Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1112; fax: 425–227–1149.

(3) For service information identified in this AD, contact Saab AB, Saab Aeronautics, SE–581 88, Linköping, Sweden; telephone +46 13 18 5591; fax +46 13 18 4874; email *saab340techsupport@saabgroup.com;* Internet *http://www.saabgroup.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 June 12, 2017.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–12794 Filed 6–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9386; Directorate Identifier 2016–NM–056–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Defense and Space S.A. (Formerly Known as Construcciones Aeronauticas, S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposal for all Airbus Defense and Space S.A. Model CN–235, CN–235–100, CN–235–200, and CN–235–300 airplanes; and Model C–295 airplanes. This action revises the notice of proposed rulemaking (NPRM) by reducing a certain compliance time, adding repetitive inspections and operational checks of the affected fuel valves, and providing corrective action if necessary. We are proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions impose an additional burden over those proposed in the NPRM we are reopening the comment period to allow the public the chance to comment on these changes.

DATES: The comment period for the NPRM published in the **Federal Register** on November 25, 2016 (81 FR 85169), is reopened.

We must receive comments on this SNPRM by August 7, 2017.

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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this SNPRM, contact Airbus Defense and Space Services/Engineering Support, Avenida de Aragón 404, 28022 Madrid, Spain; telephone +34 91 585 55 84; fax +34 91 585 31 27; email *MTA.TechnicalService@airbus.com.;* Internet *http://www.eads.net.* 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–2016–9386; 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 (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1112; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9386; Directorate Identifier 2016–NM–056–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 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 proposed AD.

Discussion

We issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Defense and Space S.A. Model CN–235, CN 235–100, CN–235–200, and CN–235–300 airplanes, and Model C–295 airplanes. The NPRM published in the **Federal Register** on November 25, 2016 (81 FR 85169). The NPRM was prompted by leakage of a motorized cross-feed fuel valve. The NPRM proposed to require an inspection of the affected fuel valves and, depending on findings, applicable corrective actions.

Actions Since the NPRM Was Issued

Since we issued the NPRM, an additional report of a fuel leak in a motorized cross-feed valve has resulted in the need for a change to the compliance time for the initial inspection, the addition of repetitive inspections and operational checks, and corrective action if necessary.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued AD 2017–0004, dated January 9, 2017, (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition on all Airbus Defense and Space S.A. Model CN–235, CN–235–100, CN–235–200, and CN–235–300 airplanes; and Model C–295 airplanes. The MCAI states:

> Leakage of a motorised cross-feed fuel valve Part Number (P/N) 7923227F was reported on a CN–235–100M aeroplane. The leakage was observed through the valve electrical connectors and detected during accomplishment of a functional check in accordance with task 28.007 of the CN–235 Maintenance Review Board Report (MRB CN–235–PV01). Identical motorised fuel valves are installed on civilian CN–235 and C–295 aeroplanes, as cross-feed, shut-off and defueling valves.
>
> This condition, if not detected and corrected, could lead to failure of a motorised fuel valve and consequent improper functioning of the fuel system or, in case of

an ignition source, could lead to a fire, possibly resulting in damage to the aeroplane and injury to occupants.

To address this potentially unsafe condition, Airbus Defence & Space (D&S) issued Alert Operators Transmission (AOT)–CN235–28–0001 and AOT–C295–28–0001 to provide inspection instructions.

Consequently, EASA issued AD 2016–0071 to require a one-time inspection of the affected motorised fuel valves and, depending on findings, accomplishment of applicable corrective action(s).

Since that [EASA] AD was issued, new occurrences of fuel leakage involving the affected motorised fuel valves were reported and Airbus D&S issued Revision 1 of AOT–CN235–28–0001 and Revision 1 of AOT–C295–28–0001 to introduce repetitive inspections and operational checks of the affected motorised fuel valves.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2016–0071, which is superseded, and introduces repetitive inspections and operational checks [and corrective action, if necessary] of the affected fuel valves.

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–2016–9386.

Related Service Information Under 1 CFR Part 51

Airbus Defense and Space S.A. has issued Alert Operators Transmission (AOT) AOT–CN235–28–0001, Revision 1, dated September 27, 2016; and AOT AOT–C295–28–0001, Revision 1, dated September 27, 2016. The service information describes procedures for repetitive inspections, replacement of the motorized fuel valves, and performing operational checks and corrective actions on affected motorized fuel valves. These documents are distinct since they apply to different airplane models. 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.

Comments

We gave the public the opportunity to participate in developing this proposed AD. We received no comments on the NPRM or on the determination of the cost to the public.

FAA's Determination and Requirements of This SNPRM

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.

Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Costs of Compliance

We estimate that this SNPRM affects 14 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection and operational check	3 work-hours × $85 per hour = $255	$0	$255	$3,570
Reporting	1 work-hour × $85 per hour = $85	0	85	1,190

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	5 work-hours × $85 per hour = $425	$38,448	$38,873

We have received no definitive data that would enable us to provide cost estimates for the on-condition corrective actions for the operational check specified in this proposed AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to 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 control number for the collection of information required by this proposed AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is 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.

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 Defense and Space S.A. (Formerly known as Construcciones Aeronauticas, S.A.): Docket No. FAA–2016–9386; Directorate Identifier 2016–NM–056–AD.

(a) Comments Due Date

We must receive comments by August 7, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Defense and Space S.A. (formerly known as Construcciones Aeronauticas, S.A.) Model CN–235, CN–235–100, CN–235–200, and CN–235–300 airplanes; and Model C–295 airplanes; certificated in any category, all manufacturer serial numbers.

