

Issued in Fort Worth, Texas, on January 12, 2018.

Lance T. Gant,

*Director, Compliance & Airworthiness
Division, Aircraft Certification Service.*

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0036; Product Identifier 2017-SW-015-AD]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Bell Helicopter Textron Inc. (Bell) Model 212, Model 412, and Model 412EP helicopters. This proposed AD would require replacing the emergency flotation system (EFS) tube assembly. This proposed AD is prompted by a report of an EFS tube assembly failure. The actions of this proposed AD are intended to address an unsafe condition on these helicopters.

DATES: We must receive comments on this proposed AD by March 27, 2018.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- *Fax:* 202-493-2251.

- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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-2018-0036; 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 proposed AD, the economic evaluation, any

comments received, and other information. The street address for Docket Operations (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280-3391; fax (817) 280-6466; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Rory Rieger, Aviation Safety Engineer, DSCO Branch, AIR-7J0, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5193; email rory.rieger@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We propose to adopt a new AD for Bell Model 212, Model 412, and Model 412EP helicopters with an EFS tube assembly part number (P/N) 412-073-820-101 with a date of manufacture before July 28, 2016. This proposed AD is prompted by a report from Bell that an EFS tube assembly separated from the valve during a 2-year inflation test.

A subsequent investigation found that excessive sleeve preset force during manufacturing caused cracks in the sleeve of the tube assembly, which may result in the EFS float failing to deploy. Bell determined that only those EFS tube assemblies with P/N 412-073-820-101 that were shipped prior to July 28, 2016, were subject to this manufacturing defect. Bell states that because this manufacturing defect is difficult to detect, affected EFS tube assemblies in service must be replaced. The affected parts were associated with a single Bell supplier that is no longer manufacturing the tube assembly.

Accordingly, this proposed AD would require replacing the EFS tube assemblies and would prohibit installing an affected EFS tube assembly on any helicopter. We are proposing this AD to prevent installing a cracked EFS tube assembly, which could result in failure of the EFS floats to deploy during an emergency water landing.

FAA's Determination

We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

We reviewed Bell Alert Service Bulletin (ASB) 212-11-143 and ASB 412-11-147, both Revision C and dated December 22, 2016. Each ASB describes and illustrates procedures to replace the tube assembly within 600 flight hours or by March 31, 2017.

Proposed AD Requirements

This proposed AD would require, within 300 hours time-in-service (TIS), replacing any EFS tube assembly P/N 412-073-820-101 that was manufactured before July 28, 2016. This proposed AD would also prohibit installing an EFS tube assembly P/N 412-073-820-101 that was manufactured before July 28, 2016 on any helicopter.

Differences Between This Proposed AD and the Service Information

The ASBs require compliance within 600 flight hours or by March 31, 2017; this proposed AD would require compliance within 300 hours TIS.

Costs of Compliance

We estimate that this proposed AD would affect 250 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this proposed AD. At an average

labor rate of \$85 per hour, replacing a tube assembly would require about 6 work-hours and required parts would cost \$4,902, for a total cost of \$5,412 per helicopter and \$1,353,000 for the U.S. fleet.

According to Bell's service information, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage by Bell. Accordingly, we have included all costs in our cost estimate.

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, 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);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; 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.

We prepared an economic 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 airworthiness directive (AD):

Bell Helicopter Textron Inc.: Docket No. FAA-2018-0036; Product Identifier 2017-SW-015-AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Inc. (Bell) Model 212, Model 412, and Model 412EP helicopters, certificated in any category, with an emergency flotation system (EFS) tube assembly part number (P/N) 412-073-820-101 with a date of manufacture before July 28, 2016, or an unknown date of manufacture installed.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack on an EFS tube assembly. This condition could result in failure of the emergency floats to inflate during an emergency water landing.

(c) Comments Due Date

We must receive comments by March 27, 2018.

(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

- (1) Within 300 hours time-in-service:
 - (i) Remove the EFS tube assembly from service.
 - (ii) Lubricate the shoulder of the sleeves, threads, and seat of each mating fitting with anti-seize compound.
 - (iii) Install an EFS tube assembly not listed in paragraph (a) of this AD.
- (2) After the effective date of this AD, do not install an EFS tube assembly listed in paragraph (a) of this AD on any helicopter.

(f) Alternative Methods of Compliance (AMOC)

- (1) The Manager, DSCO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Rory Rieger, Aviation Safety

Engineer, DSCO Branch, AIR-7J0, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5193; email rory.rieger@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

Bell Helicopter Alert Service Bulletins 212-11-143 and 412-11-147, both Revision C and dated December 22, 2016, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this proposed rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280-3391; fax (817) 280-6466; or at <http://www.bellcustomer.com/files/>. You may review a copy of information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 3212 Emergency Flotation Section.

Issued in Fort Worth, Texas, on January 12, 2018.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA-2017-N-7007]

RIN 0910-AH49

Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend the general biologics regulations relating to time of inspection requirements and also removing duties of inspector requirements. FDA is proposing this action to remove outdated requirements and accommodate new approaches,