

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

[Docket No. FAA-2015-0277; Directorate Identifier 2015-NE-05-AD; Amendment 39-18262; AD 2015-18-04]

RIN 2120-AA64

Airworthiness Directives; CFM International S.A. Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain CFM International S.A. (CFM) CFM56-7B and CFM56-3 turbofan engines. This AD was prompted by a report of an uncommanded in-flight shutdown (IFSD) on a CFM CFM56-7B engine following rupture of the 73-tooth gearshaft located in the engine accessory gearbox (AGB). This AD requires AGB/transfer gearbox (TGB) magnetic chip detector (MCD) inspection of the affected gearshafts until removal. We are issuing this AD to prevent failure of certain engine AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

DATES: This AD is effective October 20, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 20, 2015.

ADDRESSES: For service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877-432-3272; fax: 877-432-3329; email: aviation.fleetsupport@ge.com. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-0277.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-0277; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket

contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kyle Gustafson, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7183; fax: 781-238-7199; email: kyle.gustafson@faa.gov.

SUPPLEMENTARY INFORMATION:**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain CFM CFM56-7B series turbofan engines. The NPRM published in the **Federal Register** on May 1, 2015 (80 FR 24856). The NPRM was prompted by a report of an uncommanded IFSD on a CFM CFM56-7B engine following rupture of the 73-tooth gearshaft located in the engine AGB. The NPRM proposed to require MCD inspection of the affected gearshafts until removal.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 24856, May 1, 2015) and the FAA's response to each comment.

Request To Add CFM56-3 Engines to Applicability

CFM requested that we add CFM56-3 engines to this AD, as the CFM56-3 engines share the same 73-tooth and 41-tooth gearshafts as the CFM56-7B engines.

We agree. We revised the applicability of this AD by adding CFM56-3 engines.

Request To Clarify Discussion of IFSDs

CFM commented that the NPRM (80 FR 24856, May 1, 2015) incorrectly indicated that multiple instances of uncommanded IFSDs occurred on CFM56-7B engines following rupture of the 73-tooth gearshaft when only one IFSD actually occurred. CFM requested that this AD be revised to reflect that only one IFSD occurred following rupture of the 73-tooth gearshaft.

We agree. We revised the Summary, Discussion, and Unsafe Condition sections of this final rule to reflect the occurrence of one IFSD following

rupture of the 73-tooth gearshaft in the CFM56-7B's AGB.

Request To Clarify Inspection Requirement

CFM commented that the NPRM (80 FR 24856, May 1, 2015) did not clearly specify that the MCD inspection is of the AGB/TGB.

We agree. We revised the Summary and the Compliance sections of this final rule to reflect that the required inspection is an "AGB/TGB MCD inspection."

Request To Clarify Relevant Service Information

CFM requested that we specify in the Relevant Service Information section of the NPRM (80 FR 24856, May 1, 2015) that the referenced service bulletins (SBs) describe the procedures for removal of the affected 73-tooth and 41-tooth gearshafts and also list the affected gearshafts by serial number (S/N).

We disagree. This AD does not include a "Relevant Service Information" section. We are, however, incorporating this SB by reference and it is available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-0277. We did not change this AD.

Request To Clarify Proposed AD Requirements

CFM commented that the Proposed AD Requirements section should be revised to be consistent with the compliance and mandatory terminating action paragraphs in this AD.

We disagree. This AD incorporates changes produced as a result of the comments received, as permitted by the Administrative Procedures Act (APA) (Pub. L. 79-404, 5 U.S.C. 551, *et. seq.*). To take the action the commenter suggests would be contrary to the APA. We did not change this AD.

Request To Allow Use of Later Revisions to SBs

CFM requested that we include a provision in this AD to allow for use of later revisions to CFM SB No. CFM56-7B S/B 72-0964, Revision 1, dated December 15, 2014, and SB No. CFM56-7B S/B 72-0965, dated December 16, 2014.

We disagree. We do not know the content of future revisions of SBs and, therefore, cannot approve them before publication. We did not change this AD.

Request To Revise Description of Laboratory Analysis

CFM requested we change the wording in the Compliance section of this AD from "particles lab analysis" to "laboratory analysis."

We agree. The term “laboratory analysis” is more accurate. We revised the term “particles lab analysis” to read “laboratory analysis” in the Compliance section of this AD.

Request To Include Serial Numbers of Affected Gearshafts

CFM requested that we include the S/Ns of the affected 73-tooth and 41-tooth gearshafts in this AD instead of referencing the SBs. CFM indicated that CFM56-3 operators may not have access to the CFM56-7B SBs.

We disagree. Operators have access to CFM SB No. CFM56-7B S/B 72-0964, Revision 1, dated December 15, 2014, in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-0277, or by requesting the SB from CFM. We did not change this AD.

Request To Limit Applicability by Engine Serial Number

Sun Country Airlines requested that the Applicability of this AD be limited to CFM56-7B engines with engine S/Ns listed in Appendix A of CFM SB No. CFM56-7B S/B 72-0964 and CFM56-7B engines that have the 73-tooth gearshafts listed in Appendix B of CFM SB No. CFM56-7B S/B 72-0964 installed post-production. Sun Country Airlines noted that the applicability of the NPRM (80 FR 24856, May 1, 2015) could be misconstrued to mean to include all CFM56-7B engines unless it is proven that they do not have the affected 73-tooth or 41-tooth gearshafts.

We disagree. CFM identified the affected population of gearshafts by gearshaft S/N and by the engine S/N on which it was installed. However, an affected gearshaft may now be installed on an engine with an S/N not listed in Appendix A. To address the latter population, those engines with a gearshaft that has been installed on an unknown engine, we identified the affected population of 73-tooth and 41-tooth gearshafts by gearshaft part number and S/N. We did not change this AD.

Request To Clarify That Applicability Is by Gearshaft Serial Number

Delta Air Lines (Delta) requested that we clarify that the applicability of the AD is by gearshaft S/N rather than by engine S/N.

We agree. We revised the Applicability paragraph of this AD to read: “This AD applies to all CFM International S.A. (CFM) CFM56-7B and CFM56-3 engines with a 73-tooth or 41-tooth gearshaft installed in the accessory gearbox (AGB), that has a gearshaft serial number in Appendix A

or Appendix B of CFM Service Bulletin (SB) No. CFM56-7B S/B 72-0964, Revision 1, dated December 15, 2014.”

Request To Verify Affected Gearshafts Have Been Removed From Service and Reduce the Scope of Applicability

Delta requested that we verify which gearshafts have been removed from service per the proposed requirements of the NPRM (80 FR 24856, May 1, 2015). Delta further asked that we reduce the applicability to only those affected gearshafts that remain in service.

We disagree. This AD will ensure that all affected gearshafts are removed from service and that gearshafts already removed from service are not returned to service. We did not change this AD.

Support for the NPRM

The Boeing Company and an anonymous commenter expressed support for the NPRM (80 FR 24856, May 1, 2015) as proposed.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed CFM SB No. CFM56-7B S/B 72-0964, Revision 1, dated December 15, 2014. The service information describes procedures for removal of affected 73-tooth and 41-tooth gearshafts. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this AD.

Costs of Compliance

We estimate that this AD will affect about 67 engines installed on airplanes of U.S. registry. We also estimate that it will take about 1 hour per engine to do the inspection and 8 hours per engine to replace each affected gearshaft. We estimate thirty-six 73-tooth gearshafts and forty 41-tooth gearshafts will need replacement at a cost of \$12,480 and \$7,680 per part, respectively. The average labor rate is \$85 per hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$813,855.

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

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),
- (3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and
- (4) 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.

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 airworthiness directive (AD):

2015-18-04 CFM International S.A.:

Amendment 39-18262; Docket No. FAA-2015-0277; Directorate Identifier 2015-NE-05-AD.

(a) Effective Date

This AD is effective October 20, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to CFM International S.A. (CFM) CFM56-7B and CFM56-3 engines with a 73-tooth or 41-tooth gearshaft installed in the accessory gearbox (AGB), that has a gearshaft serial number in Appendix A or Appendix B of CFM Service Bulletin (SB) No. CFM56-7B S/B 72-0964, Revision 1, dated December 15, 2014.

