Rules and Regulations

Federal Register
Vol. 85, No. 140
Tuesday, July 21, 2020

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–1113; Project Identifier MCAI–2019–00117–E; Amendment 39–21161; AD 2020–14–07]

RIN 2120–AA64

Airworthiness Directives; Austro Engine GmbH Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Austro Engine GmbH model E4 and E4P diesel piston engines. This AD was prompted by reports of considerable wear of the timing chain and failure of fuel injectors on these engines. This AD requires replacement of the timing chain and fuel injectors on the affected Austro Engine GmbH model E4 and E4P diesel piston engines. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 25, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 25, 2020.

ADDRESSES: For service information identified in this final rule, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; fax: +43 2622 23000–2711; website: *www.austroengine.at.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–1113.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–1113; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7743; fax: 781–238–7199; email: *Mehdi.Lamnyi@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Austro Engine GmbH model E4 and E4P diesel piston engines. The NPRM published in the **Federal Register** on March 20, 2020 (85 FR 16014). The NPRM was prompted by reports of considerable wear of the timing chain and failure of fuel injectors on these engines. The NPRM proposed to require replacement of the timing chain and fuel injectors on the affected Austro Engine GmbH model E4 and E4P diesel piston engines. The FAA is issuing this AD to address the unsafe condition on these products.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2019–0041, dated February 25, 2019 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

The airworthiness limitations and maintenance tasks for the Austro Engine E4 and E4P engines, which are approved by EASA, are currently defined and published in the Austro Engine MM, Chapter 04. These instructions have been identified as mandatory for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

Austro Engine recently revised the ALS, introducing life limit for the engine timing chain and for the fuel injectors. For the reason described above, this [EASA] AD requires accomplishment of the actions specified in the ALS.

You may obtain further information by examining the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–1113.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Austro Engine Mandatory Service Bulletin (MSB) No. MSB–E4–025, Rev. No. 3, dated January 8, 2019. The MSB describes procedures for replacing the fuel injectors. 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.

Other Related Service Information

The FAA reviewed Austro Engine Maintenance Manual (MM) Temporary Revision (TR) MM–TR–MDC–E4–454, dated October 3, 2018. The MM TR updates the time limits for the fuel injectors and timing chain and describes procedures for updating the Airworthiness Limitation Section in the existing approved MM.

Costs of Compliance

The FAA estimates that this AD affects 263 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace the timing chain	2.5 work-hours × $85 per hour = $212.50	$2,980	$3,192.50	$839,627.50
Replace the fuel injectors	2.5 work-hours × $85 per hour = $212.50	2,590	2,802.50	737,057.50

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.

The FAA is 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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2020–14–07 Austro Engine GmbH: Amendment 39–21161; Docket No. FAA–2019–1113; Project Identifier MCAI–2019–00117–E.

(a) Effective Date

This AD is effective August 25, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Austro Engine GmbH Model E4 and E4P diesel piston engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7322, Fuel Control/Reciprocating Engines and Code 8520, Reciprocating Engine Power Section.

(e) Unsafe Condition

This AD was prompted by reports of considerable wear of the timing chain and failure of fuel injectors on the affected engines. The FAA is issuing this AD to prevent failure of the timing chain and fuel injectors. The unsafe condition, if not addressed, could result in loss of engine thrust control and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) For engines that have had a windmill restart before the effective date of this AD or for engines with a timing chain in which it cannot be determined if the engine has experienced any windmilling, after the effective date of this AD, remove the timing chain and replace with a part eligible for installation as follows, whichever occurs later:

(i) Before the timing chain exceeds 900 flight hours (FHs) since new, or;

(ii) Within 100 FHs after the windmilling restart, or;

(iii) Before further flight.

(2) For engines that have a windmill restart after the effective date of this AD, remove the timing chain before it exceeds 900 FHs since new or within 100 FHs after the windmilling restart, whichever occurs later, and replace with a part eligible for installation.

(3) Remove the fuel injectors and replace with parts eligible for installation before they exceed 900 FHs since new or before further flight after the effective date of this AD, whichever occurs later.

(i) Use Accomplishment/Instructions, paragraph 2.1, of Austro Engine Mandatory Service Bulletin (MSB) No. MSB–E4–025, Rev. No. 3, dated January 8, 2019, to perform the required actions in paragraph (g)(3) of this AD.

(ii) [Reserved]

(4) Thereafter, repeat the replacement of the fuel injectors required by paragraph (g)(3) of this AD at intervals not exceeding 900 FHs since new.

(h) Exception to Paragraph (g)(3)(i)

The tagging and returning of the removed fuel injectors to the manufacturer, referenced in the Accomplishment/Instructions, paragraph 2.1, of Austro Engine MSB No. MSB–E4–025, Rev. No. 3, dated January 8, 2019, are not required by this AD.

(i) Credit for Previous Actions

You may take credit for the replacement of the timing chain that is required by paragraph (g)(1) of this AD if you performed this replacement before the effective date of this AD using Austro Engine MSB No. MSB–E4–017/2, Revision 2, dated December 2, 2016.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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 ECO Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) 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.

(k) Related Information

(1) For more information about this AD, contact Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: 781–238–7743; fax: 781–238–7199; email: *Mehdi.Lamnyi@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2019–0041, dated February 25, 2019, for more information. You

may examine the EASA AD in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–1113.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Austro Engine Mandatory Service Bulletin No. MSB–E4–025, Rev. No. 3, dated January 8, 2019.

(ii) [Reserved]

(3) For Austro Engine GmbH service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; fax: +43 2622 23000–2711; website: *www.austroengine.at.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781–238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 9, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–15606 Filed 7–20–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2017–D–6146]

Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry and FDA staff entitled ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' The guidance does not alter FDA's current thinking on the regulatory criteria of minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based product (HCT/P). The guidance announced in this notice supersedes the guidance of the same title dated November 2017 and corrected December 2017. The guidance revises section V of the November 2017 guidance to communicate that the Agency is extending the period of time during which FDA intends to exercise enforcement discretion regarding certain regulatory requirements for certain HCT/Ps; this time period will run through May 31, 2021, instead of November 30, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on July 21, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–6146 for ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' 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, 240–402–7500.

- 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 copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.