

Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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Federal Motor Carrier Safety Administration

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RIN 2105-AE80

Revisions to Civil Penalty Amounts

Correction

In rule document 2019-14101 beginning on page 37059 in the issue of Wednesday, July 31, 2019, make the following correction:

§ 222.11 [Amended]

■ On page 37073, in the second column, amendatory instruction 47c should read as follows:

c. Remove the dollar amount “\$113,894” and add in its place “\$116,766”.

[FR Doc. C1-2019-14101 Filed 10-28-19; 8:45 am]

BILLING CODE 1301-00-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2019-0843; Product Identifier 2019-NE-27-AD; Amendment 39-19777; AD 2019-21-11]

RIN 2120-AA64

Airworthiness Directives; Pratt & Whitney Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019-19-11 for certain Pratt & Whitney (PW) PW1519G, PW1521G, PW1521GA, PW1524G, PW1525G, PW1521G-3, PW1524G-3, PW1525G-3, PW1919G, PW1921G, PW1922G, PW1923G, and PW1923G-A model turbofan engines. AD 2019-19-11 required initial and repetitive inspections of the low-pressure compressor (LPC) inlet guide vane (IGV) and the LPC rotor 1 (R1) and, depending on the results of the inspections, possible replacement of the LPC. This AD requires the same inspection of the LPC R1 for cracks or damage, removes the inspection of the LPC IGV for proper alignment, and expands the applicability to certain additional PW turbofan engines. This AD also reduces the compliance time for these inspections for certain PW turbofan engines. This AD was prompted by recent findings of cracks in the LPC R1 and an additional in-flight failure of the LPC R1. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 29, 2019.

The FAA must receive any comments on this AD by December 13, 2019.

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 <https://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 Pratt & Whitney, 400 Main Street, East Hartford, CT 06118; phone: 800-565-0140; fax: 860-565-5442; email: help24@pw.utc.com; internet: <https://fleetcare.pw.utc.com>. 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 <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0843.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0843; 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 is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kevin M. Clark, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7088; fax: 781-238-7199; email: kevin.m.clark@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued AD 2019-19-11, Amendment 39-19747 (84 FR 50719,

September 26, 2019) (“AD 2019–19–11”), for certain PW PW1519G, PW1521G, PW1521GA, PW1524G, PW1525G, PW1521G–3, PW1524G–3, PW1525G–3, PW1919G, PW1921G, PW1922G, PW1923G, and PW1923G–A model turbofan engines. AD 2019–19–11 required initial and repetitive borescope inspections of the LPC IGV and the LPC R1 and, depending on the results of the inspections, possible replacement of the LPC. AD 2019–19–11 resulted from two in-flight shutdowns (IFSDs) that occurred as the result of failures of the LPC R1. The FAA issued AD 2019–19–11 to prevent failure of the LPC R1, which could result in uncontained release of the LPC R1, damage to the engine, damage to the airplane, and loss of control of the airplane.

Actions Since AD 2019–19–11 Was Issued

Since the FAA issued AD 2019–19–11, another LPC R1 failure occurred that resulted in an IFSD of the engine and diversion of the airplane. This failure occurred on an engine with more than 300 flight cycles since new (CSN) accumulated but fewer than 300 flight cycles with a certain version (v2.11.7 or v2.11.8) of electronic engine control (EEC) software installed. In addition, the inspections required by AD 2019–19–11 led to cracks being discovered in the LPC R1 on two other affected engines. These cracks were found on LPC R1s installed on “zero time spare engines” (spare engines installed on airplanes already in service) with fewer than 50 flight CSN. Because of these additional findings, the FAA will continue to require inspection of the LPC R1 within 50 flight cycles for certain engines while reducing compliance time to 15 flight cycles for certain other affected engines.

In addition, inspections of the LPC IGV stem for proper alignment, required by AD 2019–19–11, have not detected any misalignment of the LPC IGV stem. The FAA agrees with the manufacturer’s determination that alignment of the LPC IGV stem is not linked to the unsafe condition represented by this LPC R1 failure. The FAA is therefore not requiring inspection of the LPC IGV stem in this AD. The FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information

The FAA reviewed Pratt & Whitney Service Bulletin (SB) PW1000G–A–72–00–0125–00A–930A–D, Issue No. 002, dated October 22, 2019, and PW SB PW1000G–A–72–00–0075–00B–930A–D, Issue No. 003, dated October 22, 2019. The SBs contain procedures for

performing borescope inspections of the LPC R1 on engines that have less than 300 flight CSN or on engines that have less than 300 flight cycles since installation of the affected EEC software.

FAA’s Determination

The FAA is issuing this AD because it 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 borescope inspections of the LPC R1 and, depending on the results of the inspections, replacement of the LPC.

Interim Action

The FAA considers this AD interim action. The investigation into the failures on the PW PW1524G model turbofan engines is on-going and the FAA may pursue further rulemaking action at a later date.

FAA’s Justification and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C.) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking. Similarly, Section 553(d) of the APA authorizes agencies to make rules effective in less than 30 days, upon a finding of good cause.

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. In addition to two recent failures of the LPC R1 installed on PW1524G–3 model turbofan engines, an additional in-flight failure of the LPC occurred on October 15, 2019. LPC rotor failures can release high-energy debris from the engine and damage the airplane (see AC 39–8, “Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes,” dated September 8, 2003).

The earlier failures of the LPC R1 occurred at low flight CSN (154 and 230 flight cycles). The most recent failure of the LPC R1 occurred at a higher flight CSN (1,654 flight cycles) but within 300

flight cycles of the installation of a certain version of EEC software. The manufacturer has recommended that the FAA continue to require inspections of the LPC R1 within the next 50 flight cycles for engines with low CSN and to add engines that have accumulated less than 300 flight cycles since installation of the affected software to the applicability of this AD. In addition to the failures of the LPC R1 in flight, inspections mandated by AD 2019–19–11 have found cracks in the LPC R1 on two zero time spare engines affected by that AD. Both engines also had accumulated less than 300 flight CSN. The manufacturer has recommended inspecting these engines within 15 flight cycles.

The FAA has adopted these recommendations. Based on current operational usage of the affected airplanes, 15 flight cycles equates to approximately 2 to 3 operating days and 50 flight cycles equates to approximately 7 to 10 operating days. Therefore, the FAA has determined that low flight cycle engines, as well as those with recently installed software, require inspections within the next 50 flight cycles from the effective date of this AD, while zero time spare engines require inspection within 15 flight cycles from the effective date of this AD. Because of the need for operators to begin the required inspections within 15 or 50 flight cycles, the FAA has made this AD effective upon publication in the **Federal Register**. Accordingly, the FAA determined that the risk of operation of the affected engines without initial and repetitive inspections of the LPC R1 is unacceptable.

The FAA considers the need for initial and repetitive inspections of the LPC R1 to be an urgent safety issue. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to public interest pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the reasons stated above, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) 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 the FAA did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, the FAA invites 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–2019–0843 and product identifier 2019–NE–27–AD at

the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Costs of Compliance

The FAA estimates that this AD affects 18 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Borescope inspection per inspection cycle	2 work-hours × \$85 per hour = \$170	0	\$170	\$3,060

The FAA estimates the following costs to do any necessary replacements that would be required based on the

results of the borescope inspections. The FAA has 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 LPC	40 work-hours × \$85 per hour = \$3,400	\$156,000	\$159,400

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.

The FAA is 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) Will not affect intrastate aviation in Alaska, and

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) 2019-19-11, Amendment 39-19747 (84

FR 50719, September 26, 2019) and adding the following new AD:

2019-21-11 Pratt & Whitney: Amendment 39-19777; Docket No. FAA-2019-0843; Product Identifier 2019-NE-27-AD.

(a) Effective Date

This AD is effective October 29, 2019.

(b) Affected ADs

This AD replaces AD 2019-19-11, Amendment 39-19747 (84 FR 50719, September 26, 2019).

(c) Applicability

This AD applies to Pratt & Whitney Model PW1519G, PW1521G, PW1521GA, PW1524G, PW1525G, PW1521G-3, PW1524G-3, PW1525G-3, PW1919G, PW1921G, PW1922G, PW1923G, and PW1923G-A model turbofan engines that have accumulated fewer than 300 flight cycles since new (CSN) or that have accumulated fewer than 300 flight cycles since installation of v2.11.7 or v2.11.8 electronic engine control (EEC) software.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a recent in-flight shutdown due to failure of the low-pressure compressor (LPC) rotor 1 (R1) and by findings of cracked LPC R1s during inspections. The FAA is issuing this AD to prevent failure of the LPC R1. The unsafe condition, if not addressed, could result in uncontained release of the LPC R1, damage to the engine, damage to the airplane, and loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) Except for those engines identified in paragraph (g)(2) of this AD, borescope inspect the LPC R1 for damage and cracks at the locations in paragraph (g)(1)(iv) of this AD as follows:

(i) For engines that have accumulated fewer than 300 flight cycles since new (CSN), inspect within 50 flight cycles from September 26, 2019 (the effective date of AD 2019-19-11).

(ii) For engines that have accumulated fewer than 300 flight cycles since installation of v2.11.7 or v2.11.8 electronic engine control (EEC) software, inspect within 50 flight cycles from the effective date of this AD.

(iii) Thereafter, at intervals not to exceed 50 flight cycles until the engine accumulates 300 flight CSN or accumulates 300 flight cycles since the installation of v2.11.7 or v2.11.8 EEC software, whichever occurs later, repeat this borescope inspection for damage and cracks at the locations in paragraph (g)(1)(iv) of this AD.

(iv) Perform the borescope inspection required by paragraphs (g)(1)(i) through (iii) of this AD at the following locations:

- (A) the blades tips;
- (B) the leading edge;
- (C) the leading edge fillet to rotor platform radius; and
- (D) the airfoil convex side root fillet to rotor platform radius.

(2) For all affected PW model turbofan engines installed as a “zero time spare,” except for PW1519G, PW1521GA and PW1919G model turbofan engines, within 15 flight cycles from the effective date of this AD, and thereafter at intervals not to exceed 15 flight cycles until the engine accumulates 300 flight CSN, perform the borescope inspections required by paragraph (g)(1) of this AD.

(3) As the result of the inspections required by paragraphs (g)(1) and (2) of this AD, before further flight, remove and replace the LPC if:

- (i) there is damage on an LPC R1 that exceeds serviceable limits; or
- (ii) there is any crack in the LPC R1.

Note 1 to paragraph (g): Guidance on determining serviceable limits can be found in PW Service Bulletin (SB) PW1000G-A-72-00-0125-00A-930A-D, Issue No. 002, dated October 22, 2019, and PW SB PW1000G-A-72-00-0075-00B-930A-D, Issue No. 003, dated October 22, 2019.

(h) Definition

For the purpose of this AD, a “zero time spare” is an engine that had zero flight hours time-in-service when it was installed on an airplane after the airplane had entered service.

(i) 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 (j) 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.

(j) Related Information

For more information about this AD, contact Kevin M. Clark, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7088; fax: 781-238-7199; email: kevin.m.clark@faa.gov.

(k) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on October 25, 2019.

Karen M. Grant,

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

[FR Doc. 2019-23715 Filed 10-25-19; 4:15 pm]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA-2019-N-2484]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Continuous Glucose Monitor Data Management System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the continuous glucose monitor data management system into class I (general controls). We are taking this action because we have determined that classifying the device into class I (general controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens. **DATES:** This order is effective October 29, 2019. The classification was applicable on August 19, 2014.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4545, Silver Spring, MD 20993-0002, 240-402-6357, ryan.lubert@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Upon request, FDA has classified the continuous glucose monitor data management system as class I (general controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k) and part 807 (21 CFR part 807)).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After