

2015-00237R1, dated December 16, 2015, for related information. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1177.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone 425-227-1112; fax 425-227-1149.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(3) and (m)(4) of this AD.

(m) 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) ATR Service Bulletin ATR42-31-0091, Revision 1, dated May 05, 2015.

(ii) ATR Service Bulletin ATR72-31-1092, Revision 2, dated March 31, 2015.

(3) For service information identified in this AD, contact ATR-GIE Avions de Transport Régional, 1, Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email continued.airworthiness@atr-aircraft.com.

(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(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 Renton, Washington, on December 20, 2017.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017-28147 Filed 1-2-18; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-0519; Product Identifier 2017-NM-001-AD; Amendment 39-19138; AD 2017-26-07]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 757-200, -200CB, and -300 series airplanes. This AD was prompted by a report of fatigue cracking found in a certain fuselage frame web. This AD requires inspection of the fuselage frame for existing repairs, repetitive inspections of the frame, and applicable repairs. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 7, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 7, 2018.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740; telephone 562-797-1717; internet <https://www.myboeingfleet.com>. You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0519.

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-2017-0519; 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 this final rule, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Docket 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 FURTHER INFORMATION CONTACT: Muoi Vuong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712-4137; phone: 562-627-5205; fax: 562-627-5210; email: muoi.vuong@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 certain The Boeing Company Model 757-200, -200CB, and -300 series airplanes. The NPRM published in the **Federal Register** on June 2, 2017 (82 FR 25550). The NPRM was prompted by a report of fatigue cracking found in the fuselage frame web at station (STA) 1681, below the floor line at stringer S-17L. The NPRM proposed to require inspection of the fuselage frame for existing repairs, repetitive inspections of the frame, and applicable repairs. We are issuing this AD to detect and correct cracking of the fuselage frame at STA 1681, which could result in reduced structural integrity of the airplane.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

United Airlines agreed with the content of the NPRM, and has started the proposed inspections.

FedEx's fleet of Model 757-200 airplanes was converted by VT Mobile Aerospace Engineering, Inc. (VT MAE), supplemental type certificate (STC) ST03562AT to a configuration similar to that of Boeing Model 757-200SF airplanes, and is no longer configured as passenger airplanes. FedEx stated, however, that per the VT MAE comments to the NPRM, the AD would still be effective for the converted FedEx fleet. FedEx noted that VT MAE has recommended that the airplane configuration groups identified in Boeing Alert Service Bulletin 757-53A0100, dated November 14, 2016, apply to the FedEx fleet. FedEx stated that it agrees with the airplane configuration groups cited by VT MAE and will comply with the actions in the proposed AD accordingly.

Request To Reference the Latest Service Information

Boeing asked that we add Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017, to paragraphs (c), (g), (h)(1), and (h)(2) of the proposed AD as an alternative to using Boeing Alert Service Bulletin 757-53A0100, dated November 14, 2016 (referenced in the NPRM as the appropriate source of service information for accomplishing the actions). Boeing stated that the revised service information provides alternative inspections that allow longer inspection intervals.

We agree that this final rule should refer to the latest service information. Since we issued the NPRM, Boeing has released Boeing Alert Service Bulletin 757–53A0100, Revision 1, dated September 14, 2017. No additional work is necessary on airplanes on which the actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016. We have therefore revised paragraphs (c), (g), (h)(1), and (h)(2) of this AD to refer to Boeing Alert Service Bulletin 757–53A0100, Revision 1, dated September 14, 2017. We have also added paragraph (i) to this AD to provide credit for using Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016, to accomplish the required actions before the effective date of this AD, and redesignated subsequent paragraphs accordingly.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the STC ST01518SE does not affect compliance with the actions specified in the NPRM.

We agree with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) and added paragraph (c)(2) to this AD to state that installation of STC ST01518SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01518SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Clarify Exception Paragraph

Delta Air Lines (Delta) asked that we clarify the following compliance time exception specified by paragraph (h)(1) of the proposed AD: “Where Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016, uses the phrase ‘after the original issue of this service bulletin’ for determining compliance, for purposes of this AD, compliance is based on the effective date of this AD.” Delta noted that the allowance for the phrase “after the effective date of this AD” could not strictly be applied without requesting further clarification in accordance with paragraph (i) of the proposed AD. Delta recommended that this phrase match the language specified in the referenced service bulletin.

We agree with the commenter’s request. We have revised the language in paragraph (h)(1) of this AD to address the commenter’s concern.

Request To Change Repair Procedures

FedEx asked that we revise the NPRM to specify that after repairs are done due to a crack finding, repetitive inspections be required only as based on the original equipment manufacturer (OEM), STC holder, or FAA requirements of the repair. FedEx also asked that the repetitive inspections be terminated for the portion of the inspection area covered by the repair. FedEx stated that Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016, specifies repetitive high frequency eddy current inspections in accordance with the applicable figure in the referenced service information, regardless of whether a repair is installed due to a crack finding. FedEx added that if a repair is installed due to a crack finding, repetitive inspections of the repair are required in accordance with the OEM/STC holder and FAA requirements.

