic Use” and it is identified as a cooling system for aesthetic use. FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

- Discomfort and pain during and following treatment are possible due to the application of mechanical or vacuum massage at levels in excess of those recommended in the labeling. These effects and tenderness at the treatment site may also occur following treatment. Prevention of these effects are addressed by adequate bench testing demonstrating that the feedback controls for temperature/cooling are functional and do maintain target temperature within the stated value. Proper function of mechanical controls to insure use of the mechanical or vacuum massager within safe limits