

(ii) If the inspections were done prior to the effective date of this AD: Within 30 days after the effective date of this AD.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: Although the MCAI allows further flight after cracks are found during compliance with the required action, this AD requires that you repair the crack(s) before further flight.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, 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 on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(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, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2008-0066, dated March 31, 2008; Airbus Service Bulletin A310-54-2032, Revision 01, dated October 8, 2007; and Airbus Mandatory Service Bulletin A310-54-2036, Revision 02, dated September 28, 2007; for related information.

Material Incorporated by Reference

(i) You must use Airbus Service Bulletin A310-54-2032, Revision 01, dated October 8, 2007; and Airbus Mandatory Service Bulletin A310-54-2036, including Appendix 01, Revision 02, dated September 28, 2007; as applicable; 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, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 33 33; Internet <http://www.airbus.com>.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind

Avenue, SW., Renton, Washington; or 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 October 9, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-25767 Filed 11-10-08; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2008-0667; Directorate Identifier 2008-NM-009-AD; Amendment 39-15717; AD 2008-22-20]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A330-200, A330-300, and A340-300 Series 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:

During fatigue tests (EF3) on the A340-600, damages were found in longitudinal doubler at VTP [vertical tail plane] attachment cutout between Frame (FR) 80 and FR86. This damage occurred between 58341 and 72891 simulated Flight Cycles (FC).

Due to the higher Design Service Goal and different design (e.g., doubler thickness) [of the] A330-200/-300 and A340-300 aircraft series, the damage assessment concluded [there was] potential impact on [the airplanes specified in the] applicability.

* * * * *
The unsafe condition is crack propagation in the VTP attachment cutout, which could reduce airplane structural integrity in the tail section. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference

of certain publications listed in this AD as of December 17, 2008.

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:

Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1138; 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 June 24, 2008 (73 FR 35603). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

During fatigue tests (EF3) on the A340-600, damages were found in longitudinal doubler at VTP [vertical tail plane] attachment cutout between Frame (FR) 80 and FR86. This damage occurred between 58341 and 72891 simulated Flight Cycles (FC).

Due to the higher Design Service Goal and different design (e.g., doubler thickness) [of the] A330-200/-300 and A340-300 aircraft series, the damage assessment concluded [there was] potential impact on [the airplanes specified in the] applicability.

[T]o allow early detection of cracks, which could [prevent] possible crack propagation and consequently to maintain the structural integrity of the upper shell structure between FR80 and FR86, this Airworthiness Directive (AD) mandates an inspection program [for cracking] of this area using a high frequency eddy current (HFEC) method, and a modification to improve the upper shell structure.

The unsafe condition is crack propagation in the VTP attachment cutout, which could reduce airplane structural integrity in the tail section. Corrective actions include doing eddy current inspections for cracking of certain fastener rows, and contacting Airbus for repair instructions and repairing. 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 Allow Flight With Cracks

Northwest Airlines (NWA) requests that we reconsider eliminating the provision for flight with certain cracks. NWA states that the MCAI and Airbus service bulletins (that were referenced in the NPRM as appropriate sources of service information) provide for flight with certain cracks if follow-on inspections are accomplished in accordance with the service bulletin.

We do not concur. Our policy specifies the requirement to repair known cracks before further flight (though we may make exceptions to this policy in certain cases of unusual need, as discussed below). This policy is based on the fact that such damaged airplanes do not conform to the FAA-certificated type design and, therefore, are not airworthy until a properly approved repair is made. While recognizing that repair deferrals might be necessary at times, our policy is intended to minimize adverse human factors relating to the lack of reliability of long-term repetitive inspections, which might reduce the safety of the type-certificated design if such repair deferrals are practiced routinely.

As noted above, we may make an exception to this policy in certain cases, if there is an unusual need for a temporary deferral. Unusual needs include such circumstances as legitimate difficulty in acquiring parts to accomplish repairs. Under such conditions, we may allow a temporary deferral of the repair, subject to a stringent inspection program acceptable to the FAA. We acknowledge that the manufacturer has specified inspection intervals that are intended to allow continued operation with known cracks, and to prevent the need for extensive repairs. However, since we are not aware of any unusual need for repair deferral in regard to this AD, we have not evaluated these inspection intervals.

