

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2016-6671; Directorate Identifier 2015-NM-164-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus 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 Airbus Model A300B4-203 and A300B4-2C airplanes. This proposed AD was prompted by cracks found on pylon side panels (upper section) at rib 8. This proposed AD would require a detailed inspection for crack indications of the pylon side panels, a high frequency eddy current (HFEC) inspection to confirm any crack indications, modification of the pylon side panels, and repetitive inspections and repair if necessary. We are proposing this AD to detect and correct cracking of the pylon side panels. Such cracking could result in pylon structural failure and in-flight loss of an engine.

DATES: We must receive comments on this proposed AD by July 7, 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 service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.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.

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-2016-6671; 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: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-2125; fax 425-227-1149.

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-2016-6671; Directorate Identifier 2015-NM-164-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

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015-0201, dated October 7, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A300B4-203 and A300B4-2C airplanes. The MCAI states:

Cracks were found on pylon side panels (upper section) at rib 8 on Airbus A300, A310 and A300-600 aeroplanes equipped with General Electric engines. Investigation of these findings indicated that this problem was likely to also affect aeroplanes of this type design with other engine installations.

This condition, if not detected and corrected, could lead to reduced strength of the pylon primary structure, possibly resulting in pylon structural failure and in-flight loss of an engine.

Prompted by these findings, EASA issued AD 2008-0181 [which corresponded to FAA AD 2010-06-04, Amendment 39-16228 (75 FR 11428, March 11, 2010; corrected May 4, 2010 (75 FR 23572))] to require repetitive detailed visual inspections and, depending on aeroplane configuration and/or findings, the accomplishment of applicable corrective action(s).

Since that [EASA] AD 2008-0181 was issued, a fleet survey and updated Fatigue and Damage Tolerance analyses have been performed in order to substantiate the second A300-600 Extended Service Goal (ESG2) exercise. The results of these analyses have shown that the risk for these aeroplanes is higher than initially determined and consequently, the threshold and interval were reduced to allow timely detection of these cracks and the accomplishment of applicable corrective action(s).

Consequently, EASA AD 2013-0136 was published to supersede EASA AD 2008-0181 and to require the inspections to be accomplished within reduced thresholds and intervals. Afterwards, [EASA] AD 2013-0136 was mistakenly revised [EASA AD 2013-0136R1 corresponds to FAA AD 2015-26-06, Amendment 39-18354 (81 FR January 14, 2016)] to reduce the Applicability, because it was considered at the time that aeroplanes on which Airbus mod 03599 was embodied, were not concerned by the requirements of EASA AD 2013-0136.

Since EASA AD 2013-0136R1 was issued, a more thorough analysis determined that post-mod 03599 aeroplanes could be affected by this unsafe condition after all.

[During] further deeper review, a list of nineteen A300 aeroplanes was identified as

missing in the [EASA] AD 2013–0136R1 applicability, (aeroplanes post-mod 03599).

For the reasons described above this AD retains the requirements of EASA AD 2013–0136R1 and mandates these requirements for the 19 missing A300 aeroplanes MSNs.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2016–6671.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015. The service information describes procedures for an inspection for crack indications of the pylons, a HFEC inspection to confirm cracking, modification of the pylon side panels, and repairs if cracks are found.

Airbus has also issued Service Bulletin A300–54–0081, dated August 11, 1993. This service information

describes installation of a doubler on the left pylon 1 and right pylon 2, on pylon side panels (upper section) at Rib 8.

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 and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or

develop on other products of these same type designs.

Differences Between Proposed Rule and Service Bulletin

Unlike the procedures described in Airbus Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015, this proposed AD would not permit further flight if cracks are detected in the pylon or pylon side panels. We have determined that because of the safety implications and consequences associated with that cracking, any cracked pylon or pylon side panel must be repaired or modified before further flight. This difference has been coordinated with EASA.

Costs of Compliance

We estimate that this proposed AD affects 4 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

| Action | Labor cost | Cost per product | Cost on U.S. operators |
|--------------------------------------|---|------------------------------|--------------------------------|
| Inspection of the pylon side panels. | 30 work-hours × \$85 per hour = \$2,550 per inspection cycle. | \$2,550 per inspection cycle | \$10,200 per inspection cycle. |

We estimate the following costs to do any necessary repairs that would be

required based on the results of the proposed inspection. We have no way of

determining the number of airplanes that might need this repair.

ON-CONDITION COSTS

| Action | Labor cost | Parts cost | Cost per product |
|--------------------|--|--------------------------|---------------------|
| Crack Repair | 56 work-hours × \$85 per hour = \$4,760 per repair | \$3,910 per repair | \$8,670 per repair. |

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):

Airbus: Docket No. FAA–2016–6671; Directorate Identifier 2015–NM–164–AD.

(a) Comments Due Date

We must receive comments by July 7, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A300B4–203 and A300B4–2C airplanes, certificated in any category, manufacturer serial numbers 210, 212, 218, 220, 227, 234, 235, 236, 239, 247, 255, 256, 259, 261, 274, 277, 292, 299, and 302.

(d) Subject

Air Transport Association (ATA) of America Code 54, Nacelles/Pylons.

(e) Reason

This AD was prompted by cracks found on pylon side panels (upper section) at rib 8. We are proposing this AD to detect and correct cracking of the pylon side panels. Such cracking could result in pylon structural failure and in-flight loss of an engine.

(f) Compliance

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

(g) Detailed Inspection of Pylons and Corrections

At the applicable time specified in Airbus Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015: Do a detailed inspection for crack indications of the pylons 1 and 2 side panels (upper section) at rib 8, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015.

(h) Crack Confirmation

If any crack indication is found during the inspection required by paragraph (g) of this AD: Before further flight, do a high frequency eddy current (HFEC) inspection to confirm the crack, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015.

(i) Follow-On Actions for No Crack/Indication

If the inspection required by paragraph (g) of this AD reveals no crack indication, or if the HFEC inspection specified by paragraph (h) of this AD confirms no crack: Do the actions specified in either paragraph (i)(1) or (i)(2) of this AD.

(1) Repeat the inspection required by paragraph (g) of this AD at the applicable time specified in Airbus Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015.

(2) At the applicable time specified in Airbus Service Bulletin A300–54–0081, dated August 11, 1993: Modify the pylons, in accordance with Airbus Service Bulletin 300–54–0081, dated August 11, 1993. Thereafter, repeat the HFEC inspection specified in paragraph (h) of this AD at the applicable interval specified in Airbus Service Bulletin A300–54–0075, Revision 04, dated May 26, 2015, and repair any crack before further flight 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).

(j) Follow-On Actions for Crack Findings

If any crack is confirmed during the inspection required by paragraph (h) of this AD, repair before further flight using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA.

(k) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g), (h), (i), and (j) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (k)(1) through (k)(4) of this AD.

(1) Airbus Service Bulletin A300–54–0075, dated August 11, 1993, which was incorporated by reference in AD 2010–06–04, Amendment 39–16228 (75 FR 11428, March 11, 2010); corrected May 4, 2010 (75 FR 23572).

(2) Airbus Service Bulletin A300–54–0075, Revision 01, dated November 9, 2007, which is not incorporated by reference in this AD.

(3) Airbus Service Bulletin A300–54–0075, Revision 02, dated June 26, 2008, which is not incorporated by reference in this AD.

(4) Airbus Service Bulletin A300–54–0075, Revision 03, dated March 27, 2013, which is not incorporated by reference in this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM–116, 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: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; 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 EASA; or Airbus's EASA 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 Airworthiness Directive 2015–0201, dated

October 7, 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–2016–6671.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@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 May 11, 2016.

Suzanne Masterson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–11681 Filed 5–20–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration**21 CFR Parts 882 and 895**

[Docket No. FDA–2016–N–1111]

Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the **Federal Register** of April 25, 2016. In the proposed rule, FDA requested comments for a ban on electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior (SIB or AB). The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published April 25, 2016 (81 FR 24386). Submit either electronic or written comments by July 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way: