

(6) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on September 4, 2025.

Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–18087 Filed 9–17–25; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2662; Project Identifier MCAI–2024–00448–T; Amendment 39–23132; AD 2025–18–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 767–300 series airplanes modified by a certain supplemental type certificate (STC). This AD was prompted by a discovery that certain pitot-static tubing of the first officer's pitot-static system was installed incorrectly in the main and mid equipment center during the airplane conversion from passenger to freighter. This AD requires a visual inspection of certain pitot-static rigid tubes and flexible hoses to determine whether low points exist, and if necessary, related investigative and corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 23, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 23, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2024–2662; 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, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of

Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Israel Aerospace Industries, Ltd. material identified in this AD, contact Israel Aerospace Industries, Ltd., Ben-Gurion International Airport, Israel 70100; telephone 972–39359826; email tmazor@iai.co.il.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety 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 at regulations.gov under Docket No. FAA–2024–2662.

FOR FURTHER INFORMATION CONTACT: Joe Salameh, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3536; email: Joe.Salameh@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA 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 767–300 series airplanes modified by FAA STC ST02040SE. The NPRM was published in the **Federal Register** on December 17, 2024 (89 FR 102019). The NPRM was prompted by a discovery that certain pitot-static tubing of the first officer's pitot-static system was installed incorrectly in the main and mid equipment center during the airplane conversion from passenger to freighter.

The Civil Aviation Authority of Israel (CAAI), which is the aviation authority for Israel, issued AD ISR I–34–2024–07–1, dated August 6, 2024 (CAAI AD ISR I–34–2024–07–1) (also referred to as the MCAI) to address the unsafe condition for The Boeing Company Model 767–300 series airplanes, that have been modified to freighters in accordance with CAAI STC SA–218 (FAA STC ST02040SE, EASA STC 10028430, CAAC VSTC0812, TCCA SA14–67, ANAC 2011S03–12). Only FAA STC ST02040SE is approved for U.S. operators.

The MCAI states that due to the pitot-static tubing improper rerouting on the airplane conversion from passenger to freighter, two erroneous conditions were found in the tubing connecting the pitot and the static system tubing to the right air data computer belonging to the first officer system: The flexible hoses part number (P/N) BACH30BC06–0097 and P/N BACH30BC05–0111, creating a potential water trap; and rigid tubes P/

N 233T9110–437 and P/N 233T9110–320/314 installed through a structure 9G rigid barrier opening, creating a potential water trap.

In the NPRM, the FAA proposed to require a visual inspection of certain pitot-static rigid tubes and flexible hoses to determine whether low points exist, and if necessary, related investigative and corrective actions. The FAA is issuing this AD to address the incorrect installation of the pitot static tubing of the first officer's pitot-static system. The unsafe conditions, if not addressed, may affect the capability to drain water or moisture collected in the first officer pitot-static tubing, and may cause malfunction to the system, leading to an increased flight crew workload and possible loss of control of the airplane.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–2662.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA), Boeing, and DHL Air Austria who supported the NPRM without change.

The FAA received additional comments from Aviation Partners Boeing (APB) and Israel Aerospace Industries (IAI). The following presents the comments received on the NPRM and the FAA's response to each comment.

Effect of Winglets on Accomplishment of the Proposed Actions

APB stated that the installation of winglets per STC ST01920SE does not affect compliance with the proposed actions.

The FAA agrees with the commenter. The installation of STC ST01920SE does not affect the ability to accomplish the actions required by this AD. The FAA has not changed this AD in this regard.

Request To Change Corrective Actions Compliance Time

IAI requested the FAA delete the text “before further flight” in paragraph (g) of the proposed AD. IAI stated that the compliance requirement of the proposed AD is within 36 months from the effective date of the proposed AD. IAI requested to delete the text “before further flight” to allow corrective actions to be performed within the 36 months compliance time, and to allow separate schedules for inspections and corrective actions.

The FAA agrees with this request for the reasons provided and has revised paragraph (g) of this AD accordingly.

