

Lithium battery installations on the Model A36 airplanes must be designed and installed as follows:

a. Safe cell temperatures and pressures must be maintained during any probable charging or discharging condition, or during any failure of the charging or battery monitoring system not shown to be extremely remote. The lithium battery installation must be designed to preclude explosion or fire in the event of those failures.

b. Lithium batteries must be designed to preclude the occurrence of self-sustaining, uncontrolled increases in temperature or pressure.

c. No explosive or toxic gasses emitted by any lithium battery in normal operation or as the result of any failure of the battery charging or monitoring system, or battery installation not shown to be extremely remote, may accumulate in hazardous quantities within the airplane.

d. Lithium batteries that contain flammable fluids must comply with the flammable fluid fire protection requirements of 14 CFR 23.863(a) through (d).

e. No corrosive fluids or gases that may escape from any lithium battery may damage airplane structure or essential equipment.

f. Each lithium battery installation must have provisions to prevent any hazardous effect on structure or essential systems that may be caused by the maximum amount of heat the battery can generate during a short circuit of the battery or of its individual cells.

g. Lithium battery installations must have—

(1) A system to control the charging rate of the battery automatically to prevent battery overheating or overcharging, or

(2) A battery temperature sensing and over-temperature warning system with a means for automatically disconnecting the battery from its charging source in the event of an over-temperature condition or,

(3) A battery failure sensing and warning system with a means for automatically disconnecting the battery from its charging source in the event of battery failure.

h. Any lithium battery installation functionally required for safe operation of the airplane, must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers, whenever the capacity and state of charge of the batteries have fallen below levels considered acceptable for dispatch of the airplane.

i. The ICAP must contain recommended manufacturer's maintenance and inspection requirements to ensure that batteries, including single cells, meet a functionally safe level essential to the aircraft's continued airworthiness.

(1) The ICAP must contain operating instructions and equipment limitations in an installation maintenance manual.

(2) The ICAP must contain installation procedures and limitations in a maintenance manual, sufficient to ensure that cells or batteries, when installed according to the installation procedures, still meet safety functional levels essential to the aircraft's continued airworthiness. The limitations must identify any unique aspects of the installation.

(3) The ICAP must contain corrective maintenance procedures to check battery capacity at manufacturer's recommended inspection intervals.

(4) The ICAP must contain scheduled servicing information to replace batteries at manufacturer's recommended replacement time.

(5) The ICAP must contain maintenance and inspection requirements how to check visually for battery and charger degradation.

j. Batteries in a rotating stock (spares) that have degraded charge retention capability or other damage due to prolonged storage must be checked at manufacturer's recommended inspection intervals.

k. If the lithium battery application contains software and/or complex hardware, in accordance with AC 20-115⁵ and AC 20-152,⁶ they should be developed to the standards of DO-178 for software and DO-254 for complex hardware.

Compliance with the requirements of this Special Condition must be shown by test or analysis, with the concurrence of the New York Aircraft Certification Office.

Issued in Kansas City, Missouri on September 28, 2016.

William Schinstock,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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⁵ http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/E35FBC0060E2159186257BBE00719FB3?OpenDocument&Highlight=ac%2020-115b.

⁶ http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/6D4AE0BF1BDE3579862570360055D119?OpenDocument&Highlight=ac%2020-152.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2016-3986; Directorate Identifier 2015-NM-147-AD; Amendment 39-18661; AD 2016-19-12]

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 747-400, 747-400D, and 747-400F series airplanes. This AD was prompted by a determination that a certain fastener type in the fuel tank walls has insufficient bond to the structure, and an electrical wiring short could cause arcing to occur at the ends of fasteners in the fuel tanks. This AD requires the installation of new clamps and polytetrafluoroethylene (TFE) sleeves on the wire bundles of the front spars and rear spars of the wings. This AD also requires inspecting the existing TFE sleeves under the wire bundle clamps for correct installation, and replacement if necessary. We are issuing this AD to prevent potential ignition sources in the fuel tank in the event of a lightning strike or high-powered short circuit, and consequent fire or explosion.

DATES: This AD is effective November 14, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 14, 2016.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone: 206-544-5000, extension 1; fax: 206-766-5680; Internet: <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 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-2016-3986.

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-2016-3986.

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You may examine the AD docket on the Internet at <http://www.regulations.gov>

www.regulations.gov by searching for and locating Docket No. FAA–2016–3986; 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 AD, 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:
Tung Tran, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6505; fax: 425–917–6590; email: Tung.Tran@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 747–400, 747–400D, and 747–400F series airplanes. The NPRM published in the **Federal Register** on March 1, 2016 (81 FR 10537) (“the NPRM”). The NPRM was prompted by a determination that a certain fastener

type in the fuel tank walls has insufficient bond to the structure, and an electrical wiring short could cause arcing to occur at the ends of fasteners in the fuel tanks. The NPRM proposed to require the installation of new clamps and TFE sleeves on the wire bundles of the front spars and rear spars of the wings. The NPRM also proposed to require inspecting the existing TFE sleeves under the wire bundle clamps for correct installation, and replacement if necessary. We are issuing this AD to prevent potential ignition sources in the fuel tank in the event of a lightning strike or high-powered short circuit, and consequent fire or explosion.

Comments

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

Support for the NPRM

Boeing supported the content of the NPRM. United Airlines had no objection to the NPRM.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this 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 Boeing Special Attention Service Bulletin 747–28–2324, Revision 1, dated July 27, 2015. The service information describes procedures for installing new clamps and TFE sleeves on the wire bundles of the front spars and rear spars of the wings. The service information also describes procedures for inspecting TFE sleeves under the wire bundle clamps that were installed using the procedures specified in Boeing Special Attention Service Bulletin 747–28–2324, dated November 3, 2014, for correct installation, and replacing them if necessary. 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 135 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
Installation of wire bundle clamps.	Up to 7 work-hours × \$85 per hour = \$595	\$138	Up to \$733	Up to \$98,955.
Inspection	Up to 5 work-hours × \$85 per hour = \$425	0	Up to \$425	Up to \$57,375.

We have received no definitive data that enables us to provide cost estimates for the on-condition actions 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.

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):

2016-19-12 The Boeing Company:

Amendment 39-18661; Docket No. FAA-2016-3986; Directorate Identifier 2015-NM-147-AD.

(a) Effective Date

This AD is effective November 14, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747-400, 747-400D, and 747-400F series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 747-28-2324, Revision 1, dated July 27, 2015.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by a determination that a certain fastener type in the fuel tank walls has insufficient bond to the structure, and an electrical wiring short could cause arcing to occur at the ends of fasteners in the fuel tanks. We are issuing this AD to prevent potential ignition sources in the fuel tank in the event of a lightning strike or high-powered short circuit, and consequent fire or explosion.

(f) Compliance

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

(g) Installation/Inspection

Within 60 months after the effective date of this AD, do the actions specified in paragraph (g)(1) or (g)(2) of this AD, as applicable.

(1) For airplanes on which the modification specified in Boeing Special Attention Service Bulletin 747-28-2324, dated November 3, 2014, has not been done as of the effective date of this AD: Install new clamps and polytetrafluoroethylene (TFE) sleeves on the wire bundles of the front spars and rear spars of the wings, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747-28-2324, Revision 1, dated July 27, 2015.

(2) For airplanes on which the modification specified in Boeing Special Attention Service Bulletin 747-28-2324, dated November 3, 2014, has been done as

of the effective date of this AD: Do a detailed inspection of the TFE sleeves under the wire bundle clamps for correct installation, and replace the sleeves if not correctly installed, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747-28-2324, Revision 1, dated July 27, 2015.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), 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 ACO, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-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, alteration, or modification required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method 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.

(i) Related Information

For more information about this AD, contact Tung Tran, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6505; fax: 425-917-6590; email: Tung.Tran@faa.gov.

(j) 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 Special Attention Service Bulletin 747-28-2324, Revision 1, dated July 27, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone: 206-544-5000, extension 1; fax: 206-766-5680; Internet: <https://www.myboeingfleet.com>.

(4) You may view this referenced service information at the FAA, Transport Airplane Directorate, 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 September 13, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-22707 Filed 10-6-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA-1999-N-0194 (Formerly 99N-4490)]

RIN 0910-AH08

Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is amending its regulations to revise the list of drug products that have been withdrawn or removed from the market because the drug products or components of such drug products have been found to be unsafe or not effective. Drugs appearing on this list may not be compounded under the exemptions provided by sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Specifically, the rule adds 24 entries to this list of drug products, modifies the description of one entry on this list, and revises the list's title and introductory language. These revisions are necessary because information has come to the Agency's attention since March 8, 1999, when FDA published the original list as a final rule.

DATES: This rule is effective November 7, 2016.

FOR FURTHER INFORMATION CONTACT: Edisa Gozun, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5199, Silver Spring, MD 20993-0002, 301-796-3110.