

and thermal conductivity of Metamic HT neutron-absorbing structural material. The commenter noted that the justification for this change is that these properties have little variability when Metamic HT is fabricated according to the manufacturer's manual. The commenter asked the NRC what it thinks testing is for if not to verify that the product has been made according to the specifications in the manufacturer's manual.

NRC Response

This issue was addressed by the NRC staff in its SER, and the commenters do not raise any additional information that would alter the staff's determination that the HI-STORM FW System, Amendment No. 1, Revision 1, casks, when used within the requirements of the proposed CoC, will safely store SNF. In its March 19, 2015, SER (ADAMS Accession No. ML14276A620), the NRC staff concluded that this was acceptable for this specific application. For a detailed discussion regarding the NRC staff's evaluation, see Section 4 of the SER.

Issue 11: Exemptions

One commenter contended that a general licensee seeking to load spent nuclear fuel into the Holtec HI-STORM FW System in accordance with the changes described in this rulemaking would have to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Another commenter asserted that once Holtec has been given its original CoC, there should be no "exemptions."

NRC Response

The revisions to Amendment No. 1 of CoC 1032 for the HI-STORM FW System is to provide changes to the cask system so that general licensees do not need to request an exemption from any requirements of 10 CFR 72.212 or 10 CFR 72.214. Like all other proposed CoC amendments or revisions, the general licensee under 10 CFR 72.212(b)(5) will have to perform written evaluations which establish that the cask will conform to the terms, conditions, and specifications of a CoC or an amended CoC listed in § 72.214.

Issue 12: Reduced Circulation of Air for Cooling

Two commenters objected that the proposed change in the HI-STORM FW System CoC would restrict the circulation of air for cooling spent fuel within the MPC or cask.

NRC Response

The NRC staff evaluated this issue as part of its SER and concluded that there is no significant reduction in the cooling capacity of the HI-STORM FW System as a result of the revisions requested by the applicant. The NRC staff's SER determined that CoC 1032, Amendment No. 1, Revision 1, casks, when used within the requirements of the CoC, will safely store SNF. The comment presents no information that the NRC has not already considered, or that would cause the NRC to change its analysis.

The purpose of the revision is to permit the more compact spent fuel assemblies now in some reactors' spent fuel storage pools to be loaded into the HI-STORM FW System for dry storage. In its March 19, 2015, SER (ADAMS Accession No. ML14276A620), the NRC staff found that approval of the application would permit a volumetric increase of 0.6 percent of the fuel and a reduction of 0.13 percent of the original flow area of the 14-rod-by-14-rod fuel assembly previously approved for use in this cask system. The NRC staff also found, however, that the reduced flow area through the 14x14B fuel assembly "is still larger than the 17x17 assembly flow area used as the bounding scenario in the thermal analysis. As a result, the flow resistance factor is still less restrictive than the one used in the bounding scenario, and the passive decay heat removal of the proposed 14x14B assembly is still conservative." The NRC staff also found that the spent fuel cladding "continues to be protected against degradation leading to gross ruptures under long-term storage by maintaining cladding temperatures below 752 °F (400 °C)," and "continues to be protected against degradation leading to gross ruptures under off-normal and accident conditions by maintaining cladding temperatures below 1058 °F (570 °C). Protection of the cladding against degradation is expected to allow ready retrieval of spent fuel for further processing or disposal."

Therefore, the NRC staff has concluded that the comments received on the companion proposed rule for the HI-STORM FW System, Amendment No. 1, Revision 1, are not significant adverse comments as defined in NUREG-BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook" (ADAMS Accession No. ML052720461). Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 27th day of May, 2015.

For the Nuclear Regulatory Commission.

Leslie Terry,

Acting Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2015-13081 Filed 5-29-15; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2014-0342; Directorate Identifier 2014-NM-007-AD; Amendment 39-18168; AD 2015-11-05]

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 certain The Boeing Company Model 747-400, 747-400D, 747-400F, 747-8F, and 747-8 series airplanes. This AD was prompted by reports of very high temperatures, near the floor in the aft lower lobe cargo compartment. This AD requires installing an additional zone temperature sensor (ZTS) assembly in the aft cargo compartment, and, for certain airplanes, installing tape and replacing the markers in the bulk cargo compartment. We are issuing this AD to prevent overheating of the aft lower lobe cargo compartment, where, if temperature sensitive cargo is present, the release of flammable vapors could result in a fire or explosion if exposed to an ignition source.

DATES: This AD is effective July 6, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of July 6, 2015.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for

and locating Docket No. FAA–2014–0342.

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–2014–0342; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, 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: Susan Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, 1601 Lind Avenue SW., Renton, WA; phone: 425–917–6457; fax: 425–917–6590; email: susan.l.monroe@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 certain The Boeing Company Model 747–400, 747–400D, 747–400F, 747–8F, and 747–8 series airplanes. The NPRM published in the **Federal Register** on June 25, 2014 (79 FR 35968). The NPRM was prompted by reports of very high temperatures, up to 67 degrees Celsius (152 degrees Fahrenheit), near the floor in the aft lower lobe cargo compartment on certain Model 747 airplanes. The NPRM proposed to require installing an additional ZTS in the aft cargo compartment. For certain airplanes, the NPRM proposed to first require installing tape and replacing the markers in the bulk cargo compartment, unless terminated by the early installation of the ZTS. We are issuing this AD to prevent overheating of the aft lower lobe cargo compartment, where, if temperature sensitive cargo is present, the release of flammable vapors could result in a fire or explosion if exposed to an ignition source.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 35968, June 25, 2014) and the FAA’s response to each comment.

Request To Clarify “Required for Compliance” (RC) Steps

United Airlines (UA) asked that we clarify the actions required in the NPRM (79 FR 35968, June 25, 2014) by adding instructions for steps labeled, and not labeled, as “RC” in the required service information. UA did not provide a reason for this request.

We infer that the commenter is referring to Boeing Special Attention Service Bulletin 747–21–2550, dated December 6, 2013, which includes “RC” language. (Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, does not include “RC” language.) We acknowledge the commenter’s request and provide the following clarification.

The actions specified in Boeing Special Attention Service Bulletin 747–21–2550, dated December 6, 2013, include steps that are identified as RC because these steps have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition. Therefore, for service information that incorporates the RC concept, steps that are identified as RC, including substeps and identified figures, must be done to comply with the AD. The RC concept does not apply to Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, which does not include any RC steps. We have added a new paragraph (j)(4) in this AD to describe the RC concept.

Request To Clarify Certain Language in the Summary Section

Boeing asked that we clarify certain language in the Summary section of the NPRM (79 FR 35968, June 25, 2014) to specify that the solution to the unsafe condition is the installation of a “zone temperature sensor assembly,” rather than a “zone temperature sensor.” Boeing stated that the ZTS is a component within the ZTS assembly, and added that omitting the word “assembly” could confuse operators.

We agree with the commenter for the reason provided. We have included the word “assembly” after references to the ZTS in the SUMMARY of this final rule.

Request To Clarify Certain Language in the Discussion Section

Boeing asked that we clarify the first sentence of the Discussion section of the NPRM (79 FR 35968, June 25, 2014) to specify that the high temperatures near the floor in the aft lower lobe cargo compartment were found only on certain Model 747 airplanes. Boeing stated that the wording in the NPRM is too broad for the investigation that took place.

We agree with the request. We have changed the Discussion section of this final rule accordingly.

Boeing also asked that we clarify the following sentence of the Discussion section of the NPRM (79 FR 35968, June 25, 2014): “Under these conditions, the switches will not command the system valves properly, and the switches may fail to shut off the flow of hot air to the lower lobe cargo compartment, causing compartment temperatures to rise beyond 60 degrees Celsius (140 degrees Fahrenheit).” Boeing asked that the word “will” be changed to “may” in that sentence, because the blockage condition does not guarantee that the temperature switches will not control the system properly.

We acknowledge and agree with the commenter’s concern. However, since that level of detail does not reappear in a final rule, no change to this final rule is necessary in this regard.

Request To Require Additional Actions for Certain Airplanes

Boeing asked that airplanes having certain variable numbers specified in paragraph (g)(1) of the proposed AD (79 FR 35968, June 25, 2014) be required to accomplish the actions specified in paragraph (g)(2) of the proposed AD. Boeing stated that airplanes having those variable numbers might have had a partial installation done in production. Boeing also stated that in the next revision of Boeing Special Attention Service Bulletin 747–21–2544, the action for those airplanes will be a general visual inspection to determine if both markers and tape are installed, and installation of the markers and tape if necessary.

We agree with the commenter. Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, has been issued and addresses the concerns identified by the commenter. Therefore, we have revised this final rule to remove paragraphs (g)(1) and (g)(2) of the proposed AD. We have also revised paragraph (g) of this AD to include Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, as well as the option of contacting the FAA for an approval method to accomplish the actions. We have added Boeing Special Attention Service Bulletin 747–21–2544, Revision 1, dated September 30, 2013, to paragraph (i) of this AD.

Request To Remove Airplane Variable Number RC520

Boeing asked that we change paragraph (g)(1)(ii) of the proposed AD (79 FR 35968, June 25, 2014) to remove airplane variable number RC520

because it is not a valid airplane variable number.

We agree with the commenter for the reason provided. That airplane was identified in paragraph (g)(1)(ii) of the NPRM (79 FR 35968, June 25, 2014). That paragraph, as explained previously, is not included in this final rule.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (79 FR 35968, June 25, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 35968, June 25, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Special Attention Service Bulletin 747-21-2544, Revision 2, dated December 11, 2014; and Boeing Special Attention

Service Bulletin 747-21-2550, dated December 6, 2013. The service information describes procedures for installing warning tape and markers in the bulk cargo compartment and installing an additional zone temperature sensor assembly in the aft cargo compartment. 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 of this AD.

Costs of Compliance

We estimate that this AD affects 130 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
Install ZTS assembly	91 work-hours × \$85 per hour = \$7,735	\$7,545	\$15,280	\$1,986,400

We estimate the following costs to do the optional actions specified in this AD.

OPTIONAL COSTS

Action	Labor cost	Parts cost	Cost per product
Install tape and markers	1 work-hour × \$85 per hour = \$85	\$33	\$118

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.

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):

2015-11-05 The Boeing Company:

Amendment 39-18168; Docket No. FAA-2014-0342; Directorate Identifier 2014-NM-007-AD.

(a) Effective Date

This AD is effective July 6, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747-400, 747-400D, 747-400F, 747-8F, and 747-8 series airplanes, certificated in any category, as identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Airplanes identified in Boeing Service Bulletin 747-21-2550, dated December 6, 2013.

(2) Airplanes identified in paragraph (h)(2) of this AD.

(d) Subject

Air Transport Association (ATA) of America Code 21, Air conditioning.

(e) Unsafe Condition

This AD was prompted by reports of very high temperatures, near the floor in the aft lower lobe cargo compartment. We are issuing this AD to prevent overheating of the aft lower lobe cargo compartment, where, if temperature sensitive cargo is present, the release of flammable vapors could result in a fire or explosion if exposed to an ignition source.

(f) Compliance

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

(g) Installation for Certain Airplanes (Interim Action)

Within 12 months after the effective date of this AD, remove the existing markers and install tape and new markers in the bulk cargo compartment, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747-21-2544, Revision 2, dated December 11, 2014; or using a method approved in accordance with the procedures specified in paragraph (j) of this AD, as applicable. Accomplishing the actions specified in paragraph (h) of this AD within 12 months after the effective date of this AD terminates the requirements of this paragraph.

(h) Installation for All Airplanes (Terminating Action)

Within 60 months after the effective date of this AD, install an additional zone temperature sensor assembly in the aft cargo compartment, as specified in paragraph (h)(1) or (h)(2) of this AD, as applicable. Doing this action within 12 months after the effective date of this AD terminates the requirements of paragraph (g) of this AD.

(1) For airplanes identified in Boeing Service Bulletin 747-21-2550, dated December 6, 2013: Do the actions in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747-21-2550, dated December 6, 2013.

(2) For airplanes having variable numbers RC021 and RC573: Do the actions using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for removing the existing markers and installing tape and new markers in the bulk cargo compartment, as required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 747-21-2544, dated January 15, 2013; or Boeing Special Attention Service Bulletin 747-21-2544, Revision 1, dated September 30, 2013. This service information is not incorporated by reference in this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), 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 ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the 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 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, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) If the service information contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) 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. 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.

(k) Related Information

(1) For more information about this AD that is not incorporated by reference, contact Susan Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, FAA, 1601 Lind Avenue SW., Renton, WA; phone: 425-917-6457; fax: 425-917-6590; email: susan.l.monroe@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(l) Material Incorporated by Reference

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

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

(i) Boeing Special Attention Service Bulletin 747-21-2544, Revision 2, dated December 11, 2014.

(ii) Boeing Special Attention Service Bulletin 747-21-2550, dated December 6, 2013.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(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 Renton, Washington, on May 21, 2015.

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-13018 Filed 5-29-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2015-N-1338]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Rectal Control System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the rectal control system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the rectal control system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 1, 2015. The classification was applicable on February 12, 2015.

FOR FURTHER INFORMATION CONTACT: Purva Pandya, Center for Devices and