

(3) *Required for Compliance (RC)*: For service information that contains steps that are labeled as RC, the provisions of paragraphs (l)(3)(i) and (l)(3)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled "RC Exempt," then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Brazilian AD 2017-04-01, effective April 25, 2017, for related information. This MCAI may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0509.

(2) For more information about this AD, contact Krista Greer, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3221.

(n) 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 this AD specifies otherwise.

(i) Embraer Service Bulletin 190-54-0016, Revision 04, dated December 7, 2017.

(ii) Embraer Service Bulletin 190LIN-54-0008, Revision 02, dated May 9, 2018.

(3) For service information identified in this AD, contact Embraer S.A., Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227-901 São Jose dos Campos—SP—Brazil; phone: +55 12 3927-5852 or +55 12 3309-0732; fax: +55 12 3927-7546; email: distrib@embraer.com.br; internet: <http://www.flyembraer.com>.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(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 Des Moines, Washington, on September 14, 2018.

John P. Piccola,

Acting Director, System Oversight Division, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0555; Product Identifier 2017-NM-152-AD; Amendment 39-19431; AD 2018-19-30]

RIN 2120-AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all BAE Systems (Operations) Limited Model 4101 airplanes. This AD was prompted by a report of an improperly installed spacer around the electrical pins in the cartridge connector for the fire bottle extinguisher cartridge. This AD requires repetitive inspections for excessive or missing spacers, and applicable corrective actions. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 2, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 2, 2018.

ADDRESSES: For service information identified in this final rule, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email RApublications@baesystems.com; internet <http://www.baesystems.com/Businesses/RegionalAircraft/index.htm>. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0555.

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-2018-0555; 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 address for Docket Operations (phone: 800-647-5527) is 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:

Todd Thompson, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3228.

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 all BAE Systems (Operations) Limited Model 4101 airplanes. The NPRM published in the **Federal Register** on June 28, 2018 (83 FR 30377).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017-0212, dated October 25, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for all BAE Systems (Operations) Limited Model 4101 airplanes. The MCAI states:

During scheduled maintenance (fire bottle extinguisher cartridge resistance check) it was noted that on the extinguisher cartridge, the blue spacer around the electrical pins appeared to be located too far forward. It was discovered that, inadvertently, an additional spacer (possibly from a previous extinguisher cartridge) was located in the extinguisher cartridge connector. This effectively shortens the electrical pins in the cartridge connector, which could result in insufficient engagement with the associated sockets on the aeroplane connector. A missing spacer would not affect the electrical connection between the extinguisher cartridge and the aeroplane wiring, but could allow moisture ingress over time.

Both conditions, if not detected and corrected, could prevent the fire extinguisher bottle from discharging when required, possibly resulting in damage to the aeroplane and injury to occupants.

To address this potential unsafe condition, BAE Systems (Operations) Ltd issued Service Bulletin (SB) J41-26-009, providing

inspection instructions to ensure that a single blue spacer is fitted on the inside of the extinguisher cartridge connector.

For the reason described above, this [EASA] AD requires a one-time [general visual] inspection [and inspection after a maintenance task that involves disconnection or re-connection of the electrical connector] of the extinguisher cartridge electrical connector and the aeroplane's electrical connector and, depending on findings, removal of excessive spacers or replacement of the fire extinguisher bottle.

You may examine the MCAI in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0555.

Comments

We gave the public the opportunity to participate in developing this final rule.

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 this final rule 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 addressing 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

BAE Systems (Operations) Limited has issued Service Bulletin J41-26-009,

dated November 23, 2016. This service information describes procedures for a general visual inspection of the cartridge electrical connector and the aircraft electrical connector for missing or excessive spacers, and corrective actions including removing excessive spacers or replacing the fire bottle extinguisher cartridge. 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.

Costs of Compliance

We estimate that this AD affects 4 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

| Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|--|------------|------------------|------------------------|
| 1 work-hour × \$85 per hour = \$85 | \$0 | \$85 | \$340 |

We estimate the following costs to do any necessary on-condition actions that would be required based on the results

of any required actions. We have no way of determining the number of aircraft

that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

| Labor cost | Parts cost | Cost per product |
|--|---------------------|------------------|
| 1 work-hour × \$85 per hour = \$85 | Up to \$1,734 | Up to \$1,819. |

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.

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 transport category airplanes and associated appliances to the Director of the System Oversight 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) 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.

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):

2018-19-30 BAE Systems (Operations)

Limited: Amendment 39-19431; Docket No. FAA-2018-0555; Product Identifier 2017-NM-152-AD.

(a) Effective Date

This AD is effective November 2, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to BAE Systems (Operations) Limited Model 4101 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Reason

This AD was prompted by a report of an improperly installed spacer around the electrical pins in the cartridge connector for the fire bottle extinguisher cartridge. We are issuing this AD to detect and correct excessive or missing spacers, which could result in the fire extinguisher bottle not discharging when required, possibly resulting in damage to the airplane.

(f) Compliance

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

(g) Inspection

Within 12 months after the effective date of this AD, do a general visual inspection of the inside of the cartridge electrical connector and the inside of the airplane electrical connector in accordance with the Accomplishment Instructions of the BAE Systems (Operations) Limited Service Bulletin J41-26-009, dated November 23, 2016.

(h) Inspections After Maintenance

As of the effective date of this AD, before further flight after each accomplishment of a maintenance task involving disconnection or (re-)connection of an electrical connector of a fire bottle extinguisher cartridge, do a general visual inspection of the inside of the cartridge electrical connector and the inside of the airplane electrical connector in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin J41-26-009, dated November 23, 2016.

(i) Corrective Actions

(1) If, during any inspection as required by paragraph (g) or (h) of this AD, as applicable, more than one spacer is found inside the cartridge electrical connector: Before further flight, remove the excessive spacer(s) from the inside of the cartridge electrical connector in accordance with the

Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin J41-26-009, dated November 23, 2016.

(2) If, during any inspection as required by paragraph (g) or (h) of this AD, as applicable, one or more spacers are found inside the airplane electrical connector: Before further flight, remove all spacers from the inside of the airplane electrical connector in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin J41-26-009, dated November 23, 2016.

(3) If, during any inspection as required by paragraph (g) or (h) of this AD, as applicable, no blue spacer is found inside the cartridge electrical connector body: Before further flight, replace the cartridge in accordance with the Accomplishment Instructions of the BAE Systems (Operations) Limited Service Bulletin J41-26-009, dated November 23, 2016.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017-0212, dated October 25, 2017, for related information. This MCAI may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0555.

(2) For more information about this AD, contact Todd Thompson, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3228.

(l) 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 this AD specifies otherwise.

(i) BAE Systems (Operations) Limited Service Bulletin J41-26-009, dated November 23, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email RAPublications@baesystems.com; internet <http://www.baesystems.com/Businesses/RegionalAircraft/index.htm>.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(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 Des Moines, Washington, on September 14, 2018.

John P. Piccola,

Acting Director, System Oversight Division, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2018-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship; Change of a Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2018. FDA is informing the public of the availability