

airplane serial number, and the number of flight cycles 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 30 days after the inspection.

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

(o) Terminating Action for AD 2014–20–18

Accomplishment of the action required by paragraph (h) of this AD and the initial inspections required by paragraphs (i) and (j), and (k) of this AD terminates all requirements of AD 2014–20–18.

(p) Credit for Previous Actions

This paragraph provides credit for actions specified in paragraph (h) of this AD, if those actions were performed before December 19, 2005 (the effective date of AD 2005–23–08), using Airbus Service Bulletin A300–57–6050, Revision 02, dated February 10, 2000.

(q) 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 (r)(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 EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Paperwork Reduction Act Burden Statement*: 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 1 work-hour 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.

(4) *Required for Compliance (RC)*: Except as required by paragraph (m) of this AD: 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.

(r) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0210, dated October 24, 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–2018–0497.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

(3) 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 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 23, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–11822 Filed 6–1–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0498; Product Identifier 2018–NM–013–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 A330–200 Freighter series airplanes; Airbus Model A330–200 series airplanes; and Airbus Model A330–300 series airplanes. This proposed AD was prompted by reports of Angle of Attack (AOA) blockages not detected by upgraded flight control primary computer (FCPC) software standards. This proposed AD would require upgrading certain FCPCs, which would terminate a certain airplane flight manual revision for certain airplanes. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by July 19, 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 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 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–2018–0498; 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: Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229.

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–2018–0498; Product Identifier 2018–NM–013–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 Airworthiness Directive 2017–0246R1, dated April 6, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A330–200 Freighter series airplanes; Airbus Model A330–200 series airplanes; and Airbus Model A330–300 series airplanes. The MCAI states:

In 2015, occurrences were reported of multiple Angle of Attack (AOA) blockages. Investigation results indicated the need for AOA monitoring in order to better detect cases of AOA blockage.

This condition, if not corrected, could, under specific circumstances, lead to undue activation of the Alpha protection, possibly resulting in reduced control of the aeroplane.

To address this potential unsafe condition, Airbus developed new FCPC software standards for enhanced AOA monitoring and, consequently, EASA issued AD 2015–0124

(later revised) [related FAA AD 2016–25–30, Amendment 39–18756, (82 FR 1175, January 5, 2017) (“AD 2016–25–30”)] to require these software standard upgrades.

Since EASA AD 2015–0124R3 was issued, it was identified that, for some cases, AOA blockages were not detected by those FCPC software standards. Consequently, new FCPC software standards, as specified in Table 1 of this [EASA] AD, have been developed (Airbus modification (mod) 206412, mod 206413 and mod 206414) to further improve the detection of AOA blockage. Airbus issued Service Bulletin (SB) A330–27–3222 and SB A330–27–3223 to implement these mods on in-service aeroplanes. Consequently, EASA issued AD 2017–0246 to require a software standard upgrade of the three FCPCs, either by modification or replacement.

Since that [EASA] AD was issued, it was determined that the Aircraft Flight Manual (AFM) Emergency Procedure, as previously required by EASA AD 2014–0267–E [related to FAA AD 2014–25–52, Amendment 39–18066, (80 FR 3161, January 22, 2015) (“AD 2014–25–52”)] can also be removed for other AOA sensors and FCPC configurations. This [EASA] AD revises paragraph (2) accordingly, also introducing Table 2 for that purpose.

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–2018–0498.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information:

- Service Bulletin A330–27–3222, dated February 16, 2017.
- Service Bulletin A330–27–3223, dated June 6, 2017.

This service information describes procedures for upgrading (by modification or replacement, as applicable) certain FCPCs. These documents are distinct since they apply to different airplanes in different configurations. 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 the same type design.

Related Rulemaking

AD 2014–25–52 applies to all Airbus Model A330–200 Freighter, –200, and –300 series airplanes and Model A340–200, –300, –500, and –600 series airplanes. AD 2014–25–52 requires revising the airplane flight manual to advise the flightcrew of emergency procedures for abnormal Alpha Protection (Alpha Prot). For certain airplanes, accomplishing the actions specified in paragraph (h) of this proposed AD would terminate the AFM requirements of paragraph (g) of AD 2014–25–52.

AD 2016–25–30 applies to all Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200, –300, –500, and –600 series airplanes. AD 2016–25–30 requires new FCPC software standards. For certain airplanes, accomplishing the actions specified in paragraph (h) of this proposed AD would terminate the requirements of paragraph (g) of AD 2016–25–30.

Costs of Compliance

We estimate that this proposed AD affects 103 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/replacement	3 work-hours × \$85 per hour = \$255	\$0	\$255	\$26,265

According to the manufacturer, some or all 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–2018–0498; Product Identifier 2018–NM–013–AD.

(a) Comments Due Date

We must receive comments by July 19, 2018.

(b) Affected ADs

This AD affects AD 2014–25–52, Amendment 39–18066 (80 FR 3161, January 22, 2015) (“AD 2014–25–52”) and AD 2016–25–30, Amendment 39–18756, (82 FR 1175, January 5, 2017) (“AD 2016–25–30”).

(c) Applicability

This AD applies to the airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD; all manufacturer serial numbers; equipped with flight control primary computers (FCPCs) having software standard P13/M22 (hardware 2K2), P14/M23 (hardware 2K1) or M23 (hardware 2K0), or earlier standard.

(1) Airbus Model A330–223F and –243F airplanes.

(2) Airbus Model A330–201, –202, –203, –223, and –243 airplanes.

(3) Airbus Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

Note 1 to paragraph (c) of this AD: The software standards specified in paragraph (c) of this AD correspond, respectively, to part number (P/N) LA2K2B100DG0000, P/N LA2K1A100DF0000 and P/N LA2K01500AF0000. All affected airplanes should be equipped with this software, as required by AD 2016–25–30.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Reason

This AD was prompted by reports of Angle of Attack (AOA) blockages not detected by upgraded FCPC software standards. We are issuing this AD to prevent Alpha protection activation due to blocked AOA probes, which could result in reduced controllability of the airplane.

(f) Compliance

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

(g) Definition of Groups

Group 1 airplanes are those in pre-mod 206412, pre-mod 206413, or pre-mod 206414 configuration, as applicable. Group 2 airplanes are those in post-mod (206412, 206413, or 206414, as applicable) configuration.

(h) Upgrade Flight Control Primary Computer Software

For Group 1 airplanes: Within 12 months after the effective date of this AD: Upgrade (by modification or replacement, as applicable) the three FCPCs, as specified in table 1 to paragraphs (h) and (k) of this AD, in accordance with the Accomplishment Instructions of the applicable service information specified in table 1 to paragraphs (h) and (k) of this AD.

Table 1 to paragraphs (h) and (k) of this AD – Software Standard Updates

Software Standard to be Installed	FCPC Hardware Standard	Applicable Service Bulletin
P15/M24	2K2	Airbus Service Bulletin A330-27-3222, dated February 16, 2017
P16/M25	2K1	Airbus Service Bulletin A330-27-3223, dated June 6, 2017
M25	2K0	Airbus Service Bulletin A330-27-3223, dated June 6, 2017

(i) Terminating Action for Certain Requirements of AD 2014–25–52

For airplanes with an AOA configuration as identified in figure 1 to paragraph (i) of

this AD, or as identified in paragraph (m)(2) of AD 2016–12–15, Amendment 39–18564 (81 FR 40160, June 21, 2016) (“AD 2016–12–15”), as applicable: Accomplishing the upgrade required by paragraph (h) of this AD

terminates the requirements of paragraph (g) of AD 2014–25–52, and the airplane flight manual (AFM) procedure required by paragraph (g) of AD 2014–25–52 may be removed from the AFM.

Figure 1 to paragraph (i) of this AD – AOA Sensor Installation Configurations

AOA Sensor P/N – Captain	AOA Sensor P/N - First Officer	AOA Sensor P/N - Standby
C16291AB or C16291AA	C16291AB or C16291AA	C16291AB, C16291AA, 0861ED or 0861ED2
Note: For AOA sensor P/N C16291AA, paragraph (j) of AD 2016-12-15 requires detailed inspections and a functional heating test of that sensor.		

(j) Terminating Action for Certain Requirements of AD 2016–25–30

Accomplishment of the actions required by paragraph (h) of this AD terminates the requirements of paragraph (g) of AD 2016–25–30 for that airplane.

(k) Parts Installation Prohibition

Installation of any software or hardware of a version earlier than the one listed in table 1 to paragraphs (h) and (k) of this AD is prohibited, as required by paragraphs (k)(1) and (k)(2) of this AD, as applicable.

(1) For Group 1 airplanes: After modification of an airplane as required by paragraph (h) of this AD.

(2) For Group 2 airplanes: As of the effective date of this AD.

(l) 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 manager of the International Branch, send it to the attention of the person identified in paragraph (m)(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 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.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0246R1, dated April 6, 2018, 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–2018–0498.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229.

(3) 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 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 23, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–11700 Filed 6–1–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 892**

[Docket No. FDA–2018–N–1553]

Radiology Devices; Reclassification of Medical Image Analyzers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing this proposed order to reclassify medical image analyzers applied to mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection as postamendments class III (premarket approval) devices (regulated under product code MYN), into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. These devices are intended to direct the clinician’s attention to portions of an image that may reveal abnormalities during interpretation of patient’s radiology images by the clinician. If finalized, this order will reclassify these types of devices from class III to class II and reduce regulatory burdens on industry as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.