Under the provisions of paragraph (g)(1) of this AD, we will consider requests for approval of an AMOC if sufficient data are submitted to substantiate that temporary deferral of repair with follow-on inspections would provide an acceptable level of safety. We have not changed the AD in this regard.

Actions Since NPRM Was Issued

Airbus has issued revisions to two service bulletins referenced in the NPRM as appropriate sources of service information. Airbus Mandatory Service Bulletins A330-53-3168 and A340-53-4174, both Revision 01, both dated February 15, 2008, are essentially the same as the original versions of those

service bulletins except for clarifications, and no additional work is required for airplanes modified per the original issue. We have changed the references in paragraphs (f)(1), (f)(2)(i), and (h) of this AD to include Revision 01 of those service bulletins, and added paragraph (f)(4) to this AD to give credit for actions performed according to the original issues.

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 26 products of U.S. registry. We also estimate that it will take about 202 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$80 per work-hour. Required parts will cost about \$19,020 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 \$914,680, or \$35,180 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:

2008–22–20 Airbus: Amendment 39–15717. Docket No. FAA–2008–0667; Directorate Identifier 2008–NM–009–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330–200, A330–300, and A340–300 series airplanes; certificated in any category; all certified models, all serial numbers; on which Airbus Modification 44205 has been embodied in production, except those on which Airbus Modification 52974 or 53223 has been embodied in production.

Subject

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

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

During fatigue tests (EF3) on the A340–600, damages were found in longitudinal doubler at VTP [vertical tail plane] attachment cutout between Frame (FR) 80 and FR86. This damage occurred between 58341 and 72891 simulated Flight Cycles (FC).

Due to the higher Design Service Goal and different design (e.g., doubler thickness) [of the] A330–200/–300 and A340–300 aircraft series, the damage assessment concluded [there was] potential impact on [the airplanes specified in the] applicability.

[T]o allow early detection of cracks, which could [prevent] possible crack propagation and consequently to maintain the structural integrity of the upper shell structure between FR80 and FR86, this Airworthiness Directive (AD) mandates an inspection program [for cracking] of this area using a high frequency eddy current (HFEC) method, and a modification to improve the upper shell structure.

The unsafe condition is crack propagation in the VTP attachment cutout, which could reduce airplane structural integrity in the tail section. Corrective actions include doing

eddy current inspections for cracking of certain fastener rows, and contacting Airbus for repair instructions and repairing.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) For Airbus Model A330–300 and A340–300 series airplanes, except Model A340–300 weight variant (WV) 027 airplanes: At the applicable compliance time specified in paragraph (f)(2) of this AD, perform a HFEC inspection of the upper shell structure between FR80 and FR86, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3168 or A340–53–4174, both Revision 01, both dated February 15, 2008, as applicable.

(i) If no crack is detected, repeat the inspection thereafter within the intervals specified in paragraph 1.E.(2) of Airbus Mandatory Service Bulletin A330–53–3168 or A340–53–4174, both Revision 01, both dated February 15, 2008, as applicable.

(ii) If any crack is detected during any inspection required by this AD: Before next flight, contact Airbus for repair instructions and do applicable repairs.

(iii) Doing the modification of the upper shell structure in accordance with Airbus Service Bulletin A330–53–3159 or A340–53–4165, both dated September 19, 2007, as applicable, ends the inspections required by paragraph (f)(1) of this AD.

(2) Do the actions required by paragraph (f)(1) of this AD at the later of the compliance times specified in paragraph (f)(2)(i) and (f)(2)(ii) of this AD.

(i) Within the compliance times specified in paragraph 1.E.(2) of Airbus Mandatory Service Bulletin A330–53–3168 or A340–53–4174, both Revision 01, both dated February 15, 2008, as applicable.

(ii) Within 3 months after the effective date of this AD.

