

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-2014-0574; Directorate Identifier 2013-NM-258-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 all Airbus Model A318 series airplanes, Model A319 series airplanes, Model A320-211, -212, -214, -231, -232, and -233 airplanes, and Model A321 series airplanes. This proposed AD was prompted by a report of skin disbonding on a composite side shell panel of a rudder. This proposed AD would require an inspection to determine if any rudder composite side shell panel has been repaired, a thermography inspection of each rudder that has received this repair, and related investigative and corrective actions if necessary. We are proposing this AD to detect and correct skin disbonding on the rudder, which could affect the structural integrity of the rudder, possibly resulting in reduced control of the airplane.

DATES: We must receive comments on this proposed AD by October 6, 2014.

ADDRESSES: You may send comments 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 proposed 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 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-2014-0574; 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 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 Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; 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-2014-0574; Directorate Identifier 2013-NM-258-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

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2013-0302, dated December 19, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

A case of skin disbonding was reported on a composite side shell panel of a rudder installed on an A310 aeroplane. Investigation results revealed that this disbonding had started from a skin panel area, previously repaired in-service, in accordance with Structural Repair Manual (SRM) instructions. The initial damage was identified as a disbonding between the core and the skin of the repaired area. This damage was not visually detectable and likely propagated during normal operation due to the variation of pressure during ground-air-ground cycles.

Composite rudder side shell panels are also installed on A320 family aeroplanes, which may have been repaired in-service using a similar method.

This condition, if not detected and corrected, could affect the structural integrity of the rudder, possibly resulting in reduced control of the aeroplane.

To address this potential unsafe condition, Airbus issued Service Bulletin (SB) A320-55-1041 to provide instructions to inspect and correct any affected composite rudder side shell panels.

For the reasons described above, this [EASA] AD requires [an inspection to determine if any rudder composite side shell panel has been repaired], a one-time [pulse] thermography inspection of each rudder that have received a composite rudder side shell panel repair, and, depending on the findings, accomplishment of applicable corrective and follow-up actions [related investigative actions and repetitive inspections].

The related investigative actions include elasticity laminate checker (ELCH) inspections, ultrasonic testing (UT) inspections, pulse thermography inspections, and tap test or woodpecker inspections. The repetitive inspections include ELCH inspections, UT inspections, pulse thermography inspections, and detailed inspections

(certain repetitive inspections are required if hole restoration is done; certain other repetitive inspections are options for certain corrective actions). The corrective actions include core venting through the inner skin, replacements, restorations, and repairs.

Depending on the applicable conditions identified in paragraph 1.E., “Compliance,” of Airbus Service Bulletin A320–55–1041, dated November 26, 2012, the compliance times for the related investigative actions range from within 24 months to before further flight after accomplishing certain inspections.

The intervals for the repetitive inspections range from 750 flight cycles to 1,000 flight cycles, depending on the applicable conditions identified in paragraph 1.E., “Compliance,” of Airbus Service Bulletin A320–55–1041, dated November 26, 2012.

Depending on the applicable conditions identified in paragraph 1.E., “Compliance,” of Airbus Service Bulletin A320–55–1041, dated November 26, 2012, the compliance times for the corrective actions range from before further flight to 4,500 flight cycles but not to exceed 24 months after accomplishing the applicable inspection.

The term “findings,” as used in this proposed AD, includes (but is not limited to) fluid ingress, damage, loose or lost tape, and repairs.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA–2014–0574.

Relevant Service Information

Airbus has issued Service Bulletin A320–55–1041, dated November 26, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

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.

“Contacting the Manufacturer” Paragraph in This Proposed AD

Since late 2006, we have included a standard paragraph titled “Airworthy Product” in all MCAI ADs in which the FAA develops an AD based on a foreign authority’s AD.

The MCAI or referenced service information in an FAA AD often directs the owner/operator to contact the manufacturer for corrective actions, such as a repair. Briefly, the Airworthy Product paragraph allowed owners/operators to use corrective actions provided by the manufacturer if those actions were FAA-approved. In addition, the paragraph stated that any actions approved by the State of Design Authority (or its delegated agent) are considered to be FAA-approved.

In an NPRM having Directorate Identifier 2012–NM–101–AD (78 FR 78285, December 26, 2013), we proposed to prevent the use of repairs that were not specifically developed to correct the unsafe condition, by requiring that the repair approval provided by the State of Design Authority or its delegated agent specifically refer to the FAA AD. This change was intended to clarify the method of compliance and to provide operators with better visibility of repairs that are specifically developed and approved to correct the unsafe condition. In addition, we proposed to change the phrase “its delegated agent” to include a design approval holder (DAH) with State of Design Authority design organization approval (DOA), as applicable, to refer to a DAH authorized to approve required repairs for the proposed AD.

One commenter to the NPRM having Directorate Identifier 2012–NM–101–AD (78 FR 78285, December 26, 2013) stated the following: “The proposed wording, being specific to repairs, eliminates the interpretation that Airbus messages are acceptable for approving minor deviations (corrective actions) needed during accomplishment of an AD mandated Airbus service bulletin.”

This comment has made the FAA aware that some operators have misunderstood or misinterpreted the Airworthy Product paragraph to allow the owner/operator to use messages provided by the manufacturer as approval of deviations during the accomplishment of an AD-mandated action. The Airworthy Product paragraph does not approve messages or other information provided by the manufacturer for deviations to the requirements of the AD-mandated actions. The Airworthy Product paragraph only addresses the

requirement to contact the manufacturer for corrective actions for the identified unsafe condition and does not cover deviations from other AD requirements. However, deviations to AD-required actions are addressed in 14 CFR 39.17, and anyone may request the approval for an alternative method of compliance to the AD-required actions using the procedures found in 14 CFR 39.19.

To address this misunderstanding and misinterpretation of the Airworthy Product paragraph, we have changed the paragraph and retitled it “Contacting the Manufacturer.” This paragraph now clarifies that for any requirement in this proposed AD to obtain corrective actions from a manufacturer, the actions must be accomplished using a method approved by the FAA, the European Aviation Safety Agency (EASA), or Airbus’s EASA DOA.

The Contacting the Manufacturer paragraph also clarifies that, if approved by the DOA, the approval must include the DOA-authorized signature. The DOA signature indicates that the data and information contained in the document are EASA-approved, which is also FAA-approved. Messages and other information provided by the manufacturer that do not contain the DOA-authorized signature approval are not EASA-approved, unless EASA directly approves the manufacturer’s message or other information.

This clarification does not remove flexibility previously afforded by the Airworthy Product paragraph. Consistent with long-standing FAA policy, such flexibility was never intended for required actions. This is also consistent with the recommendation of the Airworthiness Directive Implementation Aviation Rulemaking Committee to increase flexibility in complying with ADs by identifying those actions in manufacturers’ service instructions that are “Required for Compliance” with ADs. We continue to work with manufacturers to implement this recommendation. But once we determine that an action is required, any deviation from the requirement must be approved as an alternative method of compliance.

We also have decided not to include a generic reference to either the “delegated agent” or “design approval holder (DAH) with State of Design Authority design organization approval,” but instead we have provided the specific delegation approval granted by the State of Design Authority for the DAH throughout this proposed AD.

Costs of Compliance

We estimate that this proposed AD affects 851 airplanes of U.S. registry.

We also estimate that it would take about 42 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$3,038,070, or \$3,570 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions 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 proposed 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 proposed 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 proposed 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-2014-0574; Directorate Identifier 2013-NM-258-AD.

(a) Comments Due Date

We must receive comments by October 6, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus airplanes specified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, all manufacturer serial numbers.

- (1) Airbus Model A318-111, -112, -121, and -122 airplanes.
- (2) Airbus Model A319-111, -112, -113, -114, -115, -131, -132, and -133 airplanes.
- (3) Airbus Model A320-211, -212, -214, -231, -232, and -233 airplanes.
- (4) Airbus Model A321-111, -112, -131, -211, -212, -213, -231, and -232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Reason

This AD was prompted by a report of skin disbonding on a composite side shell panel of a rudder. We are issuing this AD to detect and correct skin disbonding on the rudder, which could affect the structural integrity of the rudder, possibly resulting in reduced control of the airplane.

(f) Compliance

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

(g) Inspection To Determine Repair Status

Within 24 months after the effective date of this AD: Inspect the airplane maintenance records to determine if the rudder composite side shell panel has been repaired since first installation of the rudder on an airplane.

(h) Inspection of Certain Repaired Rudders

If the finding of the inspection required by paragraph (g) of this AD reveals that a rudder repair has been done as described in Figure A-GBBAA (Sheet 01 and 02) or Figure A-GBCAA (Sheet 02) of Airbus Service Bulletin A320-55-1041, dated November 26, 2012: Within 24 months after the effective date of this AD, do a pulse thermography inspection on the rudder, limited to the repaired area(s), to determine type, location, and size of the repair, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-55-1041, dated November 26, 2012.

(i) Inspection of Rudders With No Records or Incomplete Records

For each rudder for which maintenance records are not available or are incomplete: Do the actions required by paragraphs (i)(1) and (i)(2) of this AD.

(1) Not later than 3 months before accomplishment of the pulse thermography inspection required by paragraph (i)(2) of this AD, send the records of each rudder by serial number to Airbus.

(2) Within 24 months after the effective date of this AD, do a pulse thermography inspection on complete rudder side shells to identify and mark the repair location, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-55-1041, dated November 26, 2012.

(j) Related Investigative Actions, Repetitive Inspections, and Corrective Actions

After accomplishing the inspections required by paragraphs (h) and (i) of this AD, as applicable: Depending on findings, do the applicable actions specified in paragraphs (j)(1) and (j)(2) of this AD, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-55-1041, dated November 26, 2012, except as required by paragraph (l)(2) of this AD. Findings are specified in Airbus Service Bulletin A320-55-1041, dated November 26, 2012.

(1) Do all applicable related investigative actions and corrective actions at the applicable times specified in Tables 3, 4A, 4B, 4C, 4D, and 5 in paragraph 1.E.(2),

“Accomplishment Timescale,” of Airbus Service Bulletin A320–55–1041, dated November 26, 2012, except as required by paragraph (l)(1) of this AD.

(2) Do all applicable repetitive inspections of the restored and repaired areas at the applicable intervals specified in Tables 3, 4A, 4B, 4C, 4D, and 5 in paragraph 1.E.(2), “Accomplishment Timescale,” of Airbus Service Bulletin A320–55–1041, dated November 26, 2012.

(k) Airplanes Excluded From Certain Requirements

Airplanes fitted with a rudder having a serial number which is not in the range TS–1001 to TS–1639 inclusive, or TS–2001 to TS–5890 inclusive; or is not TS–5927; are not affected by the requirements of paragraphs (h), (i), and (j) of this AD, provided it is determined that no repairs have been done as described in the structural repair manual (SRM) procedures identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of Airbus Service Bulletin A320–55–1041, dated November 26, 2012, on the composite side shell panel of that rudder since first installation on an airplane.

(l) Exception to Service Information

(1) Where the service bulletin specifies a compliance time “after the original Service Bulletin issue date,” this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If any damage or fluid ingress is found during any inspection required by this AD and Airbus Service Bulletin A320–55–1041, dated November 26, 2012, specifies to contact Airbus: Before further flight, repair 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). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Parts Installation Limitation

As of the effective date of this AD, in case of rudder replacement, it is allowed to install a rudder on an airplane, provided that prior to installation the rudder is determined to be compliant with the requirements of paragraphs (h), (i), (j), and (k) of this AD.

(n) Repair Prohibition

As of the effective date of this AD, do not accomplish a composite side shell panel repair on any rudder using an SRM procedure identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of Airbus Service Bulletin A320–55–1041, dated November 26, 2012.

(o) 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 ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; 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 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) *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.

(p) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency Airworthiness Directive 2013–0302, dated December 19, 2013, 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 it in Docket No. FAA–2014–0574.

(2) 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 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 August 15, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–19979 Filed 8–21–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 610 and 680

[Docket No. FDA–2014–N–1110]

Revocation of General Safety Test Regulations That Are Duplicative of Requirements in Biological License Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by removing the general safety test (GST) requirements for biological products. FDA is proposing this action because the existing codified GST regulations are duplicative of requirements that are also specified in biologics licenses, or are no longer necessary or appropriate to help ensure the safety, purity, and potency of licensed biological products. FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation, in response to an Executive order.

DATES: Submit either electronic or written comments on this proposed rule by November 20, 2014. See section V of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand Delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include Docket No. FDA–2014–N–