

at engine overhaul, using RR SB AE 3007A-72-263, Revision 1, dated March 4, 2003.

(6) Modify HP-to-LP seal assembly, P/N 23074729 or P/N 23076526, and remark to P/N 23077397, at engine overhaul, using RR SB AE 3007A-72-284, dated October 16, 2003.

(7) Using Embraer SB 145-79-0001, dated April 24, 1998, modify the airplane wiring so that the oil impending bypass message will be displayed in the cockpit when the primary engine magnetic chip detector captures debris.

Alternative Methods of Compliance

(h) The Manager, Chicago Aircraft Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(i) The Director of the Federal Register approved the incorporation by reference of the Rolls-Royce (RR) documents and Embraer document listed in Table 1 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR

part 51. You may get RR copies from Rolls-Royce Corporation, P.O. Box 420, Indianapolis, IN 46206-0420; telephone (317) 230-3030, and Embraer copies from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343-CEP 12.225, Sao Jose dos Campos-SP, Brazil. You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Table 1 follows:

TABLE 1.—INCORPORATION BY REFERENCE

| Service bulletin | Page number(s) shown on the page | Revision level shown on the page | Date shown on the page |
|------------------------|----------------------------------|----------------------------------|------------------------|
| RR SB AE 3007A-79-034 | All | Original | May 14, 2002. |
| RR SB AE 3007A-72-199 | All | 3 | May 13, 2002. |
| RR SB AE 3007A-72-213 | All | 1 | May 13, 2002. |
| RR SB AE 3007A-72-213 | All | 2 | November 20, 2003. |
| RR SB AE 3007A-72-248 | All | Original | July 29, 2003. |
| RR SB AE 3007A-72-263 | All | 1 | March 4, 2003. |
| RR SB AE 3007A-72-284 | All | Original | October 16, 2003. |
| Embraer SB-145-79-0001 | All | Original | April 24, 1998. |

Related Information

(j) None.

Issued in Burlington, Massachusetts, on February 13, 2004.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003-NE-66-AD; Amendment 39-13487; AD 2004-04-06]

RIN 2120-AA64

Airworthiness Directives; General Electric Company CT58 Series and T58 Series Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain General Electric Company (GE) CT58-100-2, CT58-140-1, -140-2, and T58-GE-1, -3, -5, -8E, -8F, -10, -100, and -402 turboshaft engines. This AD requires the removal from service of certain fuel flow divider assemblies. This AD results from a report that a certain population of flow divider end caps could crack and cause large volumes of fuel leakage. We are issuing

this AD to prevent fuel leakage from the fuel flow divider assembly, which could cause an engine fire, leading to an in-flight engine shutdown and forced landing.

DATES: This AD becomes effective March 9, 2004. The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of March 9, 2004.

We must receive any comments on this AD by April 23, 2004.

ADDRESSES: Use one of the following addresses to submit comments on this AD:

- By mail: The Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003-NE-66-AD, 12 New England Executive Park, Burlington, MA 01803-5299.
- By fax: (781) 238-7055.
- By e-mail: 9-ane-adcomment@faa.gov.

You can get the service information referenced in this AD from GE Aircraft Engines Customer Support Center, M/D 285, 1 Neumann Way, Evendale, OH 45215, telephone (513) 552-3272; fax (513) 552-3329, e-mail GEAE.csc@ae.com.

You may examine the AD docket, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA. You may examine the service information, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at

the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mark Bouyer, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park; telephone (781) 238-7755; fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: On July 25, 2003, we were made aware that 182 temperature control valve assemblies, located on the fuel flow divider assembly, are susceptible to cracking and leaking of fuel. GE has identified the affected temperature control valve assemblies by serial number (SN). An investigation by GE revealed that the end caps for the temperature control valve assemblies may be susceptible to intergranular corrosion, which can result in cracking. Even though there have been no reports of these end caps cracking, the FAA has determined that this condition represents an unsafe condition. Since the affected engines could accumulate as many as 120 hours time-in-service every two weeks, we have determined that notice and opportunity for prior public comment is impracticable, and that this AD must be issued as a final rule; request for comments. This condition, if not corrected, could cause an engine fire, leading to an in-flight engine shutdown and forced landing.

Relevant Service Information

We have reviewed and approved the technical contents of GE Alert Service Bulletin (ASB) CT58 S/B 73-A0081,

Revision 2, dated August 7, 2003, that lists the affected SNs of temperature control assemblies, part numbers (P/Ns) 5040T77G02 or 5040T87G02.

FAA's Determination and Requirements of this AD

The unsafe condition described previously is likely to exist or develop on other GE CT58 series turboshaft engines of the same type design. We are issuing this AD to prevent fuel leakage from the fuel flow divider assembly, which could cause an engine fire, leading to an in-flight engine shutdown and forced landing. This AD requires within 120 hours time-in-service:

- Locating suspect fuel flow divider assemblies, P/Ns 4050T82G02 and 4067T04G02, and
- Locating affected temperature control assemblies, P/N 5040T77G02 and 5040T87G02, by SN, and
- Removing affected fuel flow divider assemblies from service.

You must use the service information described previously by this AD to identify the affected temperature control assemblies by SN.

FAA's Determination of the Effective Date

Since an unsafe condition exists that requires the immediate adoption of this AD, we have found that notice and opportunity for public comment before issuing this AD are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Changes to 14 CFR Part 39—Effect on the AD

On July 10, 2002, we issued a new version of 14 CFR part 39 (67 FR 47998, July 22, 2002), which governs our AD system. This regulation now includes material that relates to special flight permits, alternative methods of compliance, and altered products. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include "AD Docket No. 2003-NE-66-AD" in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed,

stamped postcard with the docket number written on it; we will date-stamp your postcard and mail it back to you. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify it. If a person contacts us verbally, and that contact relates to a substantive part of this AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend the AD in light of those comments.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications with you. You can get more information about plain language at <http://www.faa.gov/language> and <http://www.plainlanguage.gov>.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Regulatory Findings

We have determined that 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 the 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); and
3. 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.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2003-NE-66-AD" in your request.

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 Federal Aviation Administration 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 adding the following new airworthiness directive:

2004-04-06 General Electric Company:
Amendment 39-13487. Docket No. 2003-NE-66-AD.

Effective Date

- (a) This airworthiness directive (AD) becomes effective March 9, 2004.

Affected ADs

- (b) None.

Applicability

(c) This AD applies to General Electric Company (GE) CT58-100-2, CT58-140-1, -140-2, and T58-GE-1, -3, -5, -8E, -8F, -10, -100, and -402 turboshaft engines, with fuel flow divider assemblies part number (P/N) 4050T82G02 or 4067T04G02, having temperature control assemblies, P/N 5040T77G02 or 5040T87G02, with serial numbers (SNs) listed in 1.A.(3) of GE Alert Service Bulletin (ASB) No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003, installed. These engines are installed on, but not limited to, Agusta S.p.A. AS-61N, AS-61N1, Boeing Vertol 107-II, and Sikorsky S-61L, S-61N, S-61R, S-61NM, S-62A helicopters, and the following surplus military helicopters that have been certified in accordance with § 21.25 or 21.27 of the Federal Aviation Regulations (14 CFR 21.25 or 21.27): CA Department of Forestry UH-1F, Carson S-61L, Firefly UH-1F, Garlick Helicopters UH-1F, UH-1P, and TH-1F, Glacier CH-3E, Robinson Air Crane CH-3C, CH-3E, HH-3C, HH-3E, UH-1F, UH-1P, and TH-1F, Sikorsky S-61A, S-61D, and S-61V, Tamarack UH-1F, and Siller Helicopters CH-3A, and SH-3A helicopters.

Unsafe Condition

(d) This AD results from a report that a certain population of flow divider end caps could crack and cause large volumes of fuel leakage. We are issuing this AD to prevent fuel leakage from the fuel flow divider assembly, which could cause an engine fire, leading to an in-flight engine shutdown and forced landing.

Compliance

(e) You are responsible for having the actions required by this AD performed within 120 hours time-in-service after the effective date of this AD:

Required Actions

(f) Locate the temperature control assembly, which is mounted on the fuel flow divider assembly and do the following:

(1) Read the SN of the temperature control assembly. The SN is located on the end cap of the temperature control assembly. The end cap has a one-inch hex flange and is threaded into the fuel flow divider body.

(2) If the SN is listed in 1.A.(3) of GE ASB No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003, or if the SN cannot be determined, remove the fuel flow divider assembly from service.

(g) After the effective date of this AD, do not install any fuel flow divider assembly P/N 4050T82G02 or 4067T04G02, that has a temperature control assembly with a SN listed in 1.A.(3) of GE ASB No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003.

Alternative Methods of Compliance

(h) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(i) You must use GE ASB No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003 to identify by SN the affected temperature control assemblies. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You can get a copy from GE Aircraft Engines Customer Support Center, M/D 285, 1 Neumann Way, Evendale, OH 45215, telephone (513) 552-3272; fax (513) 552-3329, e-mail GEAE.csc@ae.ge.com. You may review copies at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA 01803-5299, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Related Information

(j) None.

Issued in Burlington, Massachusetts, on February 13, 2004.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.
[FR Doc. 04-3680 Filed 2-20-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 203**

[Docket No.1992N-0297]

RIN 0905-AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until December 1, 2006, the effective date of certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a "health care entity" in the final rule. The agency further delayed the effective date of these requirements in three subsequent **Federal Register** notices. Most recently, in the **Federal Register** of January 31, 2003 (68 FR 4912), FDA delayed the effective date until April 1, 2004. This action further delays the effective date of these requirements until December 1, 2006. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The agency is taking this action to address concerns about the requirements in the final rule raised by affected parties.

As explained in the **SUPPLEMENTARY INFORMATION** section, FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that will generate a de facto electronic pedigree, including prior transaction history back to the original manufacturer, as a routine course of business. If this technology is widely adopted, it is expected to help fulfill the pedigree requirements of the PDMA and obviate or resolve many of

the concerns that have been raised with respect to the final rule by ensuring that an electronic pedigree travels with a drug product at all times. Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2007 to allow stakeholders time to continue to move toward this goal. In addition, the further delay of the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities is necessary to give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

DATES: The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until December 1, 2006. Submit written or electronic comments by April 23, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs and for the distribution of blood derived prescription drug products by health care entities.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720) that were to take effect on December 4, 2000. After publication of the final rule, the agency received communications from industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. Respectively, these provisions define