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(j) Related Information

For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3223.

(k) 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) European Union Aviation Safety Agency (EASA) AD 2019-0067R1, dated September 11, 2019.

(ii) [Reserved]

(3) For information about EASA AD 2019-0067R1, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email ADS@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this material 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. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0481.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on December 4, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019-28069 Filed 12-27-19; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2019-0980; Product Identifier 2019-NM-180-AD; Amendment 39-21004; AD 2019-24-15]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting an airworthiness directive (AD) for certain The Boeing Company Model 737-900ER series airplanes. This AD requires replacement of nonconforming head strike pads with conforming head strike pads. This AD was prompted by a report of nonconforming head strike pads on the left and right mid exit doors. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 14, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 14, 2020.

The FAA must receive comments on this AD by February 13, 2020.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

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

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

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 90740-5600; phone: 562-797-1717; internet: <https://www.myboeingfleet.com>. You may view this referenced 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 <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0980.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0980; 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 street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Allie Buss, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3564; email: allison.buss@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA has received a report indicating that nonconforming head strike pads were installed on the left and right mid exit doors in the passenger compartment of certain Boeing Model 737-900ER series airplanes. The nonconforming head strike pads were fabricated using eight bonded layers of 1/8-inch-thick foam, instead of the required 1-inch-thick continuous foam. This condition, if not addressed, could result in injury to passengers in an otherwise survivable emergency landing and potentially block passenger egress.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Special Attention Requirements Bulletin 737-25-1831 RB, dated September 24, 2019. This service information describes procedures for replacement of nonconforming head strike pads with conforming head strike pads on the left and right mid exit doors. 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.

FAA's Determination

The FAA is issuing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires accomplishment of the actions identified in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, described previously, except for any differences identified as exceptions in the regulatory text of this AD.

For information on the procedures and compliance times, see this service information at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0980.

Explanation of Requirements Bulletin

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are “required for compliance” (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked

between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the “Accomplishment Instructions.” The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.*, only the RC actions).

FAA’s Justification and Determination of the Effective Date

Since there are currently no domestic operators of this product, notice and opportunity for public comment before issuing this AD are unnecessary. In addition, for the reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, the FAA invites you to send any written data, views, or arguments

about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2019–0980 and Product Identifier 2019–NM–180–AD at the beginning of your comments. The FAA specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

The FAA will post all comments, without change, to <https://www.regulations.gov>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact the agency receives about this final rule.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product
Replacement	1 work-hour × \$85 per hour = \$85	Up to \$7,080	Up to \$7,165.

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the 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.

The FAA is 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) Will not affect intrastate aviation in Alaska, and
- (3) 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):

2019–24–15 The Boeing Company:
Amendment 39–21004; Docket No. FAA–2019–0980; Product Identifier 2019–NM–180–AD.

(a) Effective Date

This AD is effective January 14, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–900ER series airplanes, certificated in any category, as identified in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report of nonconforming head strike pads on the mid exit doors. The FAA is issuing this AD to address nonconforming head strike pads which could result in injury to passengers in an otherwise survivable emergency landing and potentially block passenger egress.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the “Compliance” paragraph of Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Special Attention Service Bulletin 737–25–1831, dated September 24, 2019, which is referred to in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(h) Exceptions to Service Information Specifications

Where Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, uses the phrase “the original issue date of the Requirements Bulletin 737–25–1831 RB,” this AD requires using “the effective date of this AD.”

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle 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 (j) 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, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, 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.

(j) Related Information

For more information about this AD, contact Allie Buss, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3564; email: allison.buss@faa.gov.

(k) 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 Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(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 90740–5600; phone: 562–797–1717; internet: <https://www.myboeingfleet.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, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on December 9, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–28070 Filed 12–27–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

21 CFR Parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket Nos. FDA–2017–N–1129 and FDA–2017–N–1610]

Medical Devices; Exemptions From Premarket Notification for Class I and Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) identified a list of class I devices and class II devices that are now exempt from premarket notification requirements, subject to certain limitations. FDA published the lists of final determinations in accordance with procedures established by the 21st Century Cures Act (Cures Act). Although each classification regulation for each such type of device shall be deemed amended to incorporate such exemption, we are publishing this final order to amend the codified language for each listed class I and class II device’s classification regulation to reflect the final determinations. FDA’s action decreases regulatory burden on the medical device industry and eliminates private costs and expenditures required to comply with certain Federal regulations.

DATES: This order is effective December 30, 2019.

FOR FURTHER INFORMATION CONTACT:

Karen Fikes, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5502, Silver Spring, MD 20993, 301–796–9603, email: karen.fikes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Cures Act (Pub. L. 114–255) was signed into law on December 13, 2016. Under the Cures Act, section 3054 amended section 510(l) and (m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(l) and (m)). As amended, section 510(l)(2) of the FD&C Act requires FDA to identify through publication in the **Federal Register**, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness.