

(4) One or more adverse events.

\* \* \* \* \*

## PART 116—RECORDS AND REPORTS

■ 3. The authority citation for part 116 continues to read as follows:

**Authority:** 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 4. In § 116.1, paragraph (a)(3) is revised to read as follows:

### § 116.1 Applicability and general considerations.

(a) \* \* \*

(3) Records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer, as the case may be, before any portion of a serial of any product may be marketed in the United States or exported.

\* \* \* \* \*

■ 5. Section 116.8 is revised to read as follows:

### § 116.8 Completion and retention of records.

All records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records must be retained at the licensed or foreign establishment or permittee's place of business for a period of 2 years after the expiration date of a product or longer as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

■ 6. Section 116.9 is added to read as follows:

### § 116.9 Recording and reporting adverse events.

(a) Licensees and permittees must maintain a detailed record for every adverse event report the licensee or permittee receives for any biological product it produces or distributes. These records shall be maintained for a period of 3 years after the date the adverse event report is received. The adverse event report form and guidance on how to complete it, including guidance specific to the various information blocks on the form, is available on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics> or by writing to APHIS Center for Veterinary Biologics, 1920 Dayton Avenue, P.O. Box 844, Ames, Iowa 50010.

(b) A report of all adverse events reports received by a licensee or permittee must be compiled and submitted to the Animal and Plant Health Inspection Service. The frequency of report submission is as follows:

(1) Immediate notification is required if at any time there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product.

(2) Adverse event reports determined by the licensee or permittee to be product-related, serious, and unexpected must also be reported immediately.

(3) All other adverse event reports must be reported within 90 calendar days of the date the report was first received.

(Approved by the Office of Management and Budget under control number 0579–0209)

Done in Washington, DC, this 11th day of May 2018.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2018–10540 Filed 5–16–18; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA–2018–0443; Product Identifier 2018–NE–14–AD; Amendment 39–19286; AD 2018–10–11]**

**RIN 2120–AA64**

### Airworthiness Directives; CFM International S.A. Turbofan Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** We are superseding Airworthiness Directive (AD) 2018–09–10 for all CFM International S.A. (CFM) Model CFM56–7B engines. AD 2018–09–10 required initial and repetitive inspections of the concave and convex sides of the fan blade dovetail to detect cracking and replacement of any blades found cracked. This AD requires the same initial and repetitive inspections but revises the compliance time for the initial inspections of certain higher-risk fan blades. This AD was prompted by a recent engine failure due to a fractured fan blade that resulted in the engine inlet cowl disintegrating and debris

penetrating the fuselage, causing a loss of pressurization, and prompting an emergency descent. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective June 1, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 1, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of May 14, 2018 (83 FR 19176, May 2, 2018).

We must receive any comments on this AD by July 2, 2018.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

- *Fax:* 202–493–2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, 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](mailto:aviation.fleetsupport@ge.com). You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2018–0443.

### 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–2018–0443; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–

5527) is listed above. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Christopher McGuire, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7120; fax: 781-238-7199; email: [chris.mcguire@faa.gov](mailto:chris.mcguire@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued AD 2018-09-10, Amendment 39-19267 (83 FR 19176, May 2, 2018), (“AD 2018-09-10”), for all CFM model CFM56-7B engines. AD 2018-09-10 required initial and repetitive inspections of the concave and convex sides of the fan blade dovetail to detect cracking and replacement of any blades found cracked. AD 2018-09-10 resulted from a recent event involving an engine failure due to a fractured fan blade leading to the engine inlet cowl disintegrating and debris penetrating the fuselage, causing a loss of pressurization and prompting an emergency descent. One passenger fatality occurred as a result. We issued AD 2018-09-10 to prevent failure of the fan blade due to cracking, which could lead to an engine in-flight shutdown (IFSD), uncontained release of debris, damage to the airplane, and possible airplane decompression.

**Actions Since AD 2018-09-10 Was Issued**

Since we issued AD 2018-09-10, an investigation of this event has determined new methods for identifying applicable parts as well as the need to reduce the compliance time for certain fan blades. Therefore, this AD requires inspection of higher risk fan blades, identified using one of the methods in CFM Service Bulletin (SB) CFM56-7B S/B 72-1033, Revision 01, dated May 9, 2018, within 30 days from the effective date of the AD. The remaining fan blades must be inspected within 90 days from the effective date of the AD or prior to accumulating 20,000 flight cycles. We are issuing this AD to address the unsafe condition on these products.

**Related Service Information Under 1 CFR Part 51**

We reviewed CFM SB CFM56-7B S/B 72-1033, Revision 01, dated May 9, 2018, and Subtask 72-21-01-220-091, of Task 72-21-01-200-001, from the CFM56-7B Engine Shop Manual (ESM), Revision 57, dated January 15, 2018. CFM SB CFM56-7B S/B 72-1033, Revision 01, describes procedures for performing an ultrasonic inspection (USI) of the affected fan blades. Subtask 72-21-01-220-091, of Task 72-21-01-200-001, from the CFM56-7B ESM, describes procedures for performing an eddy current inspection (ECI) of the affected fan blades. 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.

**Other Related Service Information**

We also reviewed CFM SB CFM56-7B S/B 72-1019, dated March 24, 2017, and Revision 1, dated June 13, 2017; CFM SB CFM56-7B S/B 72-1024, dated July 26, 2017; and CFM SB CFM56-7B S/B 72-1033, dated April 20, 2018, and General Electric Field Support Technology (FST) procedure 2370, dated December 9, 2016. These SBs and the FST provide information on performing the USI.

**FAA’s Determination**

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

**AD Requirements**

This AD requires initial and repetitive ultrasonic or eddy current inspection of certain fan blades and, if they fail the inspection, their replacement with parts eligible for installation.

**FAA’s Justification and Determination of the Effective Date**

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption.

The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because certain fan blades must be inspected, and, if needed, replaced before further flight. Failure to inspect and replace these parts within the required compliance times could lead to failure of the fan blades, engine IFSD, uncontained release of debris, damage to the airplane, and possible airplane decompression. Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, we find that good cause exists for making this amendment effective in less than 30 days.

**Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA-2018-0443 and product identifier 2018-NE-14-AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the closing date and may amend this final rule because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this final rule.

**Costs of Compliance**

We estimate that this AD affects 3,716 engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect engine fan blade .....	2 work-hours × \$85 per hour = \$170 .....	\$0	\$170	\$631,720

We estimate the following costs to do any necessary replacements that would

be required based on the results of the inspection. We have no way of

determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace fan blade .....	1 work-hour × \$85 per hour = \$85 .....	\$8,500	\$8,585

**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, 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 part 39 of the Federal Aviation Regulations (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 removing Airworthiness Directive (AD) 2018–09–10, Amendment 39–19267 (83 FR 19176, May 2, 2018) and adding the following new AD:

**2018–10–11 CFM International S.A.:**  
Amendment 39–19286; Docket No. FAA–2018–0443; Product Identifier 2018–NE–14–AD.

**(a) Effective Date**

This AD is effective June 1, 2018.

**(b) Affected ADs**

This AD replaces AD 2018–09–10, Amendment 39–19267 (83 FR 19176, May 2, 2018).

**(c) Applicability**

This AD applies to CFM International S.A. (CFM) CFM56–7B20, CFM56–7B22, CFM56–7B22/B1, CFM56–7B24, CFM56–7B24/B1, CFM56–7B26, CFM56–7B26/B2, CFM56–7B27, CFM56–7B27A, CFM56–7B26/B1, CFM56–7B27/B1, CFM56–7B27/B3, CFM56–7B20/2, CFM56–7B22/2, CFM56–7B24/2, CFM56–7B26/2, CFM56–7B27/2, CFM56–7B20/3, CFM56–7B22/3, CFM56–7B22/3B1, CFM56–7B24/3, CFM56–7B24/3B1, CFM56–7B26/3, CFM56–7B26/3B1, CFM56–7B26/3B2, CFM56–7B27/3, CFM56–7B27/3B1, CFM56–7B27/3B3, CFM56–7B27A/3, CFM56–7B26/3F, CFM56–7B26/3B2F, CFM56–7B27/3F, CFM56–7B27/3B1F, CFM56–7B20E, CFM56–7B22E, CFM56–7B22E/B1, CFM56–7B24E, CFM56–7B24E/B1, CFM56–7B26E, CFM56–7B26E/B1, CFM56–7B26E/B2, CFM56–7B27AE, CFM56–7B27E, CFM56–7B27E/B1, CFM56–7B27E/B3, CFM56–7B26E/F, CFM56–7B26E/B2F, CFM56–7B27E/F, and CFM56–7B27E/B1F engine models.

**(d) Subject**

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

**(e) Unsafe Condition**

This AD was prompted by a recent engine failure due to a fan blade fracture leading to the engine inlet cowl disintegrating and debris penetrating the fuselage, causing a loss of pressurization, and prompting an emergency descent. One passenger fatality occurred as a result. We are issuing this AD to prevent failure of the fan blade. The unsafe condition, if not addressed, could result in

failure of the fan blade, the engine inlet cowl disintegrating and debris penetrating the fuselage, causing a loss of pressurization, and prompting an emergency descent.

**(f) Compliance**

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

**(g) Required Actions**

(1) Perform an ultrasonic inspection (USI) or eddy current inspection (ECI) of the concave and convex sides of the fan blade dovetail as follows:

(i) Within 30 days after the effective date of this AD, perform an initial inspection of the fan blades identified using the criteria in Planning Information, either paragraph 1.C.2.(a), 1.C.2.(b), or 1.C.2.(c), of CFM Service Bulletin (SB) CFM56–7B S/B 72–1033, Revision 01, dated May 9, 2018.

(ii) For all fan blades not inspected in accordance with paragraph (g)(1)(i) of this AD, perform an initial inspection prior to accumulating 20,000 flight cycles on the fan blade or within 90 days from the effective date of this AD, whichever occurs later.

(iii) Thereafter, repeat this inspection no later than 3,000 cycles since the last inspection.

(iv) Use the Accomplishment Instructions, paragraphs 3.A.(3)(a) through (i), of CFM SB CFM56–7B S/B 72–1033, Revision 01, dated May 9, 2018, to perform a USI or use the instructions in Subtask 72–21–01–220–091, of Task 72–21–01–200–001, from CFM CFM56–7B Engine Shop Manual, Revision 57, dated January 15, 2018, to perform an ECI.

(2) If any unserviceable indication, as specified in the applicable service information in paragraph (g)(1)(iv) of this AD, is found during the inspections required by paragraph (g) of this AD, replace the fan blade before further flight with a part eligible for installation.

**(h) Installation Prohibition**

Do not install any replacement fan blade unless it meets one of the following criteria:

- (1) The replacement fan blade has fewer than 20,000 cycles since new, or;
- (2) The replacement fan blade has been inspected in accordance with paragraph (g) of this AD.

**(i) Definition**

For the purpose of this AD, a “replacement fan blade” is a fan blade that is being installed into an engine from which it was not previously removed. Removing and reinstalling a fan blade for the purpose of relubrication is not subject to the Installation Prohibition of this AD.

**(j) Credit for Previous Actions**

(1) You may take credit for the USI required by paragraph (g) of this AD, if those

actions were performed before the effective date of this AD using CFM SB CFM56-7B S/B 72-1019, dated March 24, 2017; or Revision 1, dated June 13, 2017; or CFM SB CFM56-7B S/B 72-1024, dated July 26, 2017; CFM SB CFM56-7B S/B 72-1033, dated April 20, 2018; or General Electric Field Support Technology procedure 2370, dated December 9, 2016.

(2) You may take credit for an ECI using the instructions in Subtask 72-21-01-220-091, of Task 72-21-01-200-001, from the CFM56-7B Engine Shop Manual, earlier than Revision 57, dated January 15, 2018.

#### (k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l) of this AD. You may email your request to: [ANE-AD-AMOC@faa.gov](mailto:ANE-AD-AMOC@faa.gov).

(2) 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.

(3) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(3)(i) and (k)(3)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (l) Related Information

For more information about this AD, contact Christopher McGuire, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7120; fax: 781-238-7199; email: [chris.mcguire@faa.gov](mailto:chris.mcguire@faa.gov).

#### (m) 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 June 1, 2018.

(i) CFM Service Bulletin (SB) CFM56-7B S/B 72-1033, Revision 01, dated May 9, 2018.

(ii) Reserved.

(4) The following service information was approved for IBR on May 14, 2018 (83 FR 19176, May 2, 2018).

(i) Subtask 72-21-01-220-091, of Task 72-21-01-200-001, from the CFM CFM56-7B Engine Shop Manual, Revision 57, dated January 15, 2018.

(ii) Reserved.

(5) 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](mailto:aviation.fleetsupport@ge.com).

(6) You may view this service information at the FAA, Engine and Propeller Standards Branch, Policy and Innovation Division, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7759.

(7) You may view this 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/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on May 15, 2018.

**Robert J. Ganley,**

*Manager, Engine & Propeller Standards Branch, Aircraft Certification Service.*

[FR Doc. 2018-10657 Filed 5-16-18; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2017-1089; Airspace Docket No. 17-AEA-21]

RIN 2120-AA66

#### Amendment of Class E Airspace; Hamilton, NY

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends Class E airspace extending upward from 700 feet or more above the surface at Hamilton Municipal Airport (formerly Elisha Payne Airport), Hamilton, NY, to accommodate airspace reconfiguration due to the decommissioning of the Georgetown VHF omni-directional radio range tactical air navigation aid (VORTAC), and cancellation of the VORTAC approach. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport. This action also updates the geographic coordinates of the airport, and updates the airport name.

**DATES:** Effective 0901 UTC, July 19, 2018. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

**ADDRESSES:** FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at [http://www.faa.gov/air\\_traffic/publications/](http://www.faa.gov/air_traffic/publications/). For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741-6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Av, College Park, GA 30337; telephone (404) 305-6364.

#### SUPPLEMENTARY INFORMATION:

##### Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Hamilton Municipal Airport, Hamilton, NY, to support IFR operations at the airport.

##### History

The FAA published a notice of proposed rulemaking in the **Federal Register** for Docket No. FAA-2017-1089 (83 FR 5748, February 9, 2018) proposing to amend Class E airspace extending upward from 700 feet or more