(d) Subject

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

(e) Reason

This AD was prompted by leakage of a motorized cross-feed fuel valve, which was detected during accomplishment of a functional check. We are issuing this AD to detect and correct leaks in a motorized cross-feed fuel valve, which could lead to failure of the fuel valve and consequent improper fuel system functioning or, in case of the presence of an ignition source, an airplane fire.

(f) Compliance

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

(g) Inspection of Motorized Fuel Valves

Within the applicable compliance time defined in paragraph (g)(1) or (g)(2) of this AD: Do an initial general visual inspection of each motorized cross-feed fuel valve having part number (P/N) 7923227F for the presence of fuel on the electrical connectors and inside the receptacles, in accordance with the instructions of Airbus Defense and Space Alert Operators Transmission (AOT) AOT–CN235–28–0001, Revision 1, or Airbus Defense and Space AOT AOT–C295–28–0001, Revision 1, both dated September 27, 2016, as applicable. Repeat the inspection thereafter at intervals not to exceed 300 flight hours.

(1) For airplanes that, as of the effective date of this AD, have accumulated 6,000 flight cycles or more since first flight of the airplane: Do the inspection within 30 flight cycles or 30 days after the effective date of this AD, whichever occurs first.

(2) For airplanes that, as of the effective date of this AD, have accumulated less than 6,000 flight cycles since first flight of the airplane: Do the inspection within 300 flight hours or 30 days after the effective date of this AD, whichever occurs later.

(h) Replacement of Affected Parts

If, during the inspection required by paragraph (g) of this AD, any leaking of a motorized cross-feed fuel valve having P/N 7923227F is detected: Before the next flight, replace the affected fuel valve with a serviceable part, in accordance with the instructions of Airbus Defense and Space AOT AOT–CN235–28–0001, Revision 1, or Airbus Defense and Space AOT AOT–C295–28–0001, Revision 1, both dated September 27, 2016, as applicable. A serviceable part is defined as a part that is not defective; it could be a used or new part. Replacement of a motorized fuel valve on an airplane does not constitute terminating action for the repetitive inspections required by paragraph (g) of this AD for that airplane.

(i) Operational Check

Within 12 months after the effective date of this AD, and thereafter at intervals not to exceed 12 months, accomplish an operational check of each motorized fuel valve P/N 7923227F, in accordance with the instructions of Airbus Defense and Space AOT AOT–CN235–28–0001, Revision 1, or Airbus Defense and Space AOT AOT–C295–28–0001, Revision 1, both dated September 27, 2016, as applicable.

(j) Corrective Action

If, during any operational check, as required by paragraph (i) of this AD, any discrepancy is detected, as described in Airbus Defense and Space AOT AOT–CN235–28–0001, Revision 1, or Airbus Defense and Space AOT AOT–C295–28–0001, Revision 1, both dated September 27, 2016, as applicable: Before further flight, contact the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the European Aviation Safety Agency (EASA); or Airbus Defense and Space S.A.'s EASA Design Organization Approval (DOA) to obtain instructions for corrective actions, and within the compliance time indicated in those instructions accomplish the corrective actions accordingly.

(k) Parts Installation Limitation

As of the effective date of this AD, replacement of a motorized fuel valve having P/N 7923227F with a serviceable part on an airplane is allowed, provided that, within 30 flight cycles or 30 days, whichever occurs first after installation, the part passes an inspection done in accordance with the instructions of Airbus Defense and Space AOT AOT–CN235–28–0001, Revision 1, or Airbus Defense and Space AOT AOT–C295–28–0001, Revision 1, both dated September 27, 2016, as applicable.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Airbus Defense and Space AOT AOT–CN235–28–0001, or Airbus Defense and Space AOT AOT–C295–28–0001, both dated February 19, 2016, as applicable.

(m) Reporting Requirement

At the applicable time specified in paragraph (m)(1) or (m)(2) of this AD, report all inspection results to Airbus Defense and Space Technical Assistance Center (AMTAC); telephone +34 91 600 79 99; email *mta.technicalservice@airbus.com.* The report must include the inspection results, a description of any discrepancies found, operator name, the airplane model and serial number, valve part number and serial number, and the number of landings and flight hours on the airplane.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 60 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 60 days after the effective date of this AD.

(n) 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 send it to the attention of the person identified in paragraph (o)(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 Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus Defense and Space S.A.'s EASA 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.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0004, dated January 9, 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–2016–9386.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1112; fax 425–227–1149.

(3) For service information identified in this AD, contact Airbus Defense and Space Services/Engineering Support, Avenida de Aragón 404, 28022 Madrid, Spain; telephone +34 91 585 55 84; fax +34 91 585 31 27; email *MTA.TechnicalService@airbus.com.;* Internet *http://www.eads.net* 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 June 12, 2017.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–12630 Filed 6–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 312, and 812

[Docket No. FDA–2017–D–1105]

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under Part 11—Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Use of Electronic Records and Electronic Signatures in Clinical Investigations under our regulations—Questions and Answers.'' The draft guidance provides guidance to sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic records and electronic signatures under our regulations in clinical investigations of medical products. The draft guidance expands upon recommendations in the guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application'' issued in August 2003 (referred to as the 2003 part 11 guidance) for recommendations that pertain to FDA-regulated clinical investigations conducted under our regulations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 21, 2017.

ADDRESSES: You may submit comments as follows:

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 Staff, 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. FDA–2017–D–1105 for ''Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11—Questions and Answers; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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