

waste streams may contain sufficient quantities of specific radionuclides that will present a significant thermal output and/or gas generation through radiolysis. Still other waste streams may contain a significant quantity of fissile radionuclides (e.g., some isotopes of uranium and plutonium). The NRC is interested in identifying those radionuclides that could be important for evaluating the safety and security of: (1) Storage associated with the operational period at a disposal facility, and (2) the post-closure period, including inadvertent intruder protection. Additionally, the NRC is interested in obtaining available data and information to support the characteristics of GTCC and transuranic wastes.

Question 2: How might GTCC and transuranic wastes affect the safety and security of a disposal facility during operations (i.e., pre-closure period)?

The presence of sufficient quantities of high activity radionuclides and/or fissile radionuclides in GTCC and transuranic wastes may impact the design and operational activities associated with a disposal facility prior to disposal. The NRC is interested in identifying those design and operational activities at a disposal facility that may be impacted by GTCC and transuranic wastes. For example, the requirements in 10 CFR part 73 would require licensees to develop safeguards systems to protect against acts of radiological sabotage and to prevent the theft or diversion of Special Nuclear Material (i.e., transuranic waste such as plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235) if a sufficient amount of Special Nuclear Material were present above ground at the disposal facility.

Question 3: How might GTCC and transuranic wastes affect disposal facility design for post-closure safety including protection of an inadvertent intruder?

The NRC is considering disposal units (e.g., a single trench, borehole, and vault) that would contain a single category of waste (e.g., sealed sources) as well as disposal units that contain a mixture of all three waste types. However, the NRC believes the best approach for understanding the issues would be to assume that waste within a disposal unit would be separated by the waste category and not be co-mingled. Such an approach could provide a clear understanding of the issues associated with how a specific waste category might affect disposal facility design. Certain waste streams associated with GTCC and transuranic wastes have larger inventories and

concentrations of radionuclides than was typically considered at LLRW disposal facilities. For example, certain GTCC and transuranic wastes in sufficient quantities have the potential for: (1) Significant thermal output that could affect degradation processes within a disposal unit, and (2) hydrogen gas generation through radiolysis that could also affect degradation processes of the waste package and waste form. Additionally, waste streams associated with GTCC and transuranic wastes may have fissile materials that require facilities to be designed to limit the potential for a criticality event or limit the amount of fissile material that can be disposed. There is a potential balance between security/safety and economic feasibility of design, construction, and operation. The NRC would like to hear from the stakeholders on these aspects as well. The information provided on economic feasibility would be in concert with the NRC's strategies on examining the cumulative effects of potential regulatory actions. The NRC is interested in identifying the various scenarios that should be considered in evaluating the post-closure safety for the disposal of GTCC and transuranic wastes especially scenarios associated with specific issues and concerns that may not have been previously considered for commercial disposal facilities (e.g., synergistic effects of the thermal output on geochemical processes affecting release of radionuclides).

V. Public Meeting

To facilitate the understanding of the public and other stakeholders of these issues and the submission of comments, the NRC staff has scheduled a public meeting for February 22, 2018, from 1:00 p.m. to 3:00 p.m. (EST) in the NRC Auditorium at 11545 Rockville, Pike, Rockville, MD. In addition, those wishing to participate by Webinar will be able to view the presentation slides prepared by the NRC and electronically submit comments during the meeting. Participants must register to participate in the Webinar. Registration information may be found in the meeting notice (<https://www.nrc.gov/pmns/mtg?do=details&Code=20180033>). The meeting notice can also be accessed through the NRC's public website under the headings Public Meetings & Involvement > Public Meeting Schedule; see web page <https://www.nrc.gov/public-involve/publicmeetings/index.cfm>.

Additionally, the final agenda for the public meeting will be posted no fewer than 10 days prior to the Webinar at this website. Those who are unable to

participate in person or via Webinar may also participate via teleconference. For details on how to participate via teleconference, please contact Sarah Achten; telephone: 301-415-6009; email: Sarah.Achten@nrc.gov.

Dated at Rockville, Maryland, this day of February 9, 2018.

For the Nuclear Regulatory Commission.

Gregory F. Suber,

Acting Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0078; Product Identifier 2017-NM-107-AD]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2017-01-02, which applies to certain The Boeing Company Model 787-8 and 787-9 airplanes. AD 2017-01-02 requires an inspection for discrepant inboard and outboard trailing edge flap rotary actuators. Since we issued AD 2017-01-02, we have determined that it is necessary to revise the applicability to include additional airplanes, and to reduce the number of affected actuators. This proposed AD would continue to require an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, and corrective actions if necessary. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 2, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-

30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, 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, 1601 Lind Avenue SW, Renton, WA. 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-2018-0078.

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-2018-0078; 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 NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Douglas Tsuji, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 1601 Lind Avenue SW, Renton, WA 98057-3356; phone: 425-917-6546; fax: 425-917-6590; email: douglas.tsuji@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2018-0078; Product Identifier 2017-NM-107-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any

personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued AD 2017-01-02, Amendment 39-18769 (82 FR 4775, January 17, 2017) ("AD 2017-01-02"), for certain The Boeing Company Model 787-8 and 787-9 airplanes. AD 2017-01-02 requires an inspection for discrepant inboard and outboard trailing edge flap rotary actuators. AD 2017-01-02 resulted from a report that indicated that some rotary actuators of the inboard and outboard trailing edge flap may have been assembled with an incorrect no-back brake rotor-stator stack sequence during manufacturing. We issued AD 2017-01-02 to detect and replace incorrectly assembled rotary actuators, which could cause accelerated unit wear that will eventually reduce braking performance. This degradation could lead to loss of no-back brake function and reduced controllability of the airplane.

Actions Since AD 2017-01-02 Was Issued

Since we issued AD 2017-01-02, we have determined that it is necessary to revise the applicability to include additional airplanes, and to reduce the number of affected actuators.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017. The service information describes procedures for an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, and corrective actions if necessary. The related investigative action includes a functional test of the trailing edge flap no-back brake. The corrective actions include replacement of the discrepant rotary actuator with a non-discrepant rotary actuator. 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.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all requirements of AD 2017-01-02 and add airplanes to the applicability. This proposed AD would require accomplishing the actions specified in the service information described previously. For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0078.

The phrase "related investigative actions" is used in this proposed AD. Related investigative actions are follow-on actions that (1) are related to the primary action, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

The phrase "corrective actions" is used in this proposed AD. Corrective actions correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between This Proposed AD and the Service Information

To support operations, many operators have put processes in place that, given certain conditions, allow them to rotate or transfer parts or equipment within their fleets to different aircraft than what is defined in the manufacturer's type design. We have determined that the parts or equipment subject to the unsafe condition may have been rotated or transferred in this manner, due to similarity with parts or equipment not subject to the unsafe condition. Therefore, the applicability of this proposed AD is for all The Boeing Company Model 787 series airplanes.

The effectivity specified in Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015, consists of only certain Boeing Model 787-8 and 787-9 airplanes. In this proposed AD, the actions required by paragraphs (g) and (h) of this AD would be accomplished on any The Boeing Company Model 787 series airplane with an original Certificate of Airworthiness or an original Export Certificate of Airworthiness dated on or before the effective date of the final rule. Expanding the applicability of this proposed AD addresses the rotability issue of the trailing edge flap rotary actuators. We have confirmed with the manufacturer that the accomplishment instructions in the following service information are applicable to the expanded group of airplanes:

- Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 001, dated November 3, 2015.
- Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 002, dated November 3, 2016.
- Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017.

The Boeing Company Model 787 series airplanes with an original Certificate of Airworthiness or an original Export Certificate of Airworthiness dated after the effective date of the final rule are not required to complete the actions specified in paragraphs (g) and (h) of this AD, but

must comply with the parts installation prohibition in paragraph (i) of this AD.

Costs of Compliance

We estimate that this proposed AD affects 89 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	5 work-hours × \$85 per hour = \$425	\$0	\$425	\$37,825

We estimate the following costs to do any necessary on-condition actions that would be required based on the results

of the proposed inspection. We have no way of determining the number of aircraft or the number of rotary actuators

(up to 8 per shipset) that might need these on-condition actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Check to determine flight cycles on the rotary actuator.	1 work-hour × \$85 per hour = \$85	\$0	\$85 per rotary actuator.
Functional Test per rotary actuator	2 work-hours × \$85 per hour = \$170	0	\$170 per rotary actuator.
Replacement per rotary actuator	2 work-hours × \$85 per hour = \$170	0	\$170 per rotary actuator.
System Test after rotary actuator replacement(s) per airplane.	24 work-hours × \$85 per hour = \$2,040	0	\$2,040 per airplane.

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 proposed 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 to the Director of the System Oversight Division.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 the proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the 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.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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 removing Airworthiness Directive (AD) 2017–01–02, Amendment 39–18769 (82 FR 4775, January 17, 2017), and adding the following new AD:

The Boeing Company: Docket No. FAA–2018–0078; Product Identifier 2017–NM–107–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by April 2, 2018.

(b) Affected ADs

This AD replaces AD 2017–01–02, Amendment 39–18769 (82 FR 4775, January 17, 2017) (“AD 2017–01–02”).

(c) Applicability

This AD applies to all The Boeing Company Model 787 series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report indicating that some inboard and outboard trailing edge flap rotary actuators may have been assembled with an incorrect no-back brake rotor-stator stack sequence during manufacturing. We are issuing this AD to detect and replace incorrectly assembled rotary actuators, which could cause accelerated unit wear that will eventually reduce braking performance. This degradation could lead to loss of no-back brake function and reduced controllability of the airplane.

(f) Compliance

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

(g) Retained Inspection and Other Actions

For The Boeing Company Model 787-8 and 787-9 airplanes identified in Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015: Within 60 months after February 21, 2017 (the effective date of AD 2017-01-02), do an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015; or Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017. If any discrepant rotary actuator is found, within 60 months after February 21, 2017, do the actions specified in paragraph (g)(1) or (g)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015; or Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017, may be used.

(1) Replace the discrepant rotary actuator.
(2) Check the maintenance records to determine the flight cycles of each discrepant rotary actuator and, within 60 months after February 21, 2017 (the effective date of AD 2017-01-02), do all applicable related investigative and corrective actions.

(h) New Requirements: Inspection, Related Investigative and Corrective Actions

For airplanes not identified in Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015, which have an Original Certificate of Airworthiness or Export Certificate of Airworthiness with a date on or before the effective date of this AD: Within 60 months after the effective date of this AD, do an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017. If any discrepant rotary

actuator is found, within 60 months after the effective date of this AD, do the actions specified in paragraph (h)(1) or (h)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017.

(1) Replace the discrepant rotary actuator.
(2) Check the maintenance records to determine the flight cycles of each discrepant rotary actuator and, within 60 months after the effective date of this AD, do all applicable related investigative and corrective actions.

(i) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, a rotary actuator with a part number and serial number identified in Appendix A of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017, unless the actuator has been permanently marked in accordance with Task 2 of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 003, dated July 28, 2017, with "B787-81205-SB270032-00 INCORPORATED."

(j) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 002, dated November 3, 2016.

(2) 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 Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015, or Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 002, dated November 3, 2016.

(k) 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 (l)(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) AMOCs approved previously for AD 2017-01-02 are approved as AMOCs for the corresponding provisions of this AD.

(5) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(5)(i) and (k)(5)(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.

(l) Related Information

(1) For more information about this AD, contact Douglas Tsuji, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 1601 Lind Avenue SW, Renton, WA 98057-3356; phone: 425-917-6546; fax: 425-917-6590; email: douglas.tsuji@faa.gov.

(2) 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>. You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on January 30, 2018.

Michael Kaszycki,

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 514**

[Docket No. FDA-2017-N-6381]

RIN 0910-AH51

Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.