We agree to provide clarification describing why the commenter’s request to revise the NPRM is not necessary. The service bulletin is written such that the affected area is first inspected to determine if any repairs have been installed prior to the service bulletin. If an existing repair is found, then instructions are provided to contact Boeing for evaluation of the repair, to receive inspection instructions, and to do the inspection instructions. Paragraph (h)(2) of this AD requires that instructions received from Boeing are approved in accordance with AMOC procedures per paragraph (j) of this AD. The service bulletin then proceeds to address affected areas where an existing repair (as described above) does not exist by providing instructions to perform certain inspections to determine if a crack exists. When a crack is found, the service bulletin specifies to contact Boeing for repair instructions, do the repair, and then perform a repetitive inspection after a certain number of flight cycles for any crack in areas with no existing frame repair. These instructions must also be approved, per paragraph (h)(2) of this AD, in accordance with AMOC procedures per paragraph (j) of this AD. If a repair has been performed as a result of the previous inspection, the repetitive inspection is to be performed around the repair, but not of the repair itself. There are no repetitive inspections of the repairs specifically called out in the service bulletin. Each repetitive inspection in Tables 1 through Table 5 typically states at the end of the action, “in areas with no existing frame repair.” As clarified above, this means to inspect the area around the existing frame repair. Therefore, there is no need to

terminate the repetitive inspections within the service bulletin for the portion of the inspection area now covered by a repair. However, as previously stated, inspections of the repairs themselves will be addressed by AMOC. We have not changed this AD in this regard.

Request To Add Information Notice to Service Information

FedEx asked that Boeing Alert Service Bulletin Information Notice 757–53A0100 IN 01, dated December 15, 2016, be referenced in the proposed AD. FedEx stated that IN 01 contains corrections to Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016.

We do not agree with the commenter’s request. Boeing Alert Service Bulletin Information Notice 757–53A0100 IN 01, dated December 15, 2016, contains corrections to errors in Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016, but contains no technical changes. Those corrections are included in Boeing Alert Service Bulletin 757–53A0100, Revision 1, dated September 14, 2017, which, as explained previously, is referenced in this AD; therefore, we have not changed this AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and 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.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 757–53A0100, Revision 1, dated September 14, 2017. The service information describes procedures for inspection of the fuselage frame for existing frame and floor beam repairs, repetitive high frequency eddy current inspections for cracking in any area with no existing frame repair, and repetitive high and low frequency eddy current inspections for cracking in any area with no existing frame or floor beam repair; and repair. 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 606 airplanes of U.S. registry. We estimate

the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection for existing frame and floor beam repairs.	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$51,510.
Repetitive inspections ..	Up to 32 work-hours × \$85 per hour = up to \$2,720 per inspection cycle.	\$0	Up to \$2,720 per inspection cycle.	Up to \$1,648,320 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for the on-condition repair specified in this AD.

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 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 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):

2017-26-07 The Boeing Company:
Amendment 39-19138; Docket No. FAA-2017-0519; Product Identifier 2017-NM-001-AD.

(a) Effective Date

This AD is effective February 7, 2018.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to The Boeing Company Model 757-200, -200CB, and -300 series airplanes, certificated in any category,

as identified in Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017.

(2) Installation of Supplemental Type Certificate (STC) ST01518SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/312bc296830a925c86257c85006d1b1f/\\$FILE/ST01518SE.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/312bc296830a925c86257c85006d1b1f/$FILE/ST01518SE.pdf)) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01518SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53; Fuselage.

(e) Unsafe Condition

This AD was prompted by a report of fatigue cracking found in the fuselage frame web at station (STA) 1681. We are issuing this AD to detect and correct cracking of the fuselage frame at STA 1681, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Actions Required for Compliance

Except as required by paragraph (h) of this AD: Do all applicable actions identified as required for compliance (RC) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017. Do the actions at the applicable times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017.

(h) Exceptions

(1) For purposes of determining compliance with the requirements of this AD, the phrase "the effective date of this AD" may be substituted for "the original issue date of this service bulletin" as specified in Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017.

(2) Where Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017, specifies contacting Boeing for

instructions, and specifies that action as RC: This AD requires using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 757-53A0100, dated November 14, 2016.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO 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 manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to 9-ANM-LAACO-AMOC-Requests@faa.gov.

(2) 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.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h)(2) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (j)(4)(i) and (j)(4)(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.

(k) Related Information

(1) For more information about this AD, contact Muoi Vuong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712-4137; phone: 562-627-5205; fax: 562-627-5210; email: muoi.vuong@faa.gov.

(2) Service information identified in this AD that is not incorporated by reference is

available at the addresses specified in paragraphs (l)(3) and (l)(4) of this AD.

(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 the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 757-53A0100, Revision 1, dated September 14, 2017.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740; telephone 562-797-1717; internet <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(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 Renton, Washington, on December 14, 2017.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017-28148 Filed 1-2-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA-2017-N-6599]

Medical Devices; Hematology and Pathology Devices; Classification of a Cervical Intraepithelial Neoplasia Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the cervical intraepithelial neoplasia (CIN) test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the CIN test system's classification. We are taking this action because we have determined

that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective January 3, 2018. The classification was applicable on March 4, 2017.

FOR FURTHER INFORMATION CONTACT:

Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993-0002, 301-796-5866, steven.tjoe@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the cervical intraepithelial neoplasia (CIN) test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the