(3) At the applicable time specified in paragraphs (f)(3)(i), (f)(3)(ii), and (f)(3)(iii) of this AD or within 3 months after the effective date of this AD, whichever occurs later, modify the upper shell structure between FR80 and FR86 (including doing eddy current inspections for cracking of certain fastener rows and applicable corrective actions) in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3160, dated July 9, 2007; or Airbus Mandatory Service Bulletin A340–53–4172, dated July 10, 2007; as applicable. Do all applicable corrective actions before further flight.

(i) For Model A330–200 airplanes, WV 020 through WV 027: Prior to the accumulation of 13,500 total flight cycles.

(ii) For Model A330–200 airplanes, WV 050 through WV 055: Prior to the accumulation of 10,700 total flight cycles or

59,300 total flight hours, whichever occurs first.

(iii) For Model A340–300 airplanes, WV 027: Prior to the accumulation of 14,200 total flight cycles.

(4) Inspections accomplished before the effective date of this AD according to Airbus Mandatory Service Bulletins A330–53–3168 and A340–53–4174, both dated September 19, 2007, as applicable, are considered acceptable for compliance with the corresponding actions specified in this AD.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: Although the MCAI allows further flight after cracks are found during compliance with the required action, this AD requires that you repair the crack(s) before further flight.

Other FAA AD Provisions

(g) 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: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(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, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2007–0284, dated November 12, 2007, and the service bulletins specified in Table 1 of this AD, for related information.

TABLE 1—SERVICE INFORMATION

Airbus service information	Revision	Date
Mandatory Service Bulletin A330–53–3160	Original	July 9, 2007.
Mandatory Service Bulletin A330–53–3168	01	February 15, 2008.
Mandatory Service Bulletin A340–53–4172	Original	July 10, 2007.
Mandatory Service Bulletin A340–53–4174	01	February 15, 2008.
Service Bulletin A330–53–3159	Original	September 19, 2007.

TABLE 1—SERVICE INFORMATION—Continued

Airbus service information	Revision	Date
Service Bulletin A340–53–4165	Original	September 19, 2007.

Material Incorporated by Reference

(i) You must use the service information specified in Table 2 of this AD 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, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 33 33; Internet <http://www.airbus.com>.
 (3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind

Avenue, SW., Renton, Washington; or 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.

TABLE 2—MATERIAL INCORPORATED BY REFERENCE

Airbus service information	Revision	Date
Mandatory Service Bulletin A330–53–3160	Original	July 9, 2007.
Mandatory Service Bulletin A330–53–3168	01	February 15, 2008.
Mandatory Service Bulletin A340–53–4172	Original	July 10, 2007.
Mandatory Service Bulletin A340–53–4174	01	February 15, 2008.
Service Bulletin A330–53–3159	Original	September 19, 2007.
Service Bulletin A340–53–4165	Original	September 19, 2007.

Issued in Renton, Washington, on October 20, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25787 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2008–N–0561]

Maximum Civil Money Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a new regulation to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended. The last adjustment was published in the **Federal Register** of July 20, 2004 (69 FR 43299), and the FCPIAA requires Federal agencies to adjust their civil money penalties at least once every 4 years. This rule does

not adjust the civil money provisions enacted by the Food and Drug Administration Amendments Act of 2007 (FDAAA). We are using direct final rulemaking for this action because the agency expects that there will be no significant adverse comment on the rule. In the proposed rule section of this issue of the **Federal Register**, we are concurrently proposing and soliciting comments on this rule. If significant adverse comments are received, we will withdraw this final rule and address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment.

DATES: This rule is effective March 27, 2009, without further notice, unless FDA receives significant adverse comment by January 26, 2009. If we receive no timely significant adverse comments, we will publish a document in the **Federal Register** before February 25, 2009, confirming the effective date of the direct final rule. If we receive any timely significant adverse comments, we will publish a document in the **Federal Register** withdrawing this direct final rule before March 27, 2009.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0561, by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. *Written Submissions*

Submit written submissions in the following ways:

- 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. FDA–2008–N–0561 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” 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.regulations.gov> and insert the docket number(s), 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. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments