

(c) Applicability

This AD applies to Bombardier, Inc. Model DHC-8-400, -401, and -402 airplanes, certificated in any category, serial numbers 4001 through 4361 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 52: Doors.

(e) Reason

This AD was prompted by a report of the inability to open the airstair door while on the ground, because the airstair door seal did not deflate, which prevented the airstair door from opening. We are issuing this AD to prevent the airstair door seal from not deflating, which could result in the airstair door not opening and could impede evacuation in the event of an emergency.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Actions

Within 6,000 flight hours after the effective date of this AD: Incorporate ModSum 4-126513, Seal System Shut Off Valve Control Logic Change, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84-52-69, Revision C, dated June 28, 2011.

(h) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if the actions were performed before the effective date of this AD using Bombardier Service Bulletin 84-52-69, dated January 28, 2011; Revision A, dated April 26, 2011; or Revision B, dated May 9, 2011.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) **Alternative Methods of Compliance (AMOCs):** The Manager, New York Aircraft Certification Office (ACO), ANE-170, 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 ACO, send it to Attn: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516-228-7300; fax 516-794-5531. 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. The AMOC approval letter must specifically reference this AD.

(2) **Airworthy Product:** For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required

to assure the product is airworthy before it is returned to service.

(j) Related Information

Refer to MCAI Canadian Airworthiness Directive CF-2011-15, dated June 20, 2011; and Bombardier Service Bulletin 84-52-69, Revision C, dated June 28, 2011; for related information.

(k) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) of the following service information under 5 U.S.C. 552(a) and 1 CFR part 51:

(i) Bombardier Service Bulletin 84-52-69, Revision C, dated June 28, 2011.

(2) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416-375-4000; fax 416-375-4539; email thd.qseries@aero.bombardier.com; Internet <http://www.bombardier.com>.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202-741-6030, or go to http://www.archives.gov/federal-register/code-of-federal-regulations/ibr_locations.html.

Issued in Renton, Washington, on March 9, 2012.

Ali Bahrami

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 2012-6530 Filed 3-22-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2011-1194; Directorate Identifier 2011-NE-36-AD; Amendment 39-16999; AD 2012-06-18]

RIN 2120-AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Pratt & Whitney PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156,

PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines, including models with any dash number suffix. This AD was prompted by reports of five engine in-flight shutdowns and seven unplanned engine removals. This AD requires inspections, cleaning, and engine modifications to address coking in the No. 4 bearing compartment and in the oil pressure and scavenge tubes. We are issuing this AD to prevent an engine fire, a fractured fan drive shaft, and damage to the airplane.

DATES: This AD is effective April 27, 2012.

ADDRESSES: For service information identified in this AD, contact Pratt & Whitney, 400 Main St., East Hartford, CT 06108; phone: 860-565-8770; fax: 860-565-4503. You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. 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>; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Document Management Facility, 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:

James Gray, Aerospace Engineer, Engine & Propeller Directorate, FAA, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7742; fax: 781-238-7199; email: james.e.gray@faa.gov.

SUPPLEMENTARY INFORMATION:**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM published in the **Federal Register** on November 23, 2011 (76 FR 72353). That NPRM proposed to require inspections, cleaning, and engine modifications to address coking in the No. 4 bearing compartment and oil pressure and scavenge tubes.

Comments

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

Request To Not Call Out Specific Instructions

Delta Airlines requested that we do not call out specific instructions to inspect, clean, and install the modifications, because operators have developed their own maintenance practices that are adequate, but may not align 100% with the Service Bulletin (SB) instructions.

We agree. We changed the AD to not incorporate by reference the SBs, and to list them only as related information, without calling out any specific revision numbers of them.

Request To Recognize Compliance by Accomplishing SBs Before the Effective Date of the AD

Federal Express, United Parcel Service, and United Airlines requested that we recognize that their compliance by accomplishing earlier versions of Pratt & Whitney SB No. PW4ENG 72-472 and SB No. PW4ENG 79-76 before the effective date of the AD is terminating action to the AD. The commenters stated that many engines have already had the modifications accomplished but to earlier versions of the SBs.

We agree. Because we no longer incorporate the SBs by reference, if the requirements of the AD have already been done either by the current revision or an earlier revision of SB No. PW4ENG 72-472, SB No. PW4ENG 79-76, and Alert SB No. A72-436, or other methods, techniques, or practices acceptable to the Administrator, then no further action is required. We have also changed the applicability to limit the AD to only those engines that have not already made the modifications.

Update to the List of Affected Engine Models

Since we issued the NPRM (76 FR 72353, November 23, 2011), we determined that we need to update the list of affected engine models, to reflect the models listed in the title block of the type certificate data sheet. Engine models PW4060C, PW4062, PW4062A, PW4650, and PW4160 have been added in this AD. The affected engine models in operation, as listed in the NPRM, have not changed in this AD.

Conclusion

We reviewed the relevant data, considered the comments received, and

determined that air safety and the public interest require adopting the AD with the changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Costs of Compliance

We estimate that this AD will affect 44 turbofan engines installed on airplanes of U.S. registry. We estimate that it will take 8 work-hours per engine to perform an inspection and cleaning of the No. 4 bearing compartment; 7 work-hours per engine to perform the modification to stop buildup of coking in the No. 4 bearing compartment; and 33.7 work-hours per engine to perform the rerouting of the No. 4 bearing pressure and scavenge tubes. The average labor rate is \$85 per work-hour. Required parts will cost about \$69,322 per engine. Based on these figures, we estimate the total cost of the AD to U.S. operators to be \$3,232,306.

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 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):

2012-06-18 Pratt & Whitney Division:

Amendment 39-16999; Docket No. FAA-2011-1194; Directorate Identifier 2011-NE-36-AD.

(a) Effective Date

This AD is effective April 27, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines, including models with any dash number suffix, that have not incorporated Pratt & Whitney Alert Service Bulletin (ASB) No. PW4ENG-A72-436; Service Bulletin (SB) No. PW4ENG-79-76; and SB No. PW4ENG-72-472.

(d) Unsafe Condition

This AD was prompted by reports of five engine in-flight shutdowns and seven unplanned engine removals due to clogging of No. 4 bearing compartment oil pressure and scavenge tubes. We are issuing this AD to prevent an engine fire, a fractured fan drive shaft, and damage to the airplane.

(e) Compliance

(1) If you have incorporated Pratt & Whitney ASB No. PW4ENG-A72-436; SB No. PW4ENG-79-76; and SB No. PW4ENG-72-472, then no further action is required.

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

(f) Inspection and Cleaning of No. 4 Bearing Compartment for Coking

(1) Within 1,000 cycles-in-service (CIS) after the effective date of this AD, inspect and clean the No. 4 bearing compartment.

(2) Thereafter, within every additional 1,000 CIS, re-inspect and clean the No. 4 bearing compartment.

(g) Modification To Stop Buildup of Coking in the No. 4 Bearing Compartment, and Rerouting of the No. 4 Bearing Pressure and Scavenge Tubes

At the next engine shop visit, but not to exceed 5 years after the effective date of this AD, do the following:

(1) Replace the No. 4 bearing packing transfer tube assembly;

(2) Replace the No. 4 bearing internal scavenge tube assembly;

(3) Remove the No. 4 bearing shield, and the No. 4 bearing shield option; and

(4) Install the new No. 4 bearing shield options.

(5) Modify the turbine exhaust case to relocate the No. 4 bearing pressure and scavenge tube ports to below the engine centerline;

(6) Replace the internal No. 4 bearing pressure and scavenge tubes;

(7) Modify or replace the turbine case cooling brackets to support the new No. 4 bearing pressure and scavenge tubes;

(8) Replace the turbine case manifolds as necessary; and

(9) Install the new brackets and clamps to support the new routing configuration.

(h) Terminating Action to the Repetitive Inspections and Cleaning

Performing the modifications specified in paragraphs (g)(1) through (g)(9) of this AD is terminating action for the repetitive inspections and cleanings specified in paragraph (f)(2) of this AD.

(i) Definition of Shop Visit

For the purpose of this AD, a shop visit is when the engine is inducted into the shop for any maintenance involving the separation of pairs of major mating engine flanges (lettered flanges). However, the separation of engine flanges solely for the purposes of transporting the engine without subsequent engine maintenance is not an engine shop visit.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(k) Related Information

(1) For more information about this AD, contact James Gray, Aerospace Engineer, Engine & Propeller Directorate, FAA, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7742; fax: 781-238-7199; email: james.e.gray@faa.gov.

(2) Pratt & Whitney ASB No. PW4ENG-A72-436; SB No. PW4ENG-79-76; and SB No. PW4ENG-72-472, pertain to the subject of this AD.

(3) For service information identified in this AD, contact Pratt & Whitney, 400 Main

St., East Hartford, CT 06108; phone: 860-565-8770; fax: 860-565-4503. For information on the availability of this material at the FAA, call 781-238-7125.

(l) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on March 19, 2012.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012-6996 Filed 3-22-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 20**

[Docket No. FDA-2012-N-0205]

Agreements and Memoranda of Understanding Between the Food and Drug Administration and Other Departments, Agencies, and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: This direct final rule makes technical changes that will update a requirement that many of our written agreements and memoranda of understanding (MOUs) with other departments, Agencies, and organizations be published in the **Federal Register**. Because we already post and will continue to post our ongoing agreements and MOUs with other departments, Agencies, and organizations on our Web site upon their completion, this requirement is no longer necessary. This direct final rule, accordingly, eliminates it. We are making these technical changes to conserve Agency time and resources, reduce government paperwork, and eliminate unnecessary **Federal Register** printing costs while continuing to afford public access to these documents. We are proceeding in accordance with our direct final rule procedures.

We are publishing a companion proposed rule under our usual procedure for notice-and-comment rulemaking to provide a procedural framework to finalize the rule in the event we receive any significant adverse comments and withdraw this direct final rule. The companion proposed rule and this direct final rule are substantively identical.

DATES: This rule is effective August 6, 2012. Submit either electronic or

written comments on or before June 6, 2012. If we receive no significant adverse comments within the specified comment period, we will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0205, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

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

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0205 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Daniel W. Sigelman, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4706, FAX: 301-847-8616, email: daniel.sigelman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of October 3, 1974 (39 FR 35697), we announced that copies of all our MOUs transacted with