

TABLE 3—REMOVAL OF STAGE 1 HPT AIRSEAL RING, P/N 50L664, BY CYCLES-SINCE-NEW

For engine model . . .	Remove stage 1 HPT Airseal Ring by . . .
(1) Listed in paragraph (c)(2)(i) of the Applicability Section of this AD	14,800 CSN.
(2) Listed in paragraph (c)(2)(ii) of the Applicability Section of this AD	16,800 CSN.

(i) Installation Prohibition

After the effective date of this AD, do not install any stage 1 HPT airseal, P/N 50L879, stage 2 HPT airseal, P/N 53L030, or stage 1 HPT airseal ring, P/N 50L664, that is at piece-part exposure and exceeds the new life limit listed in Table 1, Table 2, or Table 3, respectively, of this AD.

(j) Definitions

For the purpose of this AD, piece-part exposure means that the part is completely disassembled and removed from the engine.

(k) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested, using the procedures found in 14 CFR 39.19.

(l) Related Information

For more information about this AD, contact James Gray, Aerospace Engineer, Engine Certification Office, FAA, 12 New England Executive Park, Burlington, MA 01803; *phone:* 781-238-7742; *fax:* 781-238-7199; *e-mail:* james.e.gray@faa.gov.

Issued in Burlington, Massachusetts, on July 8, 2011.

Peter A. White,

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

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2011-0716; Directorate Identifier 2011-NM-013-AD]

RIN 2120-AA64

Airworthiness Directives; Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.) Model Galaxy, Gulfstream G150, and Gulfstream 200 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed

AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

A broken aileron servo actuator centering spring rod was discovered on a model G100 aircraft during a routine scheduled maintenance inspection. * * * This latent failure of a centering spring rod, if not detected and corrected, in conjunction with the disconnection of the normal mechanical control system of the same servo actuator would lead to loss [of] control of the flight control surface [aileron or elevator]. This condition would reduce the control capability of the airplane and imposes a higher workload on the flight crew reducing their ability to cope with adverse operating conditions.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by August 29, 2011.

ADDRESSES: You may send comments 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:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D-25, Savannah, Georgia 31402-2206; telephone 800-810-4853; fax 912-965-3520; e-mail *pubs@gulfstream.com*; Internet http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm. You may review copies of the referenced 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.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Operations office 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 Operations office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Mike Borfitz, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2677; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2011-0716; Directorate Identifier 2011-NM-013-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on 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 proposed AD.

Discussion

The Civil Aviation Authority (CAA), which is the aviation authority for Israel, has issued Airworthiness Directives 27-10-11-03, dated December 6, 2010; and 27-10-12-29, dated January 4, 2011 (referred to after this as “the MCAI”); to correct an unsafe

condition for the specified products. The MCAI states:

A broken aileron servo actuator centering spring rod was discovered on a model G100 aircraft during a routine scheduled maintenance inspection. This centering spring rod is common to all Gulfstream Mid Cabin model (G100, G150 and G200) aileron control servo actuators and the G200 elevator control servo actuator too. The function of the centering spring rod is to maintain the affected servo actuator and its associated flight control surface in a centered position in the event of a disconnect of the normal mechanical control system input from the flight crew to the same servo actuator. This latent failure of a centering spring rod, if not detected and corrected, in conjunction with the disconnection of the normal mechanical control system of the same servo actuator would lead to loss [of] control of the flight control surface/aileron. This condition would reduce the control capability of the airplane and imposes a higher workload on the flight crew reducing their ability to cope with adverse operating conditions.

The required actions include a detailed inspection of the servo actuator centering spring rods for the aileron and elevator to detect fractured or broken rods, and replacing the rods if necessary. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Gulfstream Aerospace LP has issued Gulfstream Service Bulletins 150–27–123; and 200–27–374; both Revision 1, both dated January 27, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making

these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 200 products of U.S. registry. We also estimate that it would take about 19 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$323,000, or \$1,615 per product.

In addition, we estimate that any necessary follow-on actions would take up to 20 work-hours per product, and require parts costing \$0, for a cost of \$1,700 per product. We have no way of determining the number of products that may need these actions. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here.

