

III. Publicly Available Documents

The NRC has posted on www.regulations.gov for public availability the draft regulatory basis to strengthen and integrate onsite emergency response capabilities. This regulatory basis documents the reasons why the NRC determined rulemaking was the appropriate course of action to remedy a regulatory shortcoming.

In addition, the NRC has posted preliminary proposed rule language related to this rulemaking as Appendix C of the draft regulatory basis. This preliminary proposed rule language contains one portion of the NRC's proposed changes. This language does not represent a final NRC staff position nor has it been reviewed by the Commission. Therefore, the preliminary proposed rule language may undergo significant revision during the rulemaking process.

The NRC is requesting formal public comments on the draft regulatory basis and the preliminary proposed rule language. The NRC may post additional materials, including other preliminary proposed rule language, to the Federal rulemaking Web site at www.regulations.gov, under Docket ID NRC-2012-0031. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2012-0031); (2) click the "Email Alert" link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. Although regulations are exempt under the Act, the NRC is applying the same principles to its rulemaking documents. Therefore, the NRC has written this document, including the preliminary proposed rule language, to be consistent with the Plain Writing Act.

Dated at Rockville, Maryland, this 26th day of December, 2012.

For the Nuclear Regulatory Commission.

Sher Bahadur,

Deputy Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2012-31706 Filed 1-7-13; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 61

[NRC-2011-0012]

RIN 3150-AI92

Low-Level Waste Disposal

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory basis and preliminary rule language; second request for comment; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a document appearing in the **Federal Register** on December 7, 2012 entitled, "Low-Level Waste Disposal" that announced the availability of a regulatory basis document and requested comment on preliminary rule language. This action is necessary to correct the title and number used to access the regulatory basis document in the NRC's Agencywide Documents Access and Management System (ADAMS).

ADDRESSES: Please refer to Docket ID NRC-2011-0012 when contacting the NRC about the availability of information for this document. You may access information and comment submittals related to this document, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2011-0012.

- *ADAMS:* You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Andrew Carrera, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington,

DC 20555-0001, telephone 301-415-1078, email Andrew.Carrera@nrc.gov.

SUPPLEMENTARY INFORMATION: The NRC is correcting the accession number and title of the regulatory basis document that was referenced in a document the NRC published on December 7, 2012 (77 FR 72997). The regulatory basis document has been further corrected to remove a reference to an unavailable document.

On page 72997 of **Federal Register** document 2012-29527, published December 07, 2012 (77 FR 72997), in the third column, under the caption titled **SUPPLEMENTARY INFORMATION**, in the last paragraph of Section A, *Accessing Information*, under Section I, *Accessing Information and Submitting Comments*, "Regulatory Analysis for Proposed Revisions to Low-Level Waste Disposal Requirement (10 CFR part 61)" is corrected to read "Regulatory Basis;" and "ML12306A480" is corrected to read "ML12356A242."

Dated at Rockville, Maryland, this 28th day of December, 2012.

For the Nuclear Regulatory Commission.

Kevin O'Sullivan,

Acting Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2012-31704 Filed 1-7-13; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2012-18033; Directorate Identifier 2004-CE-16-AD]

RIN 2120-AA64

Airworthiness Directives; Cessna Aircraft Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to revise an existing airworthiness directive (AD) that applies to all Cessna Aircraft Company (Cessna) Models 190, 195 (L-126A,B,C), 195A, and 195B airplanes that are equipped with certain inboard aileron hinge brackets. The existing AD currently requires you to repetitively inspect the affected inboard aileron hinge brackets for cracks or corrosion and replace them if cracks or corrosion is found. Replacement with aluminum brackets would terminate the need for

the repetitive inspections. Since we issued AD 2004–21–08, the FAA, in recent months, has received reports of confusion between the casting number on the aileron hinge bracket and the part number (P/N) called out in the AD. This proposed AD would retain the actions of AD 2004–21–08 while requiring future compliance following a revised service bulletin that clarifies the casting numbers and part numbers to be inspected. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 22, 2013.

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 AD, contact Cessna Aircraft Company, Customer service, P.O. Box 7706, Wichita, KS 67277; telephone: (316) 517–5800; fax: (316) 517–7271; email: customercare@cessna.textron.com; Internet: <http://www.cessnasupport.com>. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Gary Park, Aerospace Engineer, Wichita ACO, FAA, 1801 Airport Road, Wichita, KS

67209; phone: (316) 946–4123; fax: (316) 946–4107; email: gary.park@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–2012–18033; Directorate Identifier 2004–CE–16–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 because of 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

On October 13, 2004, we issued AD 2004–21–08, amendment 39–13828 (69 FR 62396, October 26, 2004), for all Cessna Models 190, 195 (L–126A,B,C), 195A, and 195B airplanes that are equipped with certain inboard aileron hinge brackets. That AD requires you to repetitively inspect the affected inboard aileron hinge brackets for cracks or corrosion and replace them if cracks or corrosion is found. Replacement with aluminum brackets would terminate the need for the repetitive inspections.

AD 2004–21–08 (69 FR 62396, October 26, 2004) resulted from several reports of cracks and corrosion found on the magnesium aileron hinge brackets. Magnesium is known to be susceptible to corrosion. We issued AD 2004–21–08 (69 FR 62396, October 26, 2004) to detect and correct corrosion damage to the inboard aileron hinge brackets. Such damage could result in the brackets cracking across the bearing boss and could lead to the aileron separating from the airplane with consequent reduced or loss of control.

Actions Since Existing AD Was Issued

Since we issued AD 2004–21–08 (69 FR 62396, October 26, 2004), the FAA, in recent months, has received reports of confusion between the casting number on the aileron hinge bracket and the P/N called out in the AD. Due to this misunderstanding, proper inspections and/or replacement of the aileron hinge bracket may not be occurring following the AD. In one report, a service center provided an airworthiness compliance

record stating “aileron hinge brackets are of a different part # than those specified in the note.” However