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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0224; Project Identifier AD–2024–00055–T; Amendment 39–22673; AD 2024–03–04]

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 a new airworthiness directive (AD) for certain The Boeing Company (Boeing) Model 737–8, 737–8200, and 737–9 airplanes. This AD was prompted by a report of a missing washer and nut and consequent migrated bolt discovered by an operator during scheduled maintenance. This AD requires a one-time inspection of the aft rudder quadrant and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 12, 2024.

The FAA must receive comments on this AD by March 28, 2024

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2024–0224; 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, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Anthony Caldejon, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3534; email: *Anthony.V.Caldejon@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2024–0224 and Project Identifier AD–2024–00055–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA

will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Anthony Caldejon, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3534; email: *Anthony.V.Caldejon@faa.gov*. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received a report of a missing nut and washer and of a migrated bolt in the aft rudder quadrant, which were discovered by an operator during a scheduled routine inspection in mid-December 2023. Boeing subsequently inspected all Model 737–8, –8200, and –9 airplanes in production and found one additional under-torqued nut at the same location. It was discovered that the required run-on and final torques had not been applied to the nut in production.

A disconnect between the aft rudder quadrant and the output rod (due to the bolt falling out) would result in loss of rudder control via the rudder pedals. Rudder surface position would then be based only on the rudder trim and yaw damper systems. The pilots would be able to slowly move the rudder surface by adjusting the rudder trim position but would be limited by the maximum rudder trim authority. In the event of a disconnect, and with the limited rudder trim authority, there would not be enough rudder control to counter an engine-out scenario during takeoff/climb out or to counter a high crosswind (above 20 kts) during landing. This condition, if not addressed, could result in the loss of continued safe flight and landing. The FAA is issuing this AD to address the unsafe condition on these products.

FAA’s Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information

The FAA reviewed Boeing Multi Operator Message MOM–MOM–23–0993–01B, dated December 27, 2023. The service information specifies

performing a one-time detailed visual inspection or remote video inspection of the aft rudder quadrant for any missing bolt, nut, or washer; any gap between the bolt/nut/washer and quadrant; and insufficient thread protrusion. The service information also specifies the following corrective actions if necessary: inspection of the bolt and nut for damage and replacement as needed; torque application; and a rudder travel test.

AD Requirements

This AD requires accomplishing the actions specified in the service information described previously.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency,

upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than 30 days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because a disconnect between the aft rudder quadrant and the output rod would result in loss of rudder control via the rudder pedals and insufficient rudder control to counter an engine-out scenario during takeoff/climb out or to counter a high crosswind during landing, which could result in the loss of continued safe flight and landing. The corrective actions required by this AD must be accomplished within 30 days. This compliance time is shorter than the time necessary for the public to comment and for publication of the final

rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 482 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	0.50 work-hour × \$85 per hour = \$42.50	\$0	\$42.50	\$20,485

The FAA estimates the following costs to do any on-condition actions that would be required based on the results

of the inspection. The FAA has no way of determining the number of airplanes

that might need these on-condition actions:

ON-CONDITION COSTS

Actions	Labor cost	Parts cost	Cost per product
Inspection/replacement of bolt/nut, torque application, rudder travel test.	2 work-hours × \$85 per hour = \$170	\$3	\$173

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.

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, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

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:

2024–03–04 The Boeing Company:

Amendment 39–22673; Docket No. FAA–2024–0224; Project Identifier AD–2024–00055–T.

(a) Effective Date

This airworthiness directive (AD) is effective February 12, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–8, 737–8200, and 737–9 airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before December 20, 2023.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by a report of a missing washer and nut and consequent migrated bolt discovered by an operator during scheduled maintenance. The FAA is issuing this AD to address improper torque of the aft rudder quadrant output rod fasteners, which may cause a disconnect between the aft rudder quadrant and the output rod, which would result in loss of rudder control via the rudder pedals to counter an engine-out scenario during takeoff/climb out or to counter a high crosswind during landing. The unsafe condition, if not addressed, could result in loss of continued safe flight and landing.

(f) Compliance

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

(g) Inspection

Within 30 days after the effective date of this AD, perform a one-time detailed visual inspection or remote video inspection of the aft rudder quadrant for missing bolts, nuts, and washers; a gap between the bolt/nut/washer and quadrant; and insufficient thread protrusion.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by paragraph (g) of this AD can be found in Boeing Multi Operator Message MOM–MOM–23–0993–01B, dated December 27, 2023.

(h) On-Condition Actions

If any discrepancy is found during the inspection required by paragraph (g) of this

AD, do the actions specified in paragraphs (h)(1) through (3) of this AD before further flight.

(1) Do a detailed inspection of the bolt, washer, and nut for damage and, before further flight, replace any missing or damaged bolts, washers, and nuts.

(2) Install each bolt, washer, and nut with a torque of 65 in-lb.

(3) Perform a rudder travel test to ensure that the rudder is operating correctly. If the test fails, before further flight, do applicable corrective actions and repeat until the test is passed.

Note 2 to paragraph (h) of this AD:

Guidance for accomplishing the actions required by paragraph (h) of this AD can be found in Boeing Multi Operator Message MOM–MOM–23–0993–01B, dated December 27, 2023.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Multi Operator Message MOM–MOM–23–0993–01B, dated December 27, 2023.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety 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 responsible Flight Standards 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-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 responsible Flight Standards 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, AIR–520, Continued Operational Safety 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.

(k) Related Information

(1) For more information about this AD, contact Anthony Caldejon, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3534; email: Anthony.V.Caldejon@faa.gov.

(2) For service information identified in this AD that is not incorporated by reference, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website myboeingfleet.com.

(l) Material Incorporated by Reference

None.

Issued on February 2, 2024.

Caitlin Locke,

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

[FR Doc. 2024–02930 Filed 2–8–24; 2:00 pm]

BILLING CODE 4910–13–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 601**

[Docket No. FDA–2019–N–1363]

RIN 0910–AH50

**Biologics License Applications and
Master Files**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations to address the use of master files by applications licensed under the Public Health Service Act (PHS Act). This final rule codifies FDA's existing approach that former approved applications for certain biological products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that have been deemed to be licenses for the biological products under the PHS Act may continue to incorporate by reference drug substance, drug product (DS/DSI/DP) information contained in a drug master file (DMF) if such information was being referenced at the time the application was deemed to be a license. This final rule also codifies FDA's general practices regarding the referencing of information in master files by applications licensed under the PHS Act, including applications for combination products licensed under the PHS Act, and by investigational new drug applications (INDs) for products that would be subject to licensure under the PHS Act.

DATES: This rule is effective March 13, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.