

(a) A laboratory will be refused accreditation for failure to meet the requirements of § 439.5 or § 439.10 of this chapter.

(b) A laboratory will be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analytes, all official samples that have not been analyzed as of the notification of a loss of accreditation.

(c) A laboratory will be refused accreditation for the reasons described in § 439.60 of this chapter.

§ 439.51 Probation of accreditation.

Upon a determination by the Administrator, a laboratory will be placed on probation for the following reasons:

(a) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis as required by § 439.20(d) of this part within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this chapter.

§ 439.52 Suspension of accreditation.

The accreditation of a laboratory will be suspended for the reasons described in § 439.60 of this chapter.

§ 439.53 Revocation of accreditation.

The accreditation of a laboratory will be revoked for the following reasons:

(a) An accredited laboratory that is accredited to perform analysis under §§ 439.5, 439.10 and 439.20 of this chapter will have its accreditation revoked for failure to meet any of the requirements of § 439.20 of this chapter, except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this chapter and it has not failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has failed at any time during those 12 months, its accreditation will be revoked.

(b) An accredited laboratory will have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(1) Altered any official sample or analytical finding; or

(2) Substituted any analytical result from any other laboratory and represented the result as its own.

(c) An accredited laboratory will have its accreditation revoked for violations

of law as described in § 439.60 of this chapter.

§ 439.60 Violations of law.

An applicant or an accredited laboratory will have its accreditation refused, suspended, or revoked, as appropriate, if the laboratory or any individual or entity responsibly connected with the laboratory is convicted of, or is under indictment for, or has had charges on an information brought against them in a Federal or State court concerning any of the following violations of law:

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(c) Any misdemeanor based upon a false statement to any governmental agency.

(d) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.70 Notification and hearings.

Accreditation of any laboratory will be refused, suspended, or revoked under the conditions previously described in this Part 439. The owner or operator of the laboratory will be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing will be granted if there is any dispute of material fact joined in such responsive statement. The proceeding will be conducted thereafter in accordance with the applicable rules of practice which will be adopted for the proceeding. Any such refusal, suspension, or revocation will be effective upon the receipt by the laboratory of the notification and will continue in effect until final determination of the matter by the Administrator.

Done in Washington, DC, on January 9, 2006.

Barbara J. Masters,
Administrator.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003-NE-21-AD]

RIN 2120-AA64

Airworthiness Directives; International Aero Engines AG (IAE) V2522-A5, V2524-A5, V2527-A5, V2527E-A5, V2527M-A5, V2530-A5, and V2533-A5 Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: This notice revises an earlier proposed airworthiness directive (AD) that applies to certain IAE V2522-A5, V2524-A5, V2527-A5, V2527E-A5, V2527M-A5, V2530-A5, and V2533-A5 turbofan engines. That proposal would have required initial and repetitive inspections of the master magnetic chip detector (MCD) or the No. 1, 2, 3 bearing chamber MCD. That proposal would also have required replacing certain No. 3 bearings and replacing or recoating certain high pressure compressor (HPC) stubshaft assemblies as mandatory terminating actions to the repetitive MCD inspections. That proposal resulted from IAE developing a terminating action to the repetitive inspections of the chip detectors. This action revises the proposed rule by expanding its applicability to include additional serial-numbered engines with certain No. 3 bearings installed. We are proposing this AD to prevent failure of the No. 3 bearing, which could result in an in-flight shutdown (IFSD) and smoke in the cockpit and cabin.

DATES: We must receive comments by March 20, 2006.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

- By mail: Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003-NE-21-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

- By fax: (781) 238-7055.

- By e-mail: 9-ane-adcomment@faa.gov.

You can get the service information identified in this proposed AD from International Aero Engines AG, 400 Main Street, East Hartford, CT 06108; telephone: (860) 565-5515; fax: (860) 565-5510.

You may examine the AD docket, by appointment, at the FAA, New England

Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: James Rosa, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238-7152; fax (781) 238-7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES**. Include "AD Docket No. 2003-NE-21-AD" in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it; we will date-stamp your postcard and mail it back to you. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. If a person contacts us verbally, and that contact relates to a substantive part of this proposed AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Discussion

On September 11, 2003, we issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD) to apply to International Aero Engines AG IAE V2522-A5, V2524-A5, V2527-A5, V2527E-A5, V2527M-A5, V2530-A5, and V2533-A5 turbofan engines. The Office of the **Federal Register** published that proposal as a notice of proposed rulemaking (NPRM) supersedure in the **Federal Register** on September 17, 2003 (68 FR 54400). That NPRM would have required initial and repetitive inspections of the master magnetic chip detector (MCD) or the No. 1, 2, 3 bearing chamber MCD. Additionally, it would have required replacing certain No. 3 bearings and replacing or recoating certain HPC stubshaft assemblies as mandatory terminating actions to the repetitive MCD inspections. That NPRM

resulted from IAE developing a terminating action to the repetitive chip detector inspections. That condition, if not corrected, could result in failure of the No. 3 bearing, which could result in an IFSD and smoke in the cockpit and cabin.

Since we issued that NPRM, we have received reports that more engines experienced No. 3 bearing failures attributed to ball spalling and race fracture. A total of 55 failures of the No. 3 bearing have occurred. Of the 55 failures, 12 resulted in IFSDs and 43 resulted in unscheduled engine removals (UER). Of the 12 IFSDs, three were associated with smoke in the cabin and cockpit. The smoke is a result of the ball spalling and race fracture of failed No. 3 bearings, P/N 2A1165, and occurs when there is hard particle contamination in the oil system. The release of coating particles on HPC stubshafts with low-energy plasma coating causes the contamination. The problem exists on certain No. 3 bearings, P/N 2A1165, that are less tolerant to damage from this contamination. As a result of these failures, we have added additional serial-numbered engines to this Supplemental NPRM. Since this change expands the scope of the originally proposed rule, we determined that it is necessary to reopen the comment period to provide additional opportunity for public comment. Also, since we issued that NPRM, IAE discovered that some of the original population of engines are not at risk for No. 3 ball bearing failure, so even though we are adding at least 100 engine SNs to this proposed AD, the number of engines listed in the Costs of Compliance is smaller.

Manufacturer's Service Information

We have reviewed and approved the technical contents of IAE SB V-2500-ENG-72-0452, Revision 3, dated March 4, 2005, that describes procedures for MCD inspections for engines in the range V10600 to V11365 with No. 3 bearing, P/N 2A1165, installed. We have also reviewed and approved the technical contents of IAE SB V-2500-ENG-72-0459, Revision 2, dated March 4, 2005, that describes procedures for in shop action for engines in the range V10600 to V11365 with No. 3 bearing, P/N 2A1165, installed.

FAA's Determination of an Unsafe Condition and Proposed Actions

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. Therefore, we are

proposing this AD, which would require:

- Initial inspection of the master MCD or the No. 1, 2, 3 bearing chamber MCD within 125 hours time-in-service (TIS) after the effective date of the proposed AD; and
- Repetitive inspections of the master MCD or the No. 1, 2, 3 bearing chamber MCD within 125 hours time-since-last inspection; and
- Replacement of the No. 3 bearing, P/N 2A1165, at the next shop visit for any reason; and
- Replacement of HPC stubshafts that have a low-energy plasma coating with HPC stubshafts that have a high-energy plasma coating.

Costs of Compliance

We estimate that this proposed AD would affect 123 engines installed on airplanes of U.S. registry. We also estimate it would take 150 work hours per engine to perform the proposed actions, and that the average labor rate is \$65 per work hour. Required parts would cost about \$33,788 per engine. Based on these figures, we estimate the total cost of the proposed AD to U.S. operators to be \$5,355,174.

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 Analysis

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 the proposed regulation:

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. Would 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 summary of the costs to comply with this proposal and placed it in the AD Docket. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. Section 39.13 is amended by removing Amendment 39–13183 (68 FR 33621, June 5, 2003) and by adding the following new airworthiness directive:

International Aero Engines AG (IAE): Docket No. 2003–NE–21–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by March 20, 2006.

Affected ADs

(b) This AD supersedes AD 2003–11–23, Amendment 39–13183.

Applicability

(c) This AD applies to International Aero Engines AG (IAE) V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 turbofan engines with engine serial numbers V10600 through V11365 and bearings P/N 2A1165 installed. These engines are installed on, but not limited to, Airbus Industrie A319, A320, and A321 series airplanes.

Unsafe Condition

(d) This AD results from reports of No. 3 bearing failures that caused in-flight shutdown (IFSD) and smoke in the cockpit and cabin. We are issuing this AD to prevent failure of the No. 3 bearing, which could result in an IFSD and smoke in the cockpit and cabin.

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 of the Master Magnetic Chip Detector (MCD) or the No. 1, 2, 3 Bearing Chamber MCD

(f) For engines listed in Appendix 1, Tables 1 and 2 of IAE service bulletin (SB) V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, and that have a No. 3 bearing, part number (P/N) 2A1165, installed at new production build, do the following:

(1) Within 125 hours time-in-service (TIS) after the effective date of this AD, inspect the master MCD or the No. 1, 2, 3 bearing chamber MCD.

(2) Thereafter, within 125 hours time-since-last inspection, inspect the master MCD or the No. 1, 2, 3 bearing chamber MCD.

(3) If you find bearing material on the master MCD or No. 1, 2, 3 bearing chamber MCD, replace the engine before further flight.

Replacement of No. 3 Bearing

(g) For engines listed in Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that have a serial number (SN) from V10600 through V11365 inclusive, and that have a No. 3 bearing, part number (P/N) 2A1165, installed at new production, replace the No. 3 bearing at the next shop visit for any reason.

(h) After the effective date of this AD, do not install any No. 3 bearing, P/N 2A1165, removed in paragraph (g) of this AD, into any engine.

Replacement or Rework of High Pressure Compressor (HPC) Stubshaft

(i) For engines listed in Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that have a SN from V10600 through V11365 inclusive, at the next shop visit for any reason, replace the HPC stubshaft that has a low-energy plasma coating with an HPC stubshaft that has a high-energy plasma coating.

Terminating Action

(j) Performing the requirements specified in paragraphs (g) and (i) of this AD is terminating action to the repetitive MCD inspections specified in paragraph (f)(1) through (f)(3) of this AD.

Alternative Methods of Compliance (AMOCs)

(k) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(l) For lists identifying engines within the engine SN range of V10600 to V11365 inclusive, known to have had P/N 2A1165 installed, you must use Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, and IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005.

Related Information

(m) The following service bulletins contain additional information and procedures:

(1) You can find information on inspecting the master MCD and the No. 1, 2, 3 bearing chamber MCD in section 79–00–00–601 of the Aircraft Maintenance Manual.

(2) Additional information on inspection procedures is included in IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005.

(3) You can find information on replacing the No. 3 bearing, and replacing or recoating the HPC stubshaft in IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005.

Issued in Burlington, Massachusetts, on January 9, 2006.

Peter A. White,

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

[FR Doc. E6–379 Filed 1–13–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. 2001N–0322 (formerly 01N–0322)]

Institutional Review Boards: Requiring Sponsors and Investigators to Inform Institutional Review Boards of Any Prior Institutional Review Board Reviews; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of an advance notice of proposed rulemaking (ANPRM) entitled "Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews" that published in the **Federal Register** of March 6, 2002 (67 FR 10115).

DATES: The ANPRM is withdrawn February 16, 2006.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C24, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: In 1998, the Department of Health and Human Services, Office of the Inspector General (OIG) issued several reports on institutional review boards (IRBs). The OIG sought to identify the challenges facing IRBs and to make recommendations on improving Federal