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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-0127; Product Identifier 2016-NM-161-AD; Amendment 39-19447; AD 2018-20-13]

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 all The Boeing Company Model 737 airplanes, excluding Model 737-100, -200, -200C, -300, -400, and -500 series airplanes; all Model 757-200, -200PF, -200CB, and -300 series airplanes; and all Model 767-200, -300, -300F, and -400ER series airplanes. This AD was prompted by reports of latently failed motor-operated valve (MOV) actuators of the fuel shutoff valves. This AD requires replacing certain MOV actuators of the fuel shutoff valves for the left and right engines (on certain airplanes) and of the auxiliary power unit (APU) fuel shutoff valve (on Model 757 and Model 767 airplanes); and revising the maintenance or inspection program to incorporate certain airworthiness limitations (AWLs). We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 15, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 15, 2018.

ADDRESSES: For service information identified in this final rule, 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; internet: <https://www.myboeingfleet.com>. 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. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0127.

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-2017-0127; 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 regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800-647-5527) is Docket Operations, 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: Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3553; email: Takahisa.Kobayashi@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 all The Boeing Company Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes; Model 757 airplanes; and Model 767 airplanes. The NPRM published in the **Federal Register** on March 9, 2017 (82 FR 13073). The NPRM was prompted by reports of latently failed MOV actuators of the fuel shutoff valves. The NPRM proposed to require replacing certain MOV actuators of the fuel shutoff valves for the left and right engines (on all airplanes) and of the APU fuel shutoff valve (on Model 757 and Model 767 airplanes); and revising the maintenance or inspection program, as applicable, to incorporate certain AWLs.

We subsequently issued a supplemental NPRM (SNPRM) to amend

14 CFR part 39 by adding an AD that would apply to all Model 737 airplanes, excluding Model 737-100, -200, -200C, -300, -400, and -500 series airplanes; and all Model 757 and 767 airplanes. The SNPRM published in the **Federal Register** on April 3, 2018 (83 FR 14207). The SNPRM proposed to add Model 737-8 airplanes and future Model 737 airplanes to the applicability.

We are issuing this AD to address a latent failure of the actuator for the engine or APU fuel shutoff valves, which could result in the inability to shut off fuel to the engine or the APU, and, in case of certain engine or APU fires, could result in structural failure.

Republication

Editorial Note: Rule document 2018-21460 was originally published on pages 51304 through 51313 in the issue of Thursday, October 11, 2018. In that publication, on page 51307, in the second column, in (c)(1), "Estimated -200" should read "-200". The corrected document is published here in its entirety.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the SNPRM and the FAA's response to each comment.

Request To Exclude Model 737-8 and Future Model 737

Boeing requested that we revise the proposed AD (in the SNPRM) to exclude Model 737-8 airplanes and future Model 737 airplanes, because MOV actuator part number MA30A1017 (Boeing P/N S343T003-76) is the only certified MOV actuator for use on any future Model 737 airplanes as documented in the drawings and Illustrated Parts Catalog (IPC). The commenter stated that using airworthiness limitations to prohibit the use of parts with AD restrictions on one minor model series (Model 737 next generation (NG) airplanes) from being used on a different minor model series (Model 737-8 and future Model 737 airplanes) that does not allow the use of the restricted parts is unnecessary and implies that certified configurations and ADs can be overridden via an Advisory Circular (AC) or other means.

We disagree with the commenter's request. The MOV actuator currently allowed on Model 737-8 and 737-9 airplanes, part number MA30A1017

(Boeing P/N S343T003-76), is the only part number certificated on those models, as documented in the manufacturer's drawings. However, manufacturer's proprietary drawings are not readily available to all affected operators, and there is no prohibition against installing MOV actuator part numbers that were determined unsafe in this AD. We have been informed by operators that the practice of rotating physically interchangeable parts among airplanes is widespread, and even a key part of their operations. In the absence of an AD or AWL that restricts the installation of the affected parts, we cannot be assured that the unsafe condition will not be introduced to Model 737-8, 737-9, and future 737 airplanes. In addition, ACs are advisory in nature and do not include mandatory actions. Therefore, ACs do not take precedence over ADs. We have not changed this AD regarding this issue.

Request To Remove Requirement To Revise Maintenance Program

Boeing requested that we remove paragraph (j) of the proposed AD and revise FAA AC 120-77 or other applicable advisory material to preclude installation of equipment that both Boeing and the FAA have determined cause a potential safety issue, against certified configurations. Boeing suggested that listing parts that are not approved for use on a given model sets a precedent that can become unmanageable, and that identifying parts that are acceptable for a given airplane and installation position is a more explicit and manageable approach. Boeing added that the use of AWLs to prohibit AD-driven part installations is unnecessary and implies that certified configurations and ADs can be overridden via an AC or other means.

We disagree with the commenter's request. The FAA is currently considering revising AC 120-77 to help prevent the rotation of parts as a minor alteration. However, ACs are advisory in nature and do not include mandatory actions. Therefore, ACs cannot prohibit the installation of unsafe equipment, and they do not take precedence over ADs. In addition, the practice of rotating parts is widespread, and revising the AC will not improve the situation in a timely manner. Certain MOV actuator part numbers have been identified to be unsafe for installation at certain locations. Since those part numbers continue to be available and acceptable for installation at certain other locations, we consider the use of AWLs to prohibit specific parts installation to be a reasonable way to address the safety concern in a timely manner. We

have not changed this AD regarding this issue.

Request To Clarify Affected Part Numbers

FedEx requested that we revise paragraphs (h)(2) and (h)(3) of the proposed AD (in the SNPRM) to state that no replacement is necessary if the MOV actuator part number is one of the following alternative part numbers: AV-31-1 (Boeing P/N S343T003-111), MA11A1265 (Boeing P/N S343T003-14), or MA11A1265-1 (Boeing P/N S343T003-41). FedEx stated that the service information specified in paragraphs (h)(2) and (h)(3) of the proposed AD (in the SNPRM) explicitly state that those alternative MOV actuator part numbers are acceptable substitutes for P/N MA30A1017 (Boeing P/N S343T003-76).

We disagree with the commenter's request. However, we agree to clarify the requirements of paragraphs (h)(2) and (h)(3) of this AD. Paragraphs (h)(2) and (h)(3) of this AD require replacement of MOV actuator P/N MA20A2027 (Boeing P/N S343T003-56) and P/N MA30A1001 (Boeing P/N S343T003-66) with an acceptable MOV actuator part number. Those paragraphs do not state or imply that MOV actuator P/N AV-31-1 (Boeing P/N S343T003-111), P/N MA11A1265 (Boeing P/N S343T003-14), or P/N MA11A1265-1 (Boeing P/N S343T003-41) must be replaced. Therefore, we consider that adding the proposed statement is unnecessary. We have not changed this AD regarding this issue.

Request To Add a Terminating Action Provision

FedEx requested that we revise paragraphs (i)(2) and (i)(3) of the proposed AD (in the SNPRM) to state that the actuator installation would terminate the daily functional checks required by AWLs 28-AWL-ENG and 28-AWL-APU. The commenter added that installation of MOV actuator part number MA30A1017 (Boeing P/N S343T003-76) or an acceptable alternative part number should substantially increase the safety value.

We disagree with the commenter's request. We have determined that accomplishing the applicable maintenance or inspection program revisions specified in paragraph (j) of this AD are the appropriate terminating actions. As discussed previously in the preamble of the SNPRM, we included the conditions (accomplishing the applicable maintenance or inspection program revisions) that would terminate the requirements of AD 2015-21-10, Amendment 39-18303 (80 FR 65130,

October 26, 2015); AD 2015-19-04, Amendment 39-18267 (80 FR 55505, September 16, 2015); and AD 2015-21-09, Amendment 39-18302 (80 FR 65121, October 26, 2015). Those ADs require incorporation of the AWLs that require repetitive inspections of specific MOV actuator part numbers installed at specific locations. The requirements of those ADs may be terminated if the applicable conditions specified in paragraph (m) of this AD are met. We have not changed this AD regarding this issue.

