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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2005-22874; Directorate Identifier 2005-NM-173-AD; Amendment 39-14769; AD 2006-19-12]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 777-200 and -300 Series Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 777-200 and -300 series airplanes. This AD requires inspecting the lower web of the aft fairing of engine struts for any discoloration and doing any related investigative and corrective action if necessary; inspecting the heat shield castings for any damage and doing any corrective action if necessary; installing gap cover strips; and replacing insulation blankets with new insulation blankets. This AD results from a report that several discolored fairing lower webs and some damaged/deteriorated insulation blankets were found in the aft fairings of engine struts. We are issuing this AD to prevent cracking of lower webs of the aft fairings, which could result in flammable hydraulic fluid leaking onto or near an ignition source, and possibly result in an uncontrollable fire in the engine strut area.

EFFECTIVE DATE: This AD becomes effective October 30, 2006.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of October 30, 2006.

ADDRESSES: You may examine the AD docket on the Internet at [http://](http://dms.dot.gov)

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 Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Margaret Langsted, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6500; fax (425) 917-6590.

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 certain Boeing Model 777-200 and -300 series airplanes. That NPRM was published in the **Federal Register** on November 9, 2005 (70 FR 67952). That NPRM proposed to require inspecting the lower web of the aft fairing of engine struts for any discoloration and doing any related investigative and corrective action if necessary; inspecting the heat shield castings for any damage and doing any corrective action if necessary; installing gap cover strips; and replacing insulation blankets with new insulation blankets.

Comments

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

Supportive Comment

One commenter, Boeing, concurs with the contents of the NPRM.

Request To Address Technical Discrepancies in the Service Bulletin

Continental Airlines (CAL) concurs with the intent of the NPRM to mandate Boeing Special Attention Service Bulletin 777-54-0021, dated June 23, 2005, in an effort to minimize heat damage to the pylon aft fairing. CAL noted some technical discrepancies that may create problems for the operators if Service Bulletin 777-54-0021 is mandated as-is. CAL specifically noted that, in the procedures given for performing an inspection of the lower web for heat damage, there are no International Annealed Copper Standard (IACS) values given to determine whether the condition of the web material is acceptable for continued service. CAL considers a conductivity of 44 percent of IACS value or less acceptable for service. CAL coordinated these issues with Boeing for corrective action, confirmed that the issues would be corrected in the next revision of the service bulletin, and agreed to validate Service Bulletin 777-54-0021 for Boeing. CAL recommends that we either defer this rulemaking action until Revision 1 of the service bulletin is released, or incorporate the corrections of these discrepancies within the AD. CAL also "would like to see verbiage in the ruling that will allow us to take credit" for work accomplished on airplanes changed as shown in the initial release of the service bulletin.

We agree that the initial release of Service Bulletin 777-54-0021 has discrepancies that could create problems for operators if required as-is. Since the NPRM was published, Boeing has issued Boeing Special Attention Service Bulletin 777-54-0021, Revision 1, dated March 16, 2006. Revision 1 of the service bulletin addresses the discrepancies noted by CAL. However, Revision 1 of the service bulletin recommends that the threshold criteria for the heat damage inspection be 42 percent or less of IACS, not the 44 percent proposed by CAL. We have determined that we will require a 42 percent threshold in accordance with that service bulletin. We also have determined that no more work is necessary for airplanes modified in accordance with the initial release of the service bulletin. We have revised paragraphs (f) and (g) of this AD to reference Revision 1 of the service bulletin and have added paragraph (h)

to this AD to allow credit for previously accomplished actions in accordance with the initial release of the service bulletin, provided that the IACS threshold used is 42 percent or less.

Request To Extend Compliance Times for Airplanes With Boeing Service Bulletin 777-54A0015 Incorporated

CAL requests that the AD make a distinction between affected GE-engine-powered airplanes with and without the incorporation of Boeing Service Bulletin 777-54A0015, Revision 1, dated March 15, 2002. CAL states that according to the information in Service Bulletin 777-54-0021, reports of discolored lower webs and deteriorated thermal blankets are all from airplanes that did not have Service Bulletin 777-54A0015 incorporated. CAL notes that Service Bulletin 777-54A0015 provides instructions to modify the cover plate of the Number 1 heat shield segment to block the through-flow of hot exhaust gas in the heat shield cavity, and replace the thermal insulation blankets to protect the area above from heat damage. CAL states that it incorporated these changes on all affected airplanes in its fleet between 2002 and 2003. CAL requests/recommends that we extend the compliance time from 12 months to 24 months for airplanes that have incorporated Service Bulletin 777-54A0015.

