and in accordance with the instructions of Section 4.2.2, ''Inspection Requirements,'' of Airbus AOT A71L005–14, Revision 01, dated December 11, 2014.

(2) If, during the torque check required by paragraph (k)(1) of this AD, any discrepancy is detected (one bolt rotates, two or more bolts rotate, or one or more bolts are fully broken): Within the compliance time specified in Airbus AOT A71L005–14, Revision 01, dated December 11, 2014, accomplish all applicable corrective actions in accordance with the instructions of Section 4.2.3, ''Findings,'' of Airbus AOT A71L005–14, Revision 01, dated December 11, 2014, except as required by paragraphs (m)(1) and (m)(2) of this AD.

(l) Action for Airbus Model A340–541 and –642 Airplanes Equipped With Rolls-Royce Trent 500 Engines

(1) For Airbus Model A340–541 and –642 airplanes equipped with Rolls-Royce Trent 500 Engines: Within 2,000 flight hours after the effective date of this AD, accomplish a one-time torque check of FWD and AFT engine mount bolts on each affected engine, at the locations specified in, and in accordance with the instructions of Section 4.2.2, ''Inspection requirements,'' of Airbus AOT A71L008–14, Revision 01, dated December 18, 2014.

(2) If, during the torque check required by paragraph (l)(1) of this AD, any discrepancy is detected (one bolt rotates, two or more bolts rotate, or one or more bolts are fully broken): Within the compliance time specified in Airbus AOT A71L008–14, Revision 01, dated December 18, 2014, accomplish all applicable corrective actions, in accordance with the instructions of Section 4.2.3, ''Findings,'' of Airbus AOT A71L008–14, Revision 01, dated December 18, 2014, except as required by paragraphs (m)(1) and (m)(2) of this AD.

(m) Service Information Exceptions

(1) Where Airbus AOTs A71L005–14, Revision 01, dated December 11, 2014; A71L006–14, dated July 22, 2014; and A71L008–14, dated September 29, 2014, specify to contact Airbus for further actions, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(2) Where Airbus AOT A71L004–14, Revision 01, dated April 7, 2014; AOT A71L005–14, Revision 01, dated December 11, 2014; AOT A71L006–14, dated July 22, 2014; and AOT A71L008–14, Revision 01, dated December 18, 2014, specify actions ''if one pylon bolt fully broken,'' this AD requires that those actions be done if one or more pylon bolt is found fully broken during any torque check required by paragraph (h)(1), (j)(1), (k)(1) or (l)(1) of this AD.

(n) Reporting

At the applicable time specified in paragraphs (n)(1) and (n)(2) of this AD: After accomplishment of any torque check required by paragraphs (h), (j), (k), and (l) of this AD, report all inspection results to Airbus, including no findings, in accordance with the ''Reporting'' section of the applicable service information specified in paragraphs (h), (j), (k), and (l) of this AD.

(1) If the torque check was done on or after the effective date of this AD: Submit the report within 30 days after the torque check.

(2) If the torque check was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(o) Credit for Previous Actions

(1) This paragraph provides credit for the actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Airbus AOT A71L004–14, dated April 1, 2014 (for Airbus Model A330 Airplanes Equipped with Pratt and Whitney Engines), which is not incorporated by reference in this AD.

(2) This paragraph provides credit for the actions required by paragraph (k) of this AD, if those actions were performed before the effective date of this AD using Airbus AOT A71L005–14, dated September 29, 2014 (for Airbus Model A330 Airplanes Equipped with Rolls-Royce Trent 700 Engines), which is not incorporated by reference in this AD.

(3) This paragraph provides credit for the actions required by paragraph (l) of this AD, if those actions were performed before the effective date of this AD using Airbus AOT A71L008–14, dated September 29, 2014 (for Airbus Model A340 Airplanes Equipped with Rolls-Royce Trent 500 Engines), which is not incorporated by reference in this AD.

(p) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Reporting Requirements: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(q) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015–0082, dated May 11, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–7533.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.* 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.

Issued in Renton, Washington, on December 18, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–32547 Filed 12–28–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–7531; Directorate Identifier 2015–NM–052–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 adopt a new airworthiness directive (AD) for certain The Boeing Company Model 787–8 airplanes. This proposed AD was

prompted by reports of electrical shorts of the motor stator wiring burning a hole through the housing of the motor of the cabin air compressor (CAC). This proposed AD would require installing modified inboard and outboard CAC modules on the left side and right side cabin air conditioning and temperature control system (CACTCS) packs. We are proposing this AD to prevent an electrical short from burning through the housing of the motor of the CAC, which could result in a fire in the pack bay, and consequent reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by February 12, 2016.

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 Boeing service information identified in this proposed 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, 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.

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–2015–7531; 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 proposed AD, 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: Eric Brown, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6476; fax: 425–917–6590; email: *eric.m.brown@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–2015–7531; Directorate Identifier 2015–NM–052–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD 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 received reports of electrical shorts of the motor stator wiring burning a hole through the housing of the motor of the CAC. The pack bay is classified as a flammable fluid leakage zone and the burn-through would be classified as an ignition source. This condition, if not corrected, could result in a fire in the pack bay, and consequent reduced controllability of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin B787–81205–SB210055–00, Issue 001, dated March 12, 2015. This service information describes procedures for installing modified inboard and outboard CAC modules on the left side and right side CACTCS packs. 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 NPRM.

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 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–2015–7531.

Explanation of Required for Compliance (RC) Steps in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which steps in the service information are required for compliance with an AD. Differentiating these steps from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The steps identified as RC in any service information identified previously have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

For service information that contains steps that are labeled as RC, the following provisions apply: (1) 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, and an AMOC is required for any deviations to RC steps, including substeps and identified figures; and (2) 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.

Costs of Compliance

We estimate that this proposed AD affects 22 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
Modification, installation, and installation test.	Up to 30 work-hours × $85 per hour = $2,550	$0	Up to $2,550	Up to $56,100.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

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

We 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 this 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 adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2015–7531; Directorate Identifier 2015–NM–052–AD.

(a) Comments Due Date

We must receive comments by February 12, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin B787–81205–SB210055–00, Issue 001, dated March 12, 2015.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of electrical shorts of the motor stator wiring burning a hole through the housing of the motor of the cabin air compressor (CAC). We are issuing this AD to prevent an electrical short from burning through the housing of the motor of the CAC, which could result in a fire in the pack bay and consequent reduced controllability of the airplane.

(f) Compliance

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

(g) Replacement of CAC Modules

Within 5 years after the effective date of this AD, install modified inboard and outboard CAC modules on the left side and right side cabin air conditioning and temperature control system (CACTCS) packs, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB210055–00, Issue 001, dated March 12, 2015.

(h) 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 (i)(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, to make those findings. For a repair method 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 (h)(4)(i) and (h)(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. 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.

(i) Related Information

(1) For more information about this AD, contact Eric Brown, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6476; fax: 425–917–6590; email: *eric.m.brown@faa.gov.*

(2) For Boeing 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.

Issued in Renton, Washington, on December 18, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–32548 Filed 12–28–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2014–N–1210]

Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify the electroconvulsive therapy (ECT) device for use in treating severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition, which is a preamendments class III device, into class II (special controls) based on new information. FDA is also proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for ECT devices for other intended uses specified in this proposed order. The Agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements for other intended uses specified in this proposed order. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of any of the devices mentioned in this document based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments on this proposed order by March 28, 2016. See section XVII of this document for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. 2014–N–1210 for ''Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment-Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses''. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and