

(4) AMOCs approved previously for AD 2010–25–06 are approved as AMOCs for the corresponding provisions of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, that are required by paragraphs (g) and (h) of this AD.

(o) Related Information

(1) For information about this AD, contact Galib Abumeri, Aerospace Engineer, Airframe Section, Los Angeles ACO Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5324; fax: 562–627–5210; email: galib.abumeri@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, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on May 8, 2018.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–10299 Filed 5–14–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0411; Product Identifier 2017–NM–157–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 A319–115 and –132 airplanes, and Model A320–214, –216, –232, and –233 airplanes. This proposed AD was prompted by a report indicating that certain modified airplanes do not have electrical ground wires on the fuel level sensing control unit (FLSCU), which adversely affects the fuel gravity feeding operation. This proposed AD would require modification of the FLSCU wiring. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 29, 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 Airbus, Airworthiness Office—EIAS, 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 Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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–2018–0411; 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 Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3223.

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–2018–0411; Product Identifier 2017–NM–157–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 based on 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 NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0216, dated October 30, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A319–115 and –132 airplanes, and Model A320–214, –216, –232, and –233 airplanes. The MCAI states:

Airbus introduced mod 154327 on A319 and A320 aeroplanes which substituted the pump fuel feed system from the centre fuel tank with a jet pump transfer system, based on the Airbus A321 design. Following the modification introduction, it was discovered that the modified aeroplanes do not have electrical ground signals that replicate those from the deleted centre tank pump pressure switches. These signals are used as part of the fuel recirculation inhibition request logic. Subsequent investigation determined that ground wires had not been installed on the fuel level sensor control units (FLSCU) of post-mod aeroplanes, due to a drawing error on the fuel system recirculation principle diagram. Without these ground wires providing inputs, the FLSCU logic is not correctly implemented for gravity feeding operation.

This condition, if not corrected, could lead to reduced fuel pressure at the engine inlet, possibly resulting in an uncommanded in-flight shut-down when flying at the gravity feed ceiling levels, as defined in the Aircraft Flight Manual (AFM).

To address this potential unsafe condition, Airbus issued AFM Temporary Revision (TR) 695 Issue 1 and AFM TR 699 Issue 1 to prohibit the use of Jet B and JP4 fuel, and AFM TR 700 Issue 1 to provide instructions for amendment of the gravity feed procedure for the other fuels.

Consequently, EASA issued AD 2016–0205 [which corresponds to FAA AD 2016–25–23, Amendment 39–18749 (81 FR 90971, December 16, 2016) (“AD 2016–25–23”)], requiring amendment of the applicable AFM to include the new gravity feed procedure and to reduce the list of authorised fuels.

Since that [EASA] AD was issued, Airbus developed a wiring modification to restore the intended FLSCU logic, and issued Service Bulletin (SB) A320–28–1242, later revised, providing instructions to modify affected aeroplanes.

For the reason described above, this [EASA] AD retains the requirements of EASA AD 2016–0205, which is superseded, and requires modification of FLSCU wiring. This [EASA] AD also allows, after that modification, to remove the previously inserted AFM TR’s from the applicable AFM.

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-2018-0411.

Relationship Between Proposed AD and AD 2016-25-23

This NPRM would not supersede AD 2016-25-23. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This NPRM would require modification of the FLSCU wiring. Accomplishment of the proposed actions would then terminate all of the requirements of AD 2016-25-23.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320-28-1242, Revision 01, dated October 3, 2017. The service information describes procedures for modification of the FLSCU wiring. 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.

Costs of Compliance

We estimate that this proposed AD affects 58 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	14 work-hours × \$85 per hour = \$1,190	\$204	\$1,394	\$80,852

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 known 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.

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 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-2018-0411; Product Identifier 2017-NM-157-AD.

(a) Comments Due Date

We must receive comments by June 29, 2018.

(b) Affected ADs

This AD affects AD 2016-25-23, Amendment 39-18749 (81 FR 90971, December 16, 2016) ("AD 2016-25-23").

(c) Applicability

This AD applies to Airbus Model A319-115 and -132 airplanes, and Model A320-214, -216, -232, and -233 airplanes, certificated in any category, all manufacturer serial numbers on which Airbus modification 154327 has been embodied in production, except those on which Airbus modification 158740 has been embodied.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by a report indicating that certain modified airplanes do not have electrical ground wires on the fuel level sensing control unit (FLSCU), which adversely affects the fuel gravity feeding operation. We are issuing this AD to prevent reduced fuel pressure at the engine inlet, potentially resulting in an uncommanded in-

flight shutdown when flying at the fuel gravity feed ceiling levels.

(f) Compliance

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

(g) Modification

Within 24 months after the effective date of this AD, modify the FLSCU wiring in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–28–1242, Revision 01, dated October 3, 2017.

(h) Terminating Action for AD 2016–25–23 and Amendment of the Airplane Flight Manual (AFM)

Modification of an airplane as required by paragraph (g) of this AD terminates all of the requirements of AD 2016–25–23 for that airplane. After modification of an airplane as required by paragraph (g) of this AD, remove Airbus A318/A319/A320/A321 Temporary Revision TR695, Issue 1.0, dated August 1, 2016; or Airbus A318/A319/A320/A321 Temporary Revision TR699, Issue 1.0, dated August 1, 2016; as applicable; and Airbus A318/A319/A320/A321 Temporary Revision TR700, Issue 1.0, dated August 1, 2016, from the applicable AFM of that airplane.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–28–1242, dated December 21, 2016.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. 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.

(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 Section, Transport Standards Branch, 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) *Required for Compliance (RC)*: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are

not identified as RC are recommended. Those procedures and tests that are not identified 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 procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0216, dated October 30, 2017, 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–2018–0411.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3223. (3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 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 Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on May 8, 2018.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–10298 Filed 5–14–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. FDA–2004–N–0191]

Product Jurisdiction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to amend its regulations concerning the classification of products as biological products, devices, drugs, or combination products, and their assignment to Agency components for premarket review and regulation. This proposed rule would update the regulations to clarify the scope of the regulations, streamline and clarify the appeals process, align the regulations

with more recent legislative and regulatory measures, update advisory content, and otherwise clarify the regulations, including updates to reflect Agency practices and policies. These changes are intended to enhance regulatory clarity and efficiency.

DATES: Submit either electronic or written comments on the proposed rule by July 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of July 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management