(c) Effective Date

This AD becomes effective August 31, 2017.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Before further flight, determine the accumulated retirement index number (RIN) for each part and remove it from service if it has reached or exceeded its life limit as follows. Thereafter, remove each part from service on or before reaching its life limit. For purposes of this AD, a run-on landing is defined as a landing with forward ground travel of the helicopter greater than 3 feet (0.91 m) with weight on skids.

(1) For Skid Tube Assembly part number (P/N) 429–700–101, 429–700–102, and 429–030–586–107: 16,000 RIN. Count 1 RIN for each landing; count 81 RIN for each run-on landing; and count 117 RIN for each autorotation landing.

(2) For Forward Crosstube Assembly P/N 429–712–101: 10,000 RIN. Count 1 RIN for each landing; count 50 RIN for each run-on landing; and count 118 RIN for each autorotation landing.

(3) Aft Crosstube Assembly P/N 429–723–108: 30,000 RIN. Count 1 RIN for each landing; count 32 RIN for each run-on landing; and count 186 RIN for each autorotation landing.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Bell 429 Maintenance Manual BHT–429–MM–1, Volume 1, Chapter 4, Revision 9, dated January 6, 2012, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in Transport Canada AD No. CF–2014–28, dated August 19, 2014. You may view the Transport Canada AD on the Internet at *http://www.regulations.gov* in Docket No. FAA–2017–0174.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 3200, Landing Gear System.

Issued in Fort Worth, Texas, on July 18, 2017.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2017–15552 Filed 7–26–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0395; Directorate Identifier 2017–CE–011–AD; Amendment 39–18966; AD 2017–15–06]

RIN 2120–AA64

Airworthiness Directives; British Aerospace Regional Aircraft Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for British Aerospace Regional Aircraft Model HP.137 Jetstream Mk.1, Jetstream Series 200 and 3101, and Jetstream Model 3201 airplanes that would supersede AD 97–10–05. This AD results from mandatory continuing airworthiness information (MCAI) issued 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 cracks in the main landing gear (MLG) fitting at the pintle to cylinder interface, which could cause failure of the MLG during takeoff and landing. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective August 31, 2017.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of August 31, 2017.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0395; or in person at 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 the British Aerospace Jetstream Series 3100 and 3200 service information identified in this AD, contact BAE Systems (Operations) Ltd, Business Support Team—Technical Publications, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; phone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *https://www.regional-services.com/spares_and_support/support/aircraft-technical-publications/.* For the Heroux Devtek service information identified in this AD, contact Heroux Devtek Product Support, Unit 1, Pembroke Court, Chancellor Road, Manor Park, Runcorn, Cheshire, WA7 1TG, England; phone: +44 01928 530530; fax: +44 01928 579454; email: *technical_support@herouxdevtek.com;* Internet: *http://www.herouxdevtek.com/aog-product-support.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the Internet at *http://www.regulations.gov* by searching for Docket No. FAA–2017–0395.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@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 British Aerospace Regional Aircraft Model HP.137 Jetstream Mk.1, Jetstream Series 200 and 3101, and Jetstream Model 3201 airplanes. The NPRM was published in the **Federal Register** on April 28, 2017 (82 FR 19646), and proposed to supersede AD 97–10–05, Amendment 39–10017 (62 FR 28318; May 23, 1997). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

> Cracks were found during early fatigue testing and in service on the main landing gear (MLG) main fitting at the pintle to cylinder interface.
>
> This condition, if not detected and corrected, could lead to structural failure of

the MLG, possibly resulting in loss of control of the aeroplane during take-off or landing runs.

To address this unsafe condition, BAE Systems (Operations) Ltd published several Service Bulletins (SB) which, in 1996, were consolidated into a single SB 32–JA960142 to provide instructions for inspection. CAA UK issued AD 005–03–96 accordingly to require repetitive inspections of the MLG.

Recently, a crack was found which was below the critical crack length, but unusually large compared to other similar cracks previously found in service. Further investigation into the subject determined that the existing inspection interval remains valid, but also showed that the assumed detectable defect size of 1.27 mm (0.05 in) crack cannot be guaranteed using the current accomplishment instructions for high frequency eddy current (HFEC) or fluorescent dye penetrant (FDP) inspection.

Consequently, BAE Systems (Operations) Ltd issued SB 32–JA960142 Revision 04, which provides improved procedures for HFEC and FDP inspection to ensure the detection of cracks of 1.27 mm (0.05 in).

For the reason described above, the [EASA] AD retains the requirements of CAA UK AD 005–03–96, which is superseded, and requires accomplishment of repetitive inspections in accordance with the improved procedures.

The MCAI can be found in the AD docket on the Internet at: *https://www.regulations.gov/document?D=FAA-2017-0395-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD 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 correcting 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 British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016, which describes procedures for doing non-destructive testing for cracks in the MLG and corrective actions if cracks found exceed a certain crack length. (The appendix to the service bulletin specifically describes fluorescent liquid penetrant testing.) We also reviewed Heroux Devtek Service Bulletin 32–56, Revision 4, dated August 16, 2016, which describes procedures for doing a non-destructive testing eddy current inspection for cracks in the MLG. 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 of this document.

Costs of Compliance

We estimate that this AD will affect 26 products of U.S. registry. We also estimate that it would take about 6 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be $13,260, or $510 per product.

In addition, we estimate that any necessary follow-on actions would take about 1 work-hour and require parts costing $5,000, for a cost of $5,085 per product. We have no way of determining the number of products that may need these actions.

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 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 this AD:

(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),

(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.

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–2017–0395; 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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 removing Airworthiness Directive (AD) 97–10–05, Amendment 39–10017 (62 FR 28318; May 23, 1997), and adding the following new AD:

2017–15–06 British Aerospace Regional Aircraft: Amendment 39–18966; Docket No. FAA–2017–0395; Directorate Identifier 2017–CE–011–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective August 31, 2017.

(b) Affected ADs

This AD replaces AD 97–10–05; Amendment 39–10017 (62 FR 28318; May 23, 1997) (''AD 97–10–05'').

(c) Applicability

This AD applies to British Aerospace Regional Aircraft Model HP.137 Jetstream Mk.1, Jetstream Series 200 and 3101, and

Jetstream Model 3201 airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 32: Landing Gear.

(e) Reason

This AD was prompted by 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 cracks in the main landing gear (MLG) fitting at the pintle to cylinder interface, which could cause failure of the MLG during takeoff and landing. We are issuing this AD to detect and correct cracks in the main landing gear (MLG), which could lead to structural failure of the MLG and could result in loss of control during takeoffs and landings.

(f) Actions and Compliance

Unless already done, do the following actions listed in paragraphs (f)(1) through (3) of this AD:

(1) Within the compliance times listed in paragraph (f)(1)(i) or (ii) of this AD, as applicable, inspect the MLG for cracks following Appendix 1 of British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016; or Heroux Devtek Service Bulletin 32–56, Revision 4, dated August 16, 2016, as specified in British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016.

(i) For airplanes that have been inspected following AD 97–10–05: Do the initial inspection within 1,200 flight cycles (FC) after the last inspection required by AD 97–10–05 and repetitively thereafter at intervals not to exceed 1,200 FC.

(ii) For airplanes that have not been inspected following AD 97–10–05: Do the initial inspection within 8,000 FC after installation of the MLG or within the next 100 FC after August 31, 2017 (the effective date of this AD), whichever occurs later, and repetitively thereafter at intervals not to exceed 1,200 FC.

(2) If any cracks are found during any of the inspections required in paragraph (f)(1) of this AD, before further flight, replace the MLG with an airworthy part following British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016.

(3) The compliance times in paragraphs (f)(1)(i) and (ii) of this AD are presented in FC (landings). If the total FC have not been kept, multiply the total number of airplane hours time-in-service (TIS) by 0.75 to calculate the FC. For the purposes of this AD:

(i) 100 hours TIS × .75 = 75 FC; and

(ii) 1,000 hours TIS × .75 = 750 FC.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(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.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD 2017–0053, dated March 24, 2017. The MCAI can be found in the AD docket on the Internet at: *https://www.regulations.gov/document?D=FAA-2017-0395-0002.*

(i) 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) British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016.

(ii) Heroux Devtek Service Bulletin 32–56, Revision 4, dated August 16, 2016.

(3) For British Aerospace Jetstream Series 3100 and 3200 service information related to this AD, contact BAE Systems (Operations) Ltd, Business Support Team-Technical Publications, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; phone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *https://www.regional-services.com/spares_and_support/support/aircraft-technical-publications/.* For Heroux Devtek service information identified in this proposed AD, contact Heroux Devtek Product Support, Unit 1, Pembroke Court, Chancellor Road, Manor Park, Runcorn, Cheshire, WA7 1TG, England; phone: +44 01928 530530; fax: +44 01928 579454; email: *technical_support@herouxdevtek.com;* Internet: *http://www.herouxdevtek.com/aog-product-support.*

(4) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0395.

(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 Kansas City, Missouri, on July 12, 2017.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–15224 Filed 7–26–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–1917]

Medical Devices; Immunology and Microbiology Devices; Classification of the Assayed Quality Control Material for Clinical Microbiology Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the assayed quality control material for clinical microbiology assays into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the assayed quality control material for clinical microbiology assays' classification. The Agency is classifying the device into class II (special controls) to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 27, 2017. The classification was applicable on March 28, 2016.