Request To Refer to Latest Service Information

Southwest Airlines requested that we refer to the latest revisions of the airworthiness limitations documents.

We agree with the commenter's request and have revised this AD to refer to the current airworthiness limitations as the appropriate source of service information, and have included earlier revisions of the service information as credit in this AD. There are no changes to the required actions of this AD because the tasks that must be incorporated into the maintenance or inspection program are not changed in Boeing 737-600/700/700C/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001-9-04, Revision June 2018; Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLS) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision May 2018; or Boeing 767-200/300/300F/400 Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision March 2018; except for Task 28-AWL-23 for Model 767-200, -300, -300F, and -400ER series airplanes, which adds instructions that further describe the conditions for performing electrical bonding resistance measurements, in addition to being more descriptive regarding cap seal application.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

We also determined that these changes will not increase the economic

burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information.

- Boeing Service Bulletin 737-28-1314, dated November 17, 2014, describes procedures for installing new MOV actuators of the fuel shutoff valves for the left and right engines on Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes.
- Boeing 737-600/700/700C/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001-9-04, Revision June 2018, describes AWLs for fuel tank ignition prevention on Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes.

- Boeing Special Attention Service Bulletin 757-28-0138, Revision 1, dated June 19, 2017, describes procedures for installing new MOV actuators of the fuel shutoff valves for the left and right engines, and of the APU fuel shutoff valve, on Model 757 airplanes.

- Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision May 2018, describes AWLs for fuel tank ignition prevention on Model 757 airplanes.

- Boeing Service Bulletin 767-28-0115, Revision 1, dated June 2, 2016, describes procedures for installing new MOV actuators of the fuel shutoff valves for the left and right engines, and of the

APU fuel shutoff valve, on Model 767 airplanes.

- Boeing 767-200/300/300F/400 Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision March 2018, describes AWLs for fuel tank ignition prevention on Model 767 airplanes.

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 2,557 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
Inspection and replacement Model 737 (1,440 airplanes).	Up to 6 work-hours × \$85 per hour = Up to \$510.	Up to \$12,000	Up to \$12,510	Up to \$18,014,400.
Inspection and replacement Model 757 (675 airplanes).	Up to 9 work-hours × \$85 per hour = Up to \$765.	Up to \$18,000	Up to \$18,765	Up to \$12,666,375.
Inspection and replacement Model 767 (442 airplanes).	Up to 9 work-hours × \$85 per hour = Up to \$765.	Up to \$18,000	Up to \$18,765	Up to \$8,294,130.

For the maintenance/inspection program revision, we have determined that this action takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleets, we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be \$7,650 (90 work-hours × \$85 per work-hour).

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.

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) 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):

2018–20–13 The Boeing Company:

Amendment 39–19447; Docket No. FAA–2017–0127; Product Identifier 2016–NM–161–AD.

(a) Effective Date

This AD is effective November 15, 2018.

(b) Affected ADs

This AD affects AD 2015–21–09, Amendment 39–18302 (80 FR 65121, October 26, 2015) (“AD 2015–21–09”); AD 2015–19–04, Amendment 39–18267, (80 FR 55505, September 16, 2015) (“AD 2015–19–04”); and AD 2015–21–10, Amendment 39–18303 (80 FR 65130, October 26, 2015) (“AD 2015–21–10”).

(c) Applicability

This AD applies to all The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD.

(1) Model 737 airplanes, excluding Model 737–100, –200, –200C, –300, –400, and –500 series airplanes.

(2) Model 757–200, –200PF, –200CB, and –300 series airplanes.

(3) Model 767–200, –300, –300F, and –400ER series airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of latently failed motor-operated valve (MOV) actuators of the fuel shutoff valves. We are issuing this AD to prevent a latent failure of the actuator for the engine or auxiliary power unit (APU) fuel shutoff valves, which could result in the inability to shut off fuel to the engine or the APU, and, in case of certain engine or APU fires, could result in structural failure.

(f) Compliance

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

(g) Inspection To Determine Part Number (P/N)

(1) For Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes: Within 8 years after the effective date of this AD, do an inspection to determine the part numbers of the MOV actuators of the fuel shutoff valves for the left and right engines, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–28–1314, dated November 17, 2014. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of the MOV actuator at each location can be conclusively determined from that review.

(2) For airplanes identified in paragraphs (c)(2) and (c)(3) of this AD: Within 8 years after the effective date of this AD, do an inspection to determine the part numbers of the MOV actuators of the fuel shutoff valves

for the left and right engines, and of the APU fuel shutoff valve, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–28–0138, Revision 1, dated June 19, 2017 (“SB 757–28–0138 R1”); or Boeing Service Bulletin 767–28–0115, Revision 1, dated June 2, 2016 (“SB 767–28–0115 R1”); as applicable. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of the MOV actuator at each location can be conclusively determined from that review.

(h) Replacement

(1) For Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes on which any MOV actuator having P/N MA20A2027 or P/N MA30A1001 (Boeing P/N S343T003–56 or Boeing P/N S343T003–66, respectively), is found during the inspection required by paragraph (g)(1) of this AD: Within 8 years after the effective date of this AD, replace each affected MOV actuator with an MOV actuator having P/N MA30A1017 (Boeing P/N S343T003–76), in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–28–1314, dated November 17, 2014. Where Boeing Service Bulletin 737–28–1314, dated November 17, 2014, specifies the installation of a new MOV actuator, this AD allows the installation of a new or serviceable MOV actuator. While not required by this AD, the Accomplishment Instructions specified in Boeing Service Bulletin 737–28–1314, dated November 17, 2014, for replacing MOV actuators having Boeing P/N S343T003–66 or Boeing P/N S343T003–56 may be used for replacing MOV actuators having P/N MA20A1001–1 (Boeing P/N S343T003–39).

(2) For airplanes identified in paragraph (c)(2) of this AD on which any MOV actuator having P/N MA20A2027 or P/N MA30A1001 (Boeing P/N S343T003–56 or Boeing P/N S343T003–66, respectively) is found during the inspection required by paragraph (g)(2) of this AD: Within 8 years after the effective date of this AD, replace each affected MOV actuator with an MOV actuator having P/N MA30A1017 (Boeing P/N S343T003–76), P/N AV–31–1 (Boeing P/N S343T003–111), or P/N MA11A1265–1 (Boeing P/N S343T003–41), in accordance with the Accomplishment Instructions of SB 757–28–0138 R1. Where SB 757–28–0138 R1 specifies the installation of a new MOV actuator, this AD allows the installation of a new or serviceable MOV actuator. While not required by this AD, the Accomplishment Instructions specified in SB 757–28–0138 R1 for replacing MOV actuators having Boeing P/N S343T003–66 or Boeing P/N S343T003–56 may be used for replacing MOV actuators having P/N MA20A1001–1 (Boeing P/N S343T003–39).

(3) For airplanes identified in paragraph (c)(3) of this AD on which any MOV actuator having P/N MA20A2027 (Boeing P/N S343T003–56) or P/N MA30A1001 (Boeing P/N S343T003–66) is found during the inspection required by paragraph (g)(2) of this AD: Within 8 years after the effective date of this AD, replace each affected MOV actuator with an MOV actuator having P/N MA30A1017 (Boeing P/N S343T003–76), P/N AV–31–1 (Boeing P/N S343T003–111), P/N

MA11A1265 (Boeing P/N S343T003–14), or P/N MA11A1265–1 (Boeing P/N S343T003–41), in accordance with the Accomplishment Instructions of SB 767–28–0115 R1. Where SB 767–28–0115 R1 specifies the installation of a new MOV actuator, this AD allows the installation of a new or serviceable MOV actuator. While not required by this AD, the Accomplishment Instructions specified in SB 767–28–0115 R1, for replacing MOV actuators having Boeing P/N S343T003–66 or Boeing P/N S343T003–56 may be used for replacing MOV actuators having P/N MA20A1001–1 (Boeing P/N S343T003–39).

(i) Maintenance or Inspection Program Revision

(1) For Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes with an original certificate of airworthiness or original export certificate of airworthiness issued on or before the effective date of this AD: Prior to or concurrently with the actions required by paragraph (h)(1) of this AD or within 30 days after the effective date of this AD, whichever is later, revise the maintenance or inspection program, as applicable, to add the airworthiness limitations (AWLs) specified in paragraphs (i)(1)(i), (i)(1)(ii), and (i)(1)(iii) of this AD. The initial compliance time for accomplishing the actions required by AWL No. 28–AWL–24 is within 6 years since the most recent inspection was performed in accordance with AWL No. 28–AWL–24, or within 6 years since the actions specified in Boeing Alert Service Bulletin 737–28A1207 were accomplished, whichever is later.

(i) AWL No. 28–AWL–21, Motor Operated Valve (MOV) Actuator—Lightning and Fault Current Protection Electrical Bond, as specified in Boeing 737–600/700/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001–9–04, Revision June 2018.

(ii) AWL No. 28–AWL–22, Motor Operated Valve (MOV) Actuator—Electrical Design Feature, as specified in Boeing 737–600/700/700C/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001–9–04, Revision June 2018.

(iii) AWL No. 28–AWL–24, Spar Valve Motor Operated Valve (MOV) Actuator—Lightning and Fault Current Protection Electrical Bond, as specified in Boeing 737–600/700/700C/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001–9–04, Revision June 2018.

(2) For airplanes identified in paragraph (c)(2) of this AD: Prior to or concurrently with the actions required by paragraph (h)(2) of this AD, revise the maintenance or inspection program, as applicable, to add the AWLs specified in paragraphs (i)(2)(i), (i)(2)(ii), and (i)(2)(iii) of this AD. The initial compliance time for accomplishing the actions required by AWL No. 28–AWL–25 is within 6 years since the most recent inspection was performed in accordance with AWL No. 28–AWL–25, or within 6 years since the actions specified in Boeing Alert Service Bulletin 757–28A0088 were accomplished, whichever is later.

(i) AWL No. 28–AWL–23, Motor Operated Valve (MOV) Actuator—Lightning and Fault

Current Protection Electrical Bond, as specified in Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision May 2018.

(ii) AWL No. 28-AWL-24, MOV Actuator—Electrical Design Feature, as specified in Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision May 2018.

(iii) AWL No. 28-AWL-25, Motor Operated Valve (MOV) Actuator—Lightning and Fault Current Protection Electrical Bond, as specified in Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision May 2018.

(3) For airplanes identified in paragraph (c)(3) of this AD with an original certificate of airworthiness or original export certificate of airworthiness issued on or before the effective date of this AD: Prior to or concurrently with the actions required by paragraph (h)(3) of this AD, revise the maintenance or inspection program, as applicable, to add the AWLs specified in paragraphs (i)(3)(i) and (i)(3)(ii) of this AD.

(i) AWL No. 28-AWL-23, Motor Operated Valve (MOV) Actuator—Lightning and Fault Current Protection Electrical Bond, as specified in Boeing 767-200/300/300F/400 Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision March 2018.

(ii) AWL No. 28-AWL-24, Motor Operated Valve (MOV) Actuator—Electrical Design Feature, as specified in Boeing 767-200/300/300F/400 Special Compliance Items/

Airworthiness Limitations, D622T001-9-04, Revision March 2018.

(j) Maintenance or Inspection Program Revision for Parts Installation Prohibition

(1) For Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes: After accomplishing the actions required by paragraphs (g)(1), (h)(1), and (i)(1) of this AD, as applicable, on all airplanes in an operator's fleet, and within 8 years after the effective date of the AD, revise the maintenance or inspection program, as applicable, by incorporating the AWL specified in figure 1 to paragraph (j)(1) of this AD.

BILLING CODE 1301-00-D

**Figure 1 to Paragraph (j)(1) of this AD –
AWL for Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes**

AWL No.	Applicability	Description
28-AWL-MOVA	All	Motor Operated Valve (MOV) Actuator - Prohibition of Installation of Specific Part Numbers Installation of MOV actuator part number (P/N) MA30A1001 (Boeing P/N S343T003-66) and P/N MA20A2027 (Boeing P/N S343T003-56) is prohibited at the following positions: 1. Left engine fuel shutoff spar valve position 2. Right engine fuel shutoff spar valve position

(2) For airplanes identified in paragraph (c)(2) of this AD: After accomplishing the actions required by paragraphs (g)(2), (h)(2), and (i)(2) of this AD, as applicable, on all

airplanes in an operator's fleet, and within 8 years after the effective date of the AD, revise the maintenance or inspection program, as applicable, by incorporating the AWL

specified in figure 2 to paragraph (j)(2) of this AD.

**Figure 2 to Paragraph (j)(2) of this AD –
AWL for airplanes identified in paragraph (c)(2) of this AD**

AWL No.	Applicability	Description
28-AWL-MOVA	All	Motor Operated Valve (MOV) Actuator - Prohibition of Installation of Specific Part Numbers Installation of MOV actuator part number (P/N) MA30A1001 (Boeing P/N S343T003-66) and P/N MA20A2027 (Boeing P/N S343T003-56) is prohibited at the following positions: 1. Left engine fuel shutoff spar valve position 2. Right engine fuel shutoff spar valve position 3. APU fuel shutoff valve position

(3) For airplanes identified in paragraph (c)(3) of this AD: After accomplishing the actions required by paragraphs (g)(2), (h)(3), and (i)(3) of this AD, as applicable, on all

airplanes in an operator's fleet, and within 8 years after the effective date of the AD, revise the maintenance or inspection program, as applicable, by incorporating the AWL

specified in figure 3 to paragraph (j)(3) of this AD.

**Figure 3 to Paragraph (j)(3) of this AD –
AWL for airplanes identified in paragraph (c)(3) of this AD**

AWL No.	Applicability	Description
28-AWL-MOVA	All	Motor Operated Valve (MOV) Actuator - Prohibition of Installation of Specific Part Numbers Installation of MOV actuator part number (P/N) MA30A1001 (Boeing P/N S343T003-66) and P/N MA20A2027 (Boeing P/N S343T003-56) is prohibited at the following positions: 1. Left engine fuel shutoff spar valve position 2. Right engine fuel shutoff spar valve position 3. APU fuel shutoff valve position

(4) For airplanes identified in paragraph (c)(1) of this AD, excluding Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes: Within 30 days since the date of issuance of the original standard

airworthiness certificate or the date of issuance of the original export certificate of airworthiness, or within 30 days after the effective date of this AD, whichever is later, revise the maintenance or inspection

program, as applicable, by incorporating the AWL specified in figure 4 to paragraph (j)(4) of this AD.

Figure 4 to Paragraph (j)(4) of this AD –
AWL for airplanes identified in paragraph (c)(1) of this AD,
excluding Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes

AWL No.	Applicability	Description
28-AWL-MOVA	All	<p>Motor Operated Valve (MOV) Actuator – Prohibition of Installation of Specific Part Numbers</p> <p>Concern: Installation of the following MOV actuator part numbers (P/N) is not part of the airplane type design: P/N MA30A1001 (Boeing P/N S343T003-66), P/N MA20A2027 (Boeing P/N S343T003-56), P/N MA20A1001-1 (Boeing P/N S343T003-39). However, there is a potential for those part numbers to be installed on the airplane using provisions provided in FAA Advisory Circular 120-77 or other means due to their continued availability and use on other Model 737 airplanes. Such an alteration will create unsafe conditions.</p> <ol style="list-style-type: none"> 1. Installation of MOV actuator P/N MA20A1001-1 (Boeing P/N S343T003-39) is prohibited at any location. 2. Installation of MOV actuator part number (P/N) MA30A1001 (Boeing P/N S343T003-66) and P/N MA20A2027 (Boeing P/N S343T003-56) is prohibited at the following positions: <ol style="list-style-type: none"> a. Left engine fuel shutoff spar valve position b. Right engine fuel shutoff spar valve position

BILLING CODE 1301-00-C**(k) No Alternative Actions, Intervals, and Critical Design Configuration Control Limitations (CDCCLs)**

(1) After the maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (e.g., inspections), intervals, or CDCCLs, may be used unless the actions, intervals, and CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (o) of this AD.

(2) After the maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (e.g., inspections), intervals, or CDCCLs, may be used unless the actions, intervals, and CDCCLs are approved as an

AMOC in accordance with the procedures specified in paragraph (o) of this AD.

(l) Parts Installation Prohibition

(1) For Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes: As of the effective date of this AD, no person may replace an MOV actuator having P/N MA30A1017 (Boeing P/N S343T003-76) with an MOV actuator having P/N MA20A2027 or P/N MA30A1001 (Boeing P/N S343T003-56 or Boeing P/N S343T003-66, respectively) for the left engine and right engine fuel shutoff valves.

(2) For airplanes identified in paragraph (c)(2) of this AD: As of the effective date of this AD, no person may replace an MOV actuator having P/N AV-31-1 (Boeing P/N S343T003-111), P/N MA11A1265 (Boeing P/N S343T003-14), P/N MA11A1265-1 (Boeing

P/N S343T003-41), or P/N MA30A1017 (Boeing P/N S343T003-76) with an MOV actuator having P/N MA30A1001 (Boeing P/N S343T003-66) or P/N MA20A2027 (Boeing P/N S343T003-56) for the left engine and right engine fuel shutoff valves and the APU fuel shutoff valve.

(3) For airplanes identified in paragraph (c)(3) of this AD: As of the effective date of this AD, no person may replace an MOV actuator having P/N AV-31-1 (Boeing P/N S343T003-111), P/N MA11A1265 (Boeing P/N S343T003-14), P/N MA11A1265-1 (Boeing P/N S343T003-41), or P/N MA30A1017 (Boeing P/N S343T003-76) with an MOV actuator having P/N MA30A1001 (Boeing P/N S343T003-66) or P/N MA20A2027 (Boeing P/N S343T003-56) for the left engine and right engine fuel shutoff valves and the APU fuel shutoff valve.

(4) For airplanes identified in paragraph (c)(1) of this AD, excluding Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes: As of the effective date of this AD, no person may install an MOV actuator having P/N MA20A1001-1 (Boeing P/N S343T003-39) or replace an MOV actuator with an MOV actuator having P/N MA20A2027 or P/N MA30A1001 (Boeing P/N S343T003-56 or Boeing P/N S343T003-66, respectively) for the left engine and right engine fuel shutoff valves.

(m) Terminating Action

(1) For Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes:

Accomplishing the actions required by paragraph (j)(l) of this AD terminates the requirements of paragraph (l)(1) of this AD and all requirements of AD 2015-21-10.

(2) For airplanes identified in paragraph (c)(2) of this AD: Accomplishing the action required by paragraph (j)(2) of this AD terminates the requirements of paragraph (l)(2) of this AD and all requirements of AD 2015-19-04.

(3) For airplanes identified in paragraph (c)(3) of this AD: Accomplishing the action required by paragraph (j)(3) of this AD terminates the requirements of paragraph (l)(3) of this AD and all requirements of AD 2015-21-09.

(4) For airplanes identified in paragraph (c)(1) of this AD, excluding Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes: Accomplishing the action required by paragraph (j)(4) of this AD terminates the requirements of paragraph (l)(4) of this AD.

(n) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (g)(2) or (h)(2) of this AD, as applicable, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 757-28-0138, dated May 18, 2016.

(2) This paragraph provides credit for the actions specified in paragraph (g)(2) or (h)(3) of this AD, as applicable, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 767-28-0115, dated September 10, 2015.

(3) For Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes with an original certificate of airworthiness or original export certificate of airworthiness issued on or before the effective date of this AD, this paragraph provides credit for the actions specified in paragraph (i)(1) of this AD if those actions were performed before the effective date of this AD using Boeing 737-600/700/700C/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001-9-04, Revision July 2016, Revision September 2016, Revision January 2017, Revision April 2018, or Revision May 2018; or Boeing 737-600/700/700C/800/900/900ER Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D626A001-CMR, Revision October 2014, Revision November 2014, Revision January 2015, or Revision April 2016.

(4) For airplanes identified in paragraph (c)(2) of this AD, this paragraph provides

credit for the actions specified in paragraph (i)(2) of this AD if those actions were performed before the effective date of this AD using Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision January 2016, Revision July 2016, or Revision February 2017.

(5) For airplanes identified in paragraph (c)(3) of this AD with an original certificate of airworthiness or original export certificate of airworthiness issued on or before the effective date of this AD, this paragraph provides credit for the actions specified in paragraph (i)(3) of this AD if those actions were performed before the effective date of this AD using Boeing 767 Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision July 2015, Revision March 2016, Revision May 2016, Revision May 2016 R1, or Revision June 2016; or Boeing 767-200/300/300F/400 Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision January 2018.

(6) For airplanes identified in paragraph (c)(3) of this AD with an original certificate of airworthiness or original export certificate of airworthiness issued on or before the effective date of this AD, this paragraph provides credit for the actions specified in paragraph (i)(3)(ii) of this AD if those actions were performed before the effective date of this AD using Boeing 767 Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision October 2014.

(o) 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 (p)(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 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 Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, 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.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (o)(4)(i) and (o)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled "RC Exempt," then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(p) Related Information

(1) For more information about this AD, contact Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3553; email: Takahisa.Kobayashi@faa.gov.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (q)(3) and (q)(4) of this AD.

(q) 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 737-600/700/700C/800/900/900ER Special Compliance Items/Airworthiness Limitations, D626A001-9-04, Revision June 2018.

(ii) Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001-9, Revision May 2018.

(iii) Boeing 767-200/300/300F/400ER Special Compliance Items/Airworthiness Limitations, D622T001-9-04, Revision March 2018.

(iv) Boeing Service Bulletin 737-28-1314, dated November 17, 2014.

(v) Boeing Service Bulletin 767-28-0115, Revision 1, dated June 2, 2016.

(vi) Boeing Special Attention Service Bulletin 757-28-0138, Revision 1, dated June 19, 2017.

(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; telephone: 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, call

202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on September 14, 2018.

John P. Piccola,

Acting Director, System Oversight 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-2018-N-3596]

Medical Devices; Immunology and Microbiology Devices; Classification of the Herpes Virus Nucleic Acid-Based Cutaneous and Mucocutaneous Lesion Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 17, 2018. The classification was applicable on May 13, 2014.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4676, Silver Spring, MD, 20993-0002, 301-796-6217, scott.mcfarland@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel as class II (special controls), which we have determined will provide

a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a

classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on February 7, 2014, finding the Lyra™ Direct HSV 1 + 2/VZV Assay not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On February 21, 2014, Quidel Corporation submitted a request for De Novo classification of the Lyra™ Direct HSV 1 + 2/VZV Assay. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 13, 2014, FDA issued an order to the requestor classifying the device into class II. FDA