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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1497; Project Identifier AD–2023–00516–T; Amendment 39–22816; AD 2024–16–10]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019–25–17, which applied to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2019–25–17 required revising the existing airplane flight manual (AFM) to prohibit selection of certain runways for airplanes equipped with certain software. Since the FAA issued AD 2019–25–17, Boeing has developed new software to address the unsafe condition. This AD was prompted by reports of display electronic unit (DEU) software errors on airplanes with a selected instrument approach to a specific runway. This AD retains the requirements of AD 2019–25–17. This AD also requires installing the new software and performing a software configuration check, which terminates the AFM revision. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 28, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 28, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1497; 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 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 Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.
- 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–2023–1497.

FOR FURTHER INFORMATION CONTACT: Douglas Y. Tsuji, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3548; email: *Douglas.Tsuji@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2019–25–17, Amendment 39–21016 (84 FR 71304, December 27, 2019) (AD 2019–25–17). AD 2019–25–17 applied to all the Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER (Model 737 NG) series airplanes (although the scope of the AD requirements is limited to operation at specific runways in the U.S., Colombia, and Guyana). The NPRM published in the **Federal Register** on August 4, 2023 (88 FR 51739). The NPRM was prompted by reports of Display Units (DUs) blanking due to Display Electronics Unit (DEU) software errors on Model 737 NG airplanes flying into runway PABR in Barrow, Alaska. The investigation revealed that the problem occurs when a certain combination of software is installed and a susceptible runway with a 270-degree true heading is selected for instrument approach, although only seven runways worldwide have latitude and longitude values that cause the blanking behavior. AD 2019–25–17 was issued to address the potential for blanking displays on flights into the affected airports. The software errors and consequent display blanking, if not addressed, could prevent continued safe flight and landing. In the NPRM, the FAA proposed to retain the requirements of AD 2019–25–17. The NPRM also proposed to require installing the new software, and performing a software configuration check, which would terminate the AFM revision requirement. The FAA is issuing this AD to address the potential for all six DUs to blank, which can prevent continued safe flight and landing.

Discussion of Final Airworthiness Directive

Comments

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

The FAA received additional comments from three commenters, including Boeing, Southwest Airlines (SWA), and Pegasus Airlines. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Continue Utilizing Common Display System Block Point 06

Boeing requested that paragraph (m), ''Alternative Methods of Compliance (AMOCs),'' of the proposed AD be revised to allow airplanes with Common Display System (CDS) Block Point (BP) 06 an AMOC to the actions specified by paragraph (h) of the proposed AD. SWA requested allowing airplanes to continue to utilize CDS BP06 in lieu of the software update that would be required by paragraph (h) of the proposed AD (*i.e.,* CDS BP15a). Boeing and SWA stated that CDS BP06 does not contain the error that leads to the display blanking for the specific airports listed in AD 2019–25–17. SWA also cited a software incompatibility issue with the Rockwell Collins Head Up Display (HUD) HGS–2350 (currently installed on 15% of their fleet) and stated that the new CDS BP15a would require disabling the HUD, which provides the flightcrew a myriad of safety features enhancements.

The FAA agrees with allowing airplanes with CDS BP06 to be excepted

from the requirements of paragraph (h) of this AD, because CDS BP06 does not contain the error that leads to the display blanking for the specific airports listed in AD 2019–25–17. The FAA has added a statement in paragraph (i)(2) of this AD accordingly. The FAA does not agree with revising paragraph (m) of this AD, because this AD has been revised to except airplanes with CDS BP06 from the requirements of paragraph (h) of this AD, thus eliminating the need for the AMOC.

Request for Adding a Note to Paragraph (c), ''Applicability''

Pegasus Airlines requested adding a note to paragraph (c), ''Applicability,'' of the proposed AD as follows: ''The scope of the AD requirements is limited to operation at the seven runways identified in figure 1 to paragraph (g) of this AD.'' The commenter stated that the note was in AD 2019–25–17 and should be included in this AD.

The FAA disagrees with the commenter. The requirements of this AD, notably the software update, must be done by all applicable airplanes regardless of runway operation. The FAA has not changed this AD in this regard.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate STC ST00830SE does not affect the accomplishment of the manufacturer's service instructions.

The FAA agrees with the commenter that STC ST00830SE does not affect the accomplishment of the manufacturer's service instructions. Therefore, the installation of STC ST00830SE does not affect the ability to accomplish the actions required by this AD. The FAA has not changed this AD in this regard.

Conclusion

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 Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020. This material specifies procedures for installing the CDS DEU OPS block point 2015A and performing a software configuration check. 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 1,739 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
Revise AFM (retained action from AD 2019–25–17).	1 work-hour × $85 per hour = $85.	$0	$85	$147,815.
Install software and perform configuration check (new actions).	2 work-hours × $85 per hour = $170.	Up to $975	Up to $1,145	Up to $1,991,155.

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:

■ a. Removing Airworthiness Directive (AD) 2019–25–17, Amendment 39–21016 (84 FR 71304, December 27, 2019); and

■ b. Adding the following new AD:

2024–16–10 The Boeing Company: Amendment 39–22816; Docket No. FAA–2023–1497; Project Identifier AD–2023–00516–T.

(a) Effective Date

This airworthiness directive (AD) is effective October 28, 2024.

(b) Affected ADs

This AD replaces AD 2019–25–17, Amendment 39–21016 (84 FR 71304, December 27, 2019) (AD 2019–25–17).

(c) Applicability

This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 31, Instruments.

(e) Unsafe Condition

This AD was prompted by reports of display electronic unit (DEU) software errors on airplanes with a selected instrument approach to a specific runway. The FAA is proposing this AD to address the potential for all six display units (DUs) to blank, which can prevent continued safe flight and landing.

(f) Compliance

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

(g) Retained AFM Revision, with No Changes

This paragraph restates the requirements of paragraph (g) of AD 2019–25–17, with no changes. Within 14 days after December 27, 2019 (the effective date of AD 2019–25–17), revise the Miscellaneous Limitations section of the existing airplane flight manual (AFM) to include the information in figure 1 to paragraph (g) of this AD. This may be done by inserting a copy of figure 1 to paragraph (g) of this AD into the Miscellaneous Limitations section of the existing AFM.

Figure 1 to Paragraph (g)—AFM Revision

Common Display System (Required by AD 2019-25-17)

The following is applicable only if configured with CDS BP15 and FMC U12 or later.

Do not select the following runways in the FMC ARRIVALS page, as it may result in blanking of all six display units:

82V RW26 Pine Bluffs, Wyoming, USA

KBJJ RW28 Wayne County, Ohio, USA

KCIU RW28 Chippewa County, Michigan, USA

KCNM RW26 Cavern City, New Mexico, USA

PABR RW25 Barrow, Alaska, USA

SKLM RW28 La Mina, La Guajira, Colombia

SYCJ RW29 Cheddi Jagan, Georgetown, Guyana

(h) Software Update

Except as specified in paragraph (i) of this AD: At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020.

Note 1 to paragraph (h): Guidance for accomplishing the actions required by paragraph (h) of this AD can be found in Boeing Alert Service Bulletin 737–31A1880, Revision 1, dated September 16, 2020, which is referred to in Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020.

(i) Exceptions to Requirements Bulletin Specifications

(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020, use the phrase ''Within 12 months—after the Revision 1 date of Requirements Bulletin 737–31A1880 RB,'' this AD requires using ''Within 12 months after the effective date of this AD.''

(2) The requirements of paragraph (h) of this AD do not apply to airplanes with Common Display System (CDS) Block Point 06 installed.

(j) Terminating Action for AFM Revision

Accomplishment of the actions specified by paragraph (h) of this AD by an operator's entire affected fleet terminates the actions required by paragraph (g) of this AD, and the AFM revision required by paragraph (g) of this AD may be removed from the AFM.

(k) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 737–31A1880 RB, dated April 17, 2020, which is not incorporated by reference in this AD.

(l) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the actions required by this AD can be performed, provided the airplane is operated in accordance with the AFM limitation required by paragraph (g) of this AD.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, 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 (n)(1) of this AD. Information may be emailed to: *AMOC@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, 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.

(n) Related Information

(1) For more information about this AD, contact Douglas Y. Tsuji, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3548; email: *Douglas.Tsuji@faa.gov*.

(2) Material identified in this AD that is not incorporated by reference is available at the addresses specified in paragraph (o)(3) of this AD.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020.

(ii) [Reserved]

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website myboeingfleet.com.

(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 that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on August 1, 2024.

Peter A. White,

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

[FR Doc. 2024–21557 Filed 9–20–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2016–N–2880]

Microbiology Devices; Reclassification of Cytomegalovirus Deoxyribonucleic Acid Quantitative Assay Devices Intended for Transplant Patient Management

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

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify cytomegalovirus (CMV) deoxyribonucleic acid (DNA) quantitative assay devices intended for transplant patient management, a postamendments class III device (product code PAB) into class II (general controls and special controls), subject to premarket notification.

DATES: This order is effective October 23, 2024.

ADDRESSES: For access to the docket to read background documents or the electronic and-written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, 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.

FOR FURTHER INFORMATION CONTACT: Silke Schlottmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3258, Silver Spring, MD 20993–0002, 301–796–9551, *Silke.Schlottmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), among other amendments, 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 (general controls and special controls), and class III (general controls and 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 FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or class II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807), subpart E, of FDA's regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

In the **Federal Register** of September 18, 2020 (85 FR 58300), FDA published a proposed order to reclassify CMV DNA quantitative assay devices intended for transplant patient management (''CMV transplant assays'') from class III into class II (general and special controls), subject to premarket notification. The comment period on the proposed order closed on November 17, 2020. FDA received two comments on the proposed order, both of which were supportive of the reclassification from Class III to Class II and agreed with FDA