

the relevant information in the general revisions is identical to that in Airbus Temporary Revision TR37, Issue 1.0, dated June 15, 2010; or Airbus Temporary Revision TR38, Issue 1.0, dated June 15, 2010.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone (425) 227-1138; 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) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(i) Related Information

(1) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2012-0069, dated April 24, 2012, and the service information specified in paragraphs (i)(1)(i) and (i)(1)(ii) of this AD, for related information.

(i) Airbus Temporary Revision TR37, Issue 1.0, dated June 15, 2010.

(ii) Airbus Temporary Revision TR38, Issue 1.0, dated June 15, 2010.

(2) 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 review copies of the 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.

Issued in Renton, Washington, on October 14, 2012.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2012-1107; Directorate Identifier 2011-NM-216-AD]

RIN 2120-AA64

Airworthiness Directives; Intertechnique Aircraft Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) that applies to certain Intertechnique Aircraft Systems oxygen mask regulators. This proposed AD was prompted by a report of a malfunctioning mask having an inflatable harness with a high premature rupture rate due to defective silicon. This proposed AD would require inspecting and replacing defective harnesses with new or modified serviceable units. We are proposing this AD to detect and correct defective harnesses which could lead, in case of a sudden depressurization event, to a harness rupture, thereby providing inadequate protection against hypoxia and possibly resulting in unconsciousness of the affected flightcrew member and consequent reduced control of the airplane.

DATES: We must receive comments on this proposed AD by December 10, 2012.

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 Intertechnique Aircraft Systems, 61 Rue Pierre Curie BP 1, 78373 Plaisir Cedex—France; telephone: (33) 1 61 34 12 32; fax: (33) 1 64 86 69 84; email: yann.laine@zodiac aerospace.com; Internet: www.zodiac aerospace.com.

You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. 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>; or in person at the Docket Operations office 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:

Caspar Wang, Aerospace Engineer, Boston Aircraft Certification Office (ACO) ANE-150, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: (781) 238-7799; fax: (781) 238-7170; email: caspar.wang@faa.gov.

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-2012-1107; Directorate Identifier 2011-NM-216-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 2011-0090R1, dated July 13, 2011 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

A malfunction of a quick donning mask was reported to Intertechnique, who initiated

an investigation in order to detect the root cause and the failure mode. Despite the fact that the analysis did not lead to any final conclusion, discrete suspected silicon batches have been identified which have shown an unusually high premature rupture rate.

Some of the affected harnesses are known to have been delivered as spares. Consequently, an inflatable harness belonging to one of the suspect batches may have become installed on an Oxygen Mask Regulator, the serial number (s/n) or [part number] P/N of which is not identified in Appendix II of Intertechnique Service Bulletin (SB) MXH-35-240.

This fact widens the Applicability of this [EASA] AD to extend beyond the individual Oxygen Mask Regulators identified by s/n and P/N in Appendix II of the SB.

This condition, if not detected and corrected, could lead, in case of a sudden depressurization event, to a harness rupture, thereby providing inadequate protection against hypoxia of the affected flight crew member, possibly resulting in unconsciousness and consequent reduced control of the aeroplane.

For the reasons described above, this [EASA] AD requires the identification and replacement of all potentially defective harnesses with serviceable units.

Note 1: The affected batches were installed on harnesses manufactured between December 2008 and August 2010, having dates codes 0850S (week 50 of 2008) through 1031S (week 31 of 2010).

Note 2: Harness assemblies that do not have a batch code were manufactured before week 33 of 2008 and are not affected by this unsafe condition.

This [EASA] AD has been revised to correct a typographical error in the Applicability, which inadvertently referred to P/N MA10-12 masks, whereas in fact, all P/N MA10 series could have an affected harness installed. In addition, this revised AD corrects Note 2 (above), which confused harness manufacturing date codes with the affected harnesses batch codes.

This [EASA] AD is also revised to make reference to the latest revisions of the referenced Intertechnique service publications which identify by s/n and P/N, in Appendix II of the SB, more oxygen mask regulators that are known or suspected to have an affected harness installed. Finally, this AD is revised to add a Note to the Required Actions section, to stress the fact that other oxygen mask regulators could be affected, in addition to those listed in Appendix II of the SB.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Zodiac Aerospace Intertechnique has issued the following service bulletins:

- Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011 (for all airplanes other than Bombardier airplanes).

- Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011 (for Bombardier airplanes).

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 the same type design.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect up to 5,500 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators up to \$467,500, or \$85 per product.

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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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 AD:

Intertechnique Aircraft Systems: Docket No. FAA-2012-1107; Directorate Identifier 2011-NM-216-AD.

(a) Comments Due Date

We must receive comments by December 10, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Intertechnique Aircraft Systems flight crew oxygen mask regulators, all part number (P/N) MA10, MC10, MC20, MF10, MF20, MLC20, MLD20, MRA005, MRA022, and MRA023 series; certificated in

any category; installed on, but not limited to, airplanes manufactured by Airbus, ATR, BAE Systems (Type Certificate previously held by British Aerospace), Boeing, Bombardier (Type Certificate previously held by Canadair, De Havilland Canada), Cessna, Dassault, EADS CASA, EMBRAER, Gulfstream, Hawker Beechcraft (Type Certificate previously held by Raytheon, Beech), Israel Aircraft Industries (IAI), McDonnell Douglas, Piaggio, Pilatus, Piper and SOCATA.

(d) Subject

Air Transport Association (ATA) of America Code 35: Oxygen.

(e) Reason

This AD was prompted by a report of a malfunctioning mask having an inflatable harness with a high premature rupture rate due to defective silicon. We are issuing this AD to detect and correct defective harnesses which could lead, in case of a sudden depressurization event, to a harness rupture, thereby providing inadequate protection against hypoxia and possibly resulting in unconsciousness of the affected flightcrew member and consequent reduced control of the airplane.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Inspection

(1) Except as provided by paragraph (i) of this AD: Within 24 months after the effective date of this AD, inspect the inflatable harness fitted to each flight crew oxygen mask regulator to determine if the inflatable harness is installed with a part number (P/N) and a batch number identified in Appendix I of Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011 (for all airplanes other than Bombardier airplanes); or Appendix I of Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011 (for Bombardier airplanes).

(2) Referring only to Appendix II of Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011 (for all airplanes other than Bombardier airplanes); or Appendix II of Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011 (for Bombardier airplanes); to identify a specific oxygen mask regulator is insufficient to demonstrate that the inflatable harness fitted to that oxygen mask regulator is not listed in Appendix I of Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011; or Appendix I of Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011.

(h) Replacement

If during the inspection required by paragraph (g)(1) of this AD, an inflatable harness has a part number and batch number identified in Appendix I of Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011 (for all airplanes other than Bombardier airplanes); or

Appendix I of Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011 (for Bombardier airplanes): Before further flight, replace the inflatable harness with a new or re-identified harness, in accordance with the Accomplishment Instructions of Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011 (for all airplanes other than Bombardier airplanes); or Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011 (for Bombardier airplanes).

(i) Exception

Oxygen mask regulators having a date of manufacturing (DMF) code of November 2008 (112008 or 11-08) or earlier, and those with a DMF of January 2011 (012011 or 01-11) or later, are excluded from the inspection and replacement requirements of paragraphs (g) and (h) of this AD, provided it can be demonstrated that the inflatable harness has not been replaced on those masks. A review of airplane delivery or maintenance records is acceptable to make the determination as specified in this paragraph if the part number, batch number, and DMF can be conclusively determined from that review.

(j) Definition

For the purpose of this AD, Bombardier airplanes include airplanes previously manufactured by Canadair or by De Havilland Canada.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install a flight crew oxygen mask regulator having a part number and batch number on the inflatable harness that is found in Appendix I of Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011 (for all airplanes other than Bombardier airplanes); or Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011 (for Bombardier airplanes) on any airplane.

(l) 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 a service bulletin specified in paragraph (l)(1), (l)(2), or (l)(3) of this AD:

- (1) Intertechnique Service Bulletin MXH-35-240, Revision 6, dated August 16, 2011.
- (2) Intertechnique Service Bulletin MXH-35-240, Revision 5, dated July 26, 2011.
- (3) Intertechnique Service Bulletin MXH-35-240, Revision 4, dated June 10, 2011.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Boston Aircraft Certification Office (ACO) ANE-150, 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 ACO, send it to ATTN: Caspar Wang, Aerospace Engineer, Boston Aircraft

Certification Office (ACO) ANE-150, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: (781) 238-7799; fax: (781) 238-7170. 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) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(n) Related Information

(1) Refer to MCAI EASA Airworthiness Directive 2011-0090R1, dated July 13, 2011, and the service information specified in paragraphs (n)(1)(i) and (n)(1)(ii) of this AD, for related information.

(i) Intertechnique Service Bulletin MXH-35-240, Revision 7, dated September 1, 2011.

(ii) Intertechnique Service Bulletin MXH-35-241, Revision 2, dated May 19, 2011.

(2) For service information identified in this AD, contact Intertechnique Aircraft Systems, 61 Rue Pierre Curie BP 1, 78373 Plaisir Cedex—France; telephone: (33) 1 61 34 12 32; fax: (33) 1 64 86 69 84; email: yann.laine@zodiac aerospace.com; Internet: www.zodiac aerospace.com. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on October 15, 2012.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2004-C-0559 (Formerly Docket No. 2004C-0078)]

Cryovac North America; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 4C0276) proposing that the color