We do not agree to extend the compliance time. The incorporation of Service Bulletin 777-54A0015 on GE-engine-powered airplanes was intended to prevent elevated temperatures from the primary exhaust from passing into the strut aft fairing cavity through a gap between the strut aft fairing heat shield cover plate and the aft fairing lower web. The incorporation of Service Bulletin 777-54-0021, Revision 1, is intended to prevent the deterioration of new insulation blankets in the strut aft fairing. The insulation blankets, located on the bottom side of the fairing lower web and above the segmented heat shield, are used to reduce the temperature inside the strut aft fairing. Gaps in the segmented heat shield allow the engine's primary exhaust to enter the heat shield cavity. The flow path blockage provided by Service Bulletin 777-54A0015 is entirely separate from the blockage provided by Service Bulletin 777-54-0021, Revision 1. We consider these two design changes independent and do not agree with extending the compliance time for those airplanes having incorporated Service Bulletin 777-54A0015. We have not revised this AD in this regard.

Clarification of Service Bulletin's Inclusion of Nutplate Inspection

Service Bulletin 777-54-0021, Revision 1, includes in the general visual inspection for damage of the heat shield casting, a missing or loose nutplate as one criterion for damage. We consider this additional criterion a relieving action. Without the nutplate inspection in the general visual inspection for damage, a missing nutplate would be discovered during re-installation of the forward-most heat shield when fasteners would fail to be torqued to the correct torque value. Finding missing or loose nutplate(s) during the general visual inspection provides scheduling and economic benefits when compared to the cost of discovering missing nutplates after heat shield reinstallation.

Clarification of Additional Available Repair Method

Service Bulletin 777-54-0021, Revision 1, also provides more detailed repair instructions that may be used for repair of conditions found during the inspections. We have revised paragraph (g) of this AD to allow repair in accordance with the repair instructions provided by Service Bulletin 777-54-0021, Revision 1.

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 with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 294 airplanes of the affected design in the worldwide fleet. This AD will affect about 72 airplanes of U.S. registry. The actions will take about 9 to 11 work hours per airplane, depending on engine manufacturer (configuration), at an average labor rate of \$65 per work hour. Required parts would cost about \$15,368 to \$16,179 per airplane. Based on these figures, the estimated cost of the AD for U.S. operators is \$1,148,616 to \$1,216,368, or \$15,953 to \$16,894 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):

2006–19–12 Boeing: Amendment 39–14769.
Docket No. FAA–2005–22874;
Directorate Identifier 2005–NM–173–AD.

Effective Date

(a) This AD becomes effective October 30, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 777–200 and –300 series airplanes, certificated in any category; as identified in Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006.

Unsafe Condition

(d) This AD results from a report that several discolored fairing lower webs and some damaged/deteriorated insulation blankets were found in the aft fairings of engine struts. We are issuing this AD to prevent cracking of lower webs of the aft fairings, which could result in flammable hydraulic fluid leaking onto or near an ignition source, and possibly result in an uncontrollable fire in the engine strut area.

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.

Inspection, Installation, and Replacement Actions

(f) Except as provided by paragraph (g) of this AD: Within 12 months after the effective date of this AD, do the actions specified in paragraphs (f)(1), (f)(2), (f)(3), and (f)(4) of this AD in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006.

(1) Do a general visual inspection of the lower web of the aft fairing for any discoloration and do any related investigative action.

(2) Do a general visual inspection of the heat shield castings for any damage (crack(s), dent(s), gouge(s), warpage, fretting, or missing/loose nutplates).

(3) Install gap cover strips on the heat shield pans.

(4) Replace insulation blankets on the heat shield pans with new insulation blankets.

Repair Instructions

(g) If any damage, discoloration, heat damage, or crack is found during any inspection required by this AD: Before further flight, do all applicable corrective actions in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, or in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006.

Previously Accomplished Actions

(h) Actions done before the effective date of this AD in accordance with Boeing Special Attention Service Bulletin 777–54–0021, dated June 23, 2005, are acceptable for

compliance with the requirements of paragraph (f) of this AD, except where the service bulletin does not provide an International Annealed Copper Standard (ICAS) value for determining the results of the inspection for heat damage, the maximum acceptable ICAS value is 42 percent.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle ACO, 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 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(j) You must use Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 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 Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, 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 September 13, 2006.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–8122 Filed 9–22–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892

[Docket No. 2006N–0335]

Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending certain classification regulations for reprocessed single-use devices (SUDs) whose exemption from premarket notification (510(k)) requirements have been terminated and other reprocessed SUDs already subject to premarket notification for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), are necessary in a 510(k). Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule, under FDA's usual procedures for notice and comment, to provide a procedural framework to finalize the rule in the event we receive any significant adverse comment and withdraw the direct final rule. This action codifies actions taken in previous **Federal Register** notices in accordance with MDUFMA.

DATES: This rule is effective February 7, 2007. Submit written or electronic comments by December 11, 2006. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0335, by any of the following methods:
Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.