(d) Unsafe Condition

This AD was prompted by a report of an uncommanded in-flight shutdown on a CFM CFM56-7B engine following rupture of the 73-tooth gearshaft located in the engine AGB. We are issuing this AD to prevent failure of certain AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Initial AGB/Transfer Gearbox (TGB)/Magnetic Chip Detector (MCD) Inspection and Analysis

(i) For affected 73-tooth gearshafts, perform an AGB/TGB MCD inspection within 250 flight hours (FHs) since last inspection, within 25 FHs from the effective date of this AD, or when the gearshaft accumulates 3,000 FHs since new, whichever comes later.

(ii) For affected 41-tooth gearshafts, perform an AGB/TGB MCD inspection within 250 FHs since last inspection, within 25 FHs from the effective date of this AD, or when the gearshaft accumulates 6,000 FHs since new, whichever comes later.

(iii) If any magnetic particles, including fuzz, are seen, determine with laboratory analysis if the particles are 73-tooth or 41-tooth gearshaft material.

(iv) If the particles are 73-tooth or 41-tooth gearshaft material, remove the affected gearshaft(s) within 75 FHs since the AGB/TGB MCD inspection.

(2) Repetitive AGB/TGB MCD Inspection and Analysis

(i) For affected 73-tooth gearshafts, perform an AGB/TGB MCD inspection and laboratory analysis within every 500 FHs since the last AGB/TGB MCD inspection until affected gearshaft is removed.

(ii) For affected 41-tooth gearshafts, perform an AGB/TGB MCD inspection and laboratory analysis within every 500 FHs since the last AGB/TGB MCD inspection until affected gearshaft is removed.

(iii) If any magnetic particles, including fuzz, are seen, determine with laboratory analysis if the particles are 73-tooth or 41-tooth gearshaft material.

(iv) If the particles are 73-tooth or 41-tooth gearshaft material, remove the affected gearshaft(s) within 75 FHs since the AGB/TGB MCD inspection.

(f) Mandatory Terminating Action

(1) Remove the affected 73-tooth gearshaft prior to the gearshaft accumulating 6,000 FHs since new or within 50 FHs after the effective date of this AD, whichever comes later.

(2) Remove the affected 41-tooth gearshaft prior to the gearshaft accumulating 9,000 FHs since new or within 50 FHs after the effective date of this AD, whichever comes later.

(g) Installation Prohibition

After the effective date of this AD, do not install an affected gearshaft into an AGB.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: ANE-AD-AMOC@faa.gov.

(i) Related Information

For more information about this AD, contact Kyle Gustafson, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7183; fax: 781-238-7199; email: kyle.gustafson@faa.gov.

(j) Material Incorporated by Reference

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

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on October 20, 2015.

(i) CFM International Service Bulletin No. CFM56-7B S/B 72-0964, Revision 1, dated December 15, 2014.

(ii) Reserved.

(4) For CFM service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877-432-3272; fax: 877-432-3329; email: aviation.fleetsupport@ge.com.

(5) You may view this service information at FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

(6) You may view this service information 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/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on August 28, 2015.

Ann C. Mollica,

Acting Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015-22598 Filed 9-14-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 1**

[Docket No. FDA-2014-N-0504]

RIN 0910-AH12

Administrative Destruction of Certain Drugs Refused Admission to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is implementing its authority to destroy a drug valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), by issuing a rule that provides to the owner or consignee notice and an opportunity to appear and introduce testimony to the Agency prior to destruction. This regulation is authorized by amendments made to the FD&C Act by the Food and Drug Administration Safety and Innovation Act (FDASIA). Implementation of this authority will allow FDA to better protect the public health by providing an administrative process for the destruction of certain refused drugs, thus increasing the integrity of the drug supply chain.

DATES: This rule is effective October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4338, Silver Spring, MD 20993-0002, 301-796-3324, FDASIAImplementationORA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**Executive Summary***Purpose of the Regulatory Action*

Implementation of FDA's administrative destruction authority will better protect the integrity of the