Clarification of Unsafe Condition Statement

The unsafe condition statement in the NPRM specified that the unsafe condition, if not addressed, may affect the capability to drain water or moisture collected in the first officer pitot-static tubing, and may cause malfunction to the system; however, it did not specify an end-level effect if the system malfunctioned. The malfunction to the system could lead to an increased flight crew workload and possible loss of control of the airplane. The FAA has revised the unsafe condition statement in this final rule accordingly.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe

condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Israel Aerospace Industries Ltd., Service Bulletin 368–34–106, dated August 2024. This material specifies procedures for a visual inspection of the pitot static rigid tubes, P/N 233T9110–437 and P/N 233T9110–314, and the flexible hoses, P/N BACH30BC06–0097 and P/N BACH30BC05–0111, to determine

whether low points exist, and related investigative and corrective actions. The related investigative action is a visual inspection for the installation of the provisions located above the right miscellaneous electrical equipment panel (P37). The corrective actions include replacement of the pitot and the static system tubing connected to the right air data computer, including installation of standoffs, rigid tubes, union fitting, elbow fitting, and flexible hoses, and performing functional tests.

This material 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

The FAA estimates that this AD affects 88 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 2 work-hours × \$85 per hour = Up to \$170	\$0	Up to \$170	Up to \$14,960.

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

the results of any required actions. The FAA has no way of determining the

number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
11 work-hours × \$85 per hour = \$935	\$600	\$1,535

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,
- (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.

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:

2025–18–05 The Boeing Company: Amendment 39–23132; Docket No.

FAA-2024-2662; Project Identifier
MCAI-2024-00448-T.

(a) Effective Date

This airworthiness directive (AD) is effective October 23, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 767-300 series airplanes, certificated in any category, that have been modified to a special freighter configuration, in accordance with FAA Supplemental Type Certificate (STC) ST02040SE, and which are listed in paragraph I.A., "Effectivity," of Israel Aerospace Industries Ltd., Service Bulletin 368-34-106, dated August 2024.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a discovery that certain pitot-static tubing of the first officer's pitot-static system was installed incorrectly in the main and mid equipment center during the airplane conversion from passenger to freighter. The FAA is issuing this AD to address the incorrect installation of the pitot-static tubing of the first officer's pitot-static system. The unsafe condition, if not addressed, may affect the capability to drain water or moisture collected in the first officer pitot-static tubing, and may cause malfunction to the system, leading to an increased flight crew workload and possible loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

Within 36 months after the effective date of this AD, do a visual inspection of the pitot-static rigid tubes, part number (P/N) 233T9110-437 and P/N 233T9110-314, and the flexible hoses, P/N BACH30BC06-0097 and P/N BACH30BC05-0111, at the locations specified in the Accomplishment Instructions of Israel Aerospace Industries Ltd., Service Bulletin 368-34-106, dated August 2024, to determine whether low points exist, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Israel Aerospace Industries Ltd., Service Bulletin 368-34-106, dated August 2024.

(h) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (i) of this AD and email to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or the Civil Aviation Authority of Israel (CAAI); or the CAAI's authorized Designee. If approved by the CAAI Designee, the approval must include the Designee's authorized signature.

(i) Additional Information

For more information about this AD, contact Joe Salameh, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206-231-3536; email: Joe.Salameh@faa.gov.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Israel Aerospace Industries Ltd., Service Bulletin 368-34-106, dated August 2024.

(ii) [Reserved]

(3) For Israel Aerospace Industries Ltd. material identified in this AD, contact Israel Aerospace Industries, Ltd., Ben-Gurion International Airport, Israel 70100; telephone 972-39359826; email tmazor@iai.co.il.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety 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 material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on September 3, 2025.

Paul R. Bernado,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2024-N-3533]

Microbiology Devices; Reclassification of Antigen, Antibody, and Nucleic Acid-Based Hepatitis B Virus Assay Devices

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order reclassifying qualitative hepatitis B virus (HBV) antigen assays (product code LOM), HBV antibody assays (product code LOM), and quantitative HBV nucleic acid-based assays (product code MKT), all of which are postamendments class III devices, into class II (special controls), subject to premarket notification. FDA is also establishing the special controls that are necessary to provide a reasonable assurance of safety and effectiveness of these device types.

DATES: This order is effective October 20, 2025. See further discussion in Section IV, "Implementation Strategy."

FOR FURTHER INFORMATION CONTACT: Bhawna Poonia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3226, Silver Spring, MD 20993, 240-402-6830, bhawna.poonia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any action taken by FDA (or the Agency). Those devices remain in class III and require premarket approval,