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); 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 regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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 AD:

Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.): Docket No. FAA–2011–0716; Directorate Identifier 2011–NM–013–AD.

Comments Due Date

- (a) We must receive comments by August 29, 2011.

Affected ADs

- (b) None.

Applicability

- (c) This AD applies to the products identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Gulfstream Aerospace LP (Type Certificate previously held by Israel Aircraft Industries, Ltd.) Model Gulfstream G150 airplanes, serial numbers 201 through 286 inclusive.

(2) Gulfstream Aerospace LP (Type Certificate previously held by Israel Aircraft Industries, Ltd.) Model Galaxy airplanes; and Gulfstream Aerospace LP Model Gulfstream 200 airplanes; serial numbers 004 through 231 inclusive.

Subject

(d) Air Transport Association (ATA) of America Code 27: Flight controls.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: A broken aileron servo actuator centering spring rod was discovered on a model G100 aircraft during a routine scheduled maintenance inspection. * * * This latent failure of a centering spring rod, if not detected and corrected, in conjunction with the disconnection of the normal mechanical control system of the same servo actuator would lead to loss [of] control of the flight control surface [aileron or elevator]. This condition would reduce the control capability of the airplane and imposes a higher workload on the flight crew reducing their ability to cope with adverse operating conditions.

Compliance

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

Inspection

(g) Within 12 months after the effective date of this AD, do the actions specified by paragraph (g)(1) or (g)(2) of this AD, as applicable.

(1) For Model Gulfstream G150 airplanes: Do a one-time detailed inspection of the aileron control servo actuators to detect fractured or broken centering spring rods, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 150-27-123, Revision 1, dated January 27, 2011.

(2) For Model Galaxy and Gulfstream 200 airplanes: Do a one-time detailed inspection of the aileron and elevator control servo actuators to detect fractured or broken centering spring rods, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 200-27-374, Revision 1, dated January 27, 2011.

Corrective Actions

(h) If any centering spring rod is found fractured or broken during any inspection required by this AD: Before further flight, replace the centering spring rod in accordance with a method approved by the Manager, International Branch, ANM 116, Transport Airplane Directorate, FAA, or the Civil Aviation Authority of Israel (CAAI) (or its delegated agent).

Credit for Actions Accomplished in Accordance With Previous Service Information

(i) Actions done before the effective date of this AD in accordance with Gulfstream Service Bulletin 150-27-123 or 200-27-374, both dated October 27, 2010, are considered acceptable for the actions required by paragraph (g) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: The MCAI AD does not specify a corrective action

for fractured or broken rods; however, paragraph (h) of this AD requires corrective action.

Other FAA AD Provisions

(j) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM-116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Mike Borfitz, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2677; fax (425) 227-1149. Information may be e-mailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. 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.

Related Information

(k) Refer to MCAI Civil Aviation Authority of Israel Airworthiness Directives 27-10-11-03, dated December 6, 2010, and 27-10-12-29, dated January 4, 2011; and Gulfstream Service Bulletins 150-27-123 and 200-27-374, both Revision 1, both dated January 27, 2011; for related information.

Issued in Renton, Washington, on July 6, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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

[Docket No. FDA-2011-N-0446]

Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove a section of the Prescription Drug Marketing Act (PDMA) regulations requiring that prior to the completion of any wholesale distribution of a prescription drug, an unauthorized distributor must provide to the purchaser "a statement identifying each prior sale, purchase, or trade of such drug," starting with the manufacturer, and that the identifying statement (also known as the "pedigree") must include certain information about the drug and each prior sale, purchase, or trade. This action is being taken in response to longstanding issues, including an injunction currently in effect, regarding the application of and compliance with this requirement. FDA is also announcing that it intends to exercise enforcement discretion with respect to certain requirements of the regulation while the rulemaking is pending and with respect to the statutory pedigree requirements of the PDMA, as long as the pedigree identifies the names and addresses of the last authorized distributor of record that handled the drug and the associated dates of transactions involving that last authorized distributor of record and the drug, as well as the names and addresses of all subsequent unauthorized distributors that handled the drug and the corresponding dates of those transactions.

DATES: Submit either electronic or written comments on the proposed rule by September 12, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0446, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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