

the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (j)(4)(i) and (j)(4)(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.

(k) Related Information

(1) For more information about this AD, contact Gaetano Settineri, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6577; fax: 425-917-6590; email: gaetano.settineri@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on April 28, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-10634 Filed 5-9-16; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2016-5872; Directorate Identifier 2016-NE-11-AD]

RIN 2120-AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all General Electric Company (GE) GENx-1B64/P2, -1B67/P2, -1B70/P2, -1B70C/

P2, -1B70/75/P2, and -1B74/75/P2 turbofan engines with engine assembly, part number (P/N) 2447M10G01 or P/N 2447M10G02, installed. This proposed AD was prompted by a report of a significant fan rub event. This proposed AD would require rework of the engine fan stator module assembly. We are proposing this AD to prevent failure of the fan blades and the load reduction device, loss of power to one or more engines, loss of thrust control, and loss of the airplane.

DATES: We must receive comments on this proposed AD by July 11, 2016.

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:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513-552-3272; email: aviation.fleetssupport@ge.com. You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7125.

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-2016-5872; 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7120; fax: 781-238-7199; email: chris.mcguire@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5872; Directorate Identifier 2016-NE-11-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM 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 NPRM.

Discussion

We received a report of a significant fan rub event involving a GE GENx-1B Performance Improvement Program 2 (PIP2) engine. The fan rub was caused by partial fan ice shedding. Asymmetric ice shedding can cause large fan imbalances leading to heavy tip rubs. The fan case geometry on PIP2 engines makes these engines susceptible to heavy fan tip rubs. This can cause substantial damage to the engine and an in-flight non-restartable power loss. We are using calendar time for compliance in this AD because the failure mode is caused by exposure to specific environmental and operational conditions. This defines the overall fleet risk in terms of calendar time, rather than engine cycles or hours.

This condition, if not corrected, could result in failure of the fan blades and the load reduction device, loss of power to one or more engines, loss of thrust control, and loss of the airplane.

Related Service Information Under 14 CFR Part 51

We reviewed GE GENx-1B Service Bulletin (SB) 72-0314 R00, dated April 1, 2016. The SB describes procedures for increasing the clearance of the fan stator module assembly. 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.

FAA's Determination

We are proposing this NPRM 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.

Proposed AD Requirements

This NPRM would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD will affect 89 engines installed on airplanes of U.S. registry. We also estimate that it will take about 40 hours per engine to comply with this proposed AD. The average labor rate is \$85 per hour. Based on these figures, we estimate the total cost of this proposed AD to U.S. operators to be \$302,600.

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 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 this 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),
- (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.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

General Electric Company: Docket No. FAA-2016-5872; Directorate Identifier 2016-NE-11-AD.

(a) Comments Due Date

We must receive comments by July 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all General Electric Company (GE) GENx-1B64/P2, -1B67/P2, -1B70/P2, -1B70C/P2, -1B70/75/P2, and -1B74/75/P2 turbofan engines with engine assembly, part number (P/N) 2447M10G01 or P/N 2447M10G02, installed.

(d) Unsafe Condition

This AD was prompted by a report of a significant fan rub event. We are issuing this AD to prevent failure of the fan blades and the load reduction device, loss of power to one or more engines, loss of thrust control, and loss of the airplane.

(e) Compliance

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

(1) Modify the fan stator module assembly before December 31, 2016.

(2) Use paragraphs 3.B.(1) through 3.B.(6) or 3.C.(1) through 3.C.(6) of the Accomplishment Instructions of GE GENx-1B Service Bulletin (SB) 72-0314 R00, dated April 1, 2016, to do the modification.

(f) Credit for Previous Action

You may take credit for the fan stator module assembly modification that is required by paragraph (e) of this AD if you performed the modification before the effective date of this AD using the Accomplishment Instructions, paragraphs 3.B. or 3.C., of GE GENx-1B SB 72-0309 R00, dated March 11, 2016.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to 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.

(h) Related Information

(1) For more information about this AD, contact Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7120; fax: 781-238-7199; email: chris.mcguire@faa.gov.

(2) AD 2016-06-08 (81 FR 14704, March 18, 2016) and AD 2016-08-12 (81 FR 23581, April 22, 2016) pertain to the subject of this proposed AD.

(3) GE GENx-1B SB 72-0314 R00, dated April 1, 2016 can be obtained from GE using the contact information in paragraph (h)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513-552-3272; email: aviation.fleetsupport@ge.com.

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

Issued in Burlington, Massachusetts, on May 3, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016-10781 Filed 5-9-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2015-D-2325]

Tobacco Product Master Files; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Tobacco Product Master Files." This guidance provides recommendations to industry on tobacco product master files (TPMFs). TPMFs are voluntary submissions used to permit the person that owns the TPMF to authorize other parties to rely on information in the TPMF to support a submission to FDA without the TPMF owner having to disclose that