in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Union Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2019–0133, dated June 11, 2019, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0698.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(n) 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 this AD specifies otherwise.

(3) The following service information was approved for IBR on January 24, 2020.

(i) Chapter 5–40, Airworthiness Limitations, Revision 16, dated September 2018, of the Dassault FALCON 900EX Maintenance Manual.

(ii) [Reserved]

(4) The following service information was approved for IBR on October 19, 2017 (82 FR 43163, September 14, 2017).

(i) Chapter 5–40, Airworthiness Limitations, Revision 14, dated November 2015, of the FALCON 900EX Maintenance Manual.

(ii) [Reserved]

(5) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *https://www.dassaultfalcon.com.*

(6) 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.

(7) 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, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on November 27, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–27467 Filed 12–19–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0406; Product Identifier 2019–NM–059–AD; Amendment 39–21006; AD 2019–24–17]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model MD–90–30 airplanes. This AD was prompted by reports indicating that certain center wing stringers and skins are potentially susceptible to cracking. This AD requires repetitive eddy current, low frequency (ETLF) inspections of the left and right side fastener holes for any crack; repetitive eddy current, high frequency (ETHF) inspections of the lower skin for any crack; and repair if any crack is found. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 24, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 24, 2020.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; 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 *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0406.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0406; 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 is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: David Truong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5224; fax: 562–627–5210; email: *david.truong@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA 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 MD–90–30 airplanes. The NPRM published in the **Federal Register** on June 21, 2019 (84 FR 29105). The NPRM was prompted by reports indicating that based on Model MD–80 airplane service experience, certain center wing stringers and skins are potentially susceptible to fatigue-related cracking on Model MD–90 airplanes. The Model MD–80 and Model MD–90 wings share the same basic design and experience similar stresses, but no such cracking has been found on Model MD–90 airplanes. Cracks on Model MD–80 airplanes were found in the center wing lower stringers, at the inboard end where they are joined to the airplane centerline by end fittings; in the lower stringer end fittings, at the outboard end where they attach to stringers; and in the lower forward and aft skins, underneath cracked stringers. If not addressed, this cracking could result in the inability of the structure to sustain limit loads, and adversely affect the structural integrity of the airplane. The NPRM proposed to require repetitive ETLF inspections of the left and right side fastener holes for any crack; repetitive ETHF inspections of the lower skin for any crack; and repair if any crack is found.

Comments

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

Request for Clarification of Other Relevant Rulemaking Section

Boeing requested clarification regarding the number of cracking occurrences reported in areas outside of those addressed by AD 2016–07–28, Amendment 39–18473 (81 FR 21253, April 11, 2016) (''AD 2016–07–28''), or Boeing Alert Service Bulletin MD80–

57A244, dated March 3, 2016. Boeing noted that in the NPRM, the Other Relevant Rulemaking section stated that since AD 2016–07–28 was issued, cracking was found at fastener holes common to stringers (S) S–11 through S–22, and around the external bracket angle at S–18 and S–19. Boeing emphasized that there was only one case of cracking, at S–13.

In addition, Boeing requested that the Other Relevant Rulemaking section in the NPRM be revised to explain that the new service information that Boeing is developing for Model MD–80 airplanes is to address potential cracking in new stringer locations and is not in response to actual in-service reports of cracking.

The FAA agrees with the commenter's assessment of crack findings. Of the cracks found since issuance of AD 2016–07–28, only one was found at S–13—the only area not addressed by AD 2016–07–28. All remaining crack findings were within the scope of the requirements of AD 2016–07–28. As a result of these cracks, Boeing made the determination to expand the inspection to stringers S–11 through S–22. This AD addresses those stringers on Model MD–90–30 airplanes.

The FAA acknowledges that the service information for the Model MD–80 airplanes, Boeing Service Bulletin MD80–57A244, dated March 3, 2016, which is mandated by AD 2016–07–28, has been revised. Boeing Service Bulletin MD80–57A244, Revision 1, dated October 1, 2019, updates the inspection method and expands the inspection area. The FAA may consider further rulemaking in the future to mandate these changes for Model MD–80 airplanes.

Because the Other Relevant Rulemaking section in **SUPPLEMENTARY INFORMATION** is not retained in final rules, the FAA has not revised this final rule in regard to these issues.

Request To Revise Cost Information

Delta Air Lines (DAL) requested clarification regarding the number of airplanes on the U.S. registry that would be affected by the NPRM. DAL stated that the Costs of Compliance paragraph indicated that an estimated 43 airplanes would be affected. However, DAL is the only U.S. operator of the affected airplanes, and DAL reports that there are 65 airplanes in their operations specification.

The FAA agrees with the commenter and has revised the Costs of Compliance paragraph in this final rule accordingly.

Request for Legible Service Information

DAL requested that better quality copies of certain sheets of Boeing Drawing SN09570007 be provided to operators. The commenter stated that the poor quality of these sheets renders them useless in terms of doing inspections and is concerned about showing compliance with the requirements specified in the proposed AD.

The FAA acknowledges the commenter's concern regarding the legibility of certain sheets of Boeing Drawing SN09570007. Since Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019, does not include Boeing Drawing SN09570007 in the ''Required for Compliance (RC)'' section, the drawing is not required to comply with this AD. The drawing is referenced in Paragraph 1.J.2., Planning Information, References, Data Supplied with the Service Bulletin, in Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019. Operators notified Boeing about the illegible drawing sheets, and in response, Boeing issued Boeing Multi Operator Message MOM–MOM–19–0549–01B, dated October 4, 2019, which provides clearer images of Boeing Drawing SN09570007. The FAA recognizes that Boeing Drawing SN09570007 may provide helpful information to operators. Therefore, the FAA has added Note 1 to paragraph (g) of this AD to notify operators that if they have illegible pages of Boeing Drawing SN09570007, additional guidance can be found in Boeing Multi Operator Message MOM–MOM–19–0549–01B, dated October 4, 2019.

Conclusion

The FAA 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. The FAA determined that these minor changes:

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

The FAA also determined that these changes will not increase the economic burden on any operator (other than the estimated number of affected airplanes as explained under the ''Request to Revise Cost Information'' section of this final rule) or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019. This service information describes procedures for repetitive ETLF inspections of the left and right side fastener holes for any crack, repetitive ETHF inspections of the lower skin for any crack, and repair if any crack is found. 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

The FAA estimates that this AD affects 65 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	30 work-hours × $85 per hour = $2,550 per inspection cycle.	$0	$2,550 per inspection cycle.	$165,750 per inspection cycle.

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA

with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

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):

2019–24–17 The Boeing Company: Amendment 39–21006; Docket No. FAA–2019–0406; Product Identifier 2019–NM–059–AD.

(a) Effective Date

This AD is effective January 24, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model MD–90–30 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports indicating that certain center wing stringers and skins are potentially susceptible to cracking. The FAA is issuing this AD to address cracking of the center wing stringers and skins, which could result in the inability of the structure to sustain limit loads, and adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019.

Note 1 to paragraph (g) of this AD: Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019, refers to Boeing Drawing SN09570007, as data supplied with this service bulletin. If the pages of Boeing Drawing SN09570007 are illegible, guidance can be found in Boeing Multi Operator Message MOM–MOM–19–0549–01B, dated October 4, 2019.

(h) Exceptions to Service Information Specifications

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019, uses the phrase ''the original issue date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Service Bulletin MD90–57A031, dated March 19, 2019, specifies contacting Boeing for repair instructions and doing the repair: This AD requires doing the repair using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles 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 (j)(1) of this AD. Information may be emailed to *9-ANM-LAACO-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 Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as specified by paragraph (h) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (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.

(j) Related Information

(1) For more information about this AD, contact David Truong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5224; fax: 562–627–5210; email: *david.truong@faa.gov.*

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

(k) 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 Alert Service Bulletin MD90–57A031, dated March 19, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740 5600; telephone 562–797–1717; 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, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on December 4, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–27465 Filed 12–19–19; 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–1209]

Neurological Devices; Reclassification of Cranial Electrotherapy Stimulator Devices Intended To Treat Anxiety and/or Insomnia; Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator Devices Intended To Treat Depression

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the cranial electrotherapy stimulator (CES) device intended to treat anxiety and/or insomnia, a preamendments class III device, into class II (special controls) and subject to premarket notification. FDA is also issuing this final order to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for CES devices intended to treat depression (product code JXK) and clarify the device identification of the CES device to include it as a prescription device.

DATES: This order is effective on December 20, 2019. See further discussion in section V, ''Implementation Strategy.''

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–6610, *Michael.Hoffmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation or acronym	What it means
2012 Panel	2012 Neurological Devices Panel.
510(k)	Premarket Notification.
AC	Alternating Current.
CES	Cranial Electrotherapy Stimulator Device.
CFR	Code of Federal Regulations.
CNS	Central Nervous System.
DC	Direct Current.
DSM–5	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.
ECT	Electroconvulsive Therapy Device.
FDA	Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
IDE	Investigational Device Exemption.
MAUDE	Manufacturer and User Facility Device Experience.
MDR	Medical Device Reporting.
OMB	Office of Management and Budget.
PDP	Product Development Protocol.
PMA	Premarket Approval Application.
PRA	Paperwork Reduction Act of 1995.
RCT	Randomized Controlled Trial.
Ref.	Reference.
RWD	Real-World Data.
RWE	Real-World Evidence.
U.S.C.	United States Code.
VSE	Valid Scientific Evidence.

II. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the