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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0368; Product Identifier 2018-NE-12-AD; Amendment 39-19469; AD 2018-21-11]

RIN 2120-AA64

Airworthiness Directives; Pratt & Whitney Division (PW) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Pratt & Whitney Division (PW) PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines with a low-pressure compressor (LPC) fan hub, part number (P/N) 51B821 or P/N 52B521, installed. This AD was prompted by updated low-cycle fatigue analysis techniques that indicate certain LPC fan hubs could crack before their published life limit. This AD requires repetitive eddy current inspections (ECIs) and fluorescent penetrant inspections (FPIs) for cracks in certain LPC fan hubs and removal of LPC fan hubs from service that fail inspection. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 5, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 5, 2018.

ADDRESSES: For service information identified in this final rule, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06118; phone: 800-565-0140; fax: 860-565-5442. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. 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-2018-0368.

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-2018-0368; 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 address for Docket Operations (phone: 800-647-5527) is 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: Jo-Ann Theriault, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7105; fax: 781-238-7199; email: jo-ann.theriault@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 all PW PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines with an LPC fan hub, P/N 51B821 or P/N 52B521, installed. The NPRM published in the **Federal Register** on July 19, 2018 (83 FR 34070). The NPRM was prompted by updated low-cycle fatigue analysis techniques that indicate certain LPC fan hubs could crack before their published life limit. The NPRM proposed to require repetitive ECIs and FPIs of the LPC fan hub. We are issuing this AD to address the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Add Maximum Allowable Life

The Air Line Pilots Association requested that we specify a maximum

allowable life for the parts affected by this AD, in addition to the prescribed inspection interval, to ensure that the affected parts are not operated beyond a life limit in which it is likely that fatigue cracks will form.

We disagree. This AD intends to specify a new inspection interval to reduce the risk of a fan hub failure due to potential low-cycle fatigue cracking. We determined that repetitive inspections, in conjunction with existing life limits for the small population of affected parts, maintains an acceptable level of safety for the fleet. The life limits for the affected parts are given in the appropriate Engine Manual, Chapter 5, Airworthiness Limitations Section. Operators are responsible for complying with those life limits. We did not change this AD.

Request To Clarify FPI Instructions

All Nippon Airways requested clarification for performing the FPIs required by this AD. The instructions for performing ECIs are specified in PW Alert Service Bulletin (ASB) PW4G-112-A72-351, dated February 22, 2018, which is incorporated by reference by this AD; however, instructions for performing FPIs are not specified.

We disagree. FPI is an industry-standard inspection. Operators are permitted to use an FPI process that is equivalent to the FPI process conducted by the original equipment manufacturer. We are incorporating by reference the instructions for performing ECIs because ECI is not an industry standard practice. ECI requires procedures, tooling, acceptance, and rejection criteria that are specific to the part being inspected. We did not change this AD.

Request To Review Applicability

PW stated that this AD should apply to all PW PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines with LPC fan hub, P/N 51B821 or P/N 52B521, installed as of or after February 22, 2018.

We disagree. The unsafe condition is present for any LPC fan hub, P/N 51B521 or P/N 52B521, installed in PW PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines regardless of the installation date. This AD requires inspections of all applicable LPC fan hubs, P/N 51B521 or P/N 52B521, in service. We did not change this AD.

Clarification to Costs of Compliance

We determined that we were not clear that only one LPC fan hub might need replacing. We clarified this in our cost estimate.

Support for the AD

The Boeing Company expressed support for the NPRM as written.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed PW ASB PW4G-112-A72-351, dated February 22, 2018. The PW ASB describes procedures for performing LPC fan hub ECIs and FPIs. 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 reviewed PW PW4000 Series 112 Inch Turbofan Engines Cleaning, Inspection and Repair (CIR) Manual, P/N 51A750, Chapter/Section 72-31-07, Inspection/Check-02, Revision No. 77, dated July 15, 2018. The CIR Manual contains additional information regarding FPI and ECI of the LPC fan hub.

Costs of Compliance

We estimate that this AD affects 32 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
Inspection	40 work-hours × \$85 per hour = \$3,400	\$0	\$3,400	\$108,800

We estimate the following costs to do any necessary replacements that would be required based on the results of the

proposed inspection. We estimate that one engine will need this replacement and estimate the parts cost using a

prorated formula that takes the early removal of the life-limited part into account.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace the LPC fan hub (prorated part cost)	0 work-hours × \$85 per hour = \$0	\$288,000	\$288,000

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the

Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

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 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):

2018-21-11 Pratt & Whitney Division:
Amendment 39-19469; Docket No. FAA-2018-0368; Product Identifier 2018-NE-12-AD.

(a) Effective Date

This AD is effective December 5, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney Division (PW) PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines with low-pressure compressor (LPC) fan hub, part number (P/N) 51B821 or P/N 52B521, installed.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by low-cycle fatigue analysis techniques, updated by the engine manufacturer, which indicated certain LPC fan hubs could crack before their published life limit. We are issuing this AD to prevent failure of the LPC fan hub. The unsafe condition, if not addressed, could result in uncontained hub release, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) After the effective date of this AD, perform a fluorescent penetrant inspection (FPI) and an eddy current inspection (ECI) of the LPC fan hub the next time the engine is separated at the M-flange and the LPC fan hub has accumulated 2,000 or more flight cycles since the last FPI and ECI.

(2) Thereafter, perform an FPI and an ECI of the LPC fan hub every time the engine is separated at the M-flange and the LPC fan hub has accumulated 2,000 or more flight cycles since the last LPC fan hub ECI and FPI.

(3) Use the Accomplishment Instructions, Step No. 11, in PW Alert Service Bulletin PW4G-112-A72-351, dated February 22, 2018, to do the ECI.

(4) If a crack is found during the inspections required by paragraphs (g)(1) or (2) of this AD, remove the LPC fan hub from service before further flight and replace with a part eligible for installation.

(h) 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 (i) of this AD. You may email your request to: 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.

(i) Related Information

For more information about this AD, contact Jo-Ann Theriault, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7105; fax: 781-238-7199; email: jo-ann.theriault@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.

(i) Pratt & Whitney Division Alert Service Bulletin PW4G-112-A72-351, dated February 22, 2018.

(ii) [Reserved.]

(3) For service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06118; phone: 800-565-0140; fax: 860-565-5442.

(4) You may view this service information at FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7759.

(5) 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 October 25, 2018.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018-23712 Filed 10-30-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 73

[Docket No. FDA-2017-C-1951]

Termination of Listing of Color Additive Exempt From Certification; Lead Acetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to no longer provide for the use of lead acetate in cosmetics intended for coloring hair on the scalp because new

data available since lead acetate was permanently listed demonstrate that there is no longer a reasonable certainty of no harm from the use of this color additive. This action is in response to a color additive petition filed by the Environmental Defense Fund, Earthjustice, Environmental Working Group, Center for Environmental Health, Healthy Homes Collaborative, Health Justice Project of Loyola University Chicago School of Law, Breast Cancer Fund, Improving Kids' Environment, Consumers Union, Natural Resources Defense Council, Consumer Federation of America, Learning Disabilities Association, Maricel Maffini, and Howard Mielke.

DATES: This rule is effective December 3, 2018. See section XIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by November 30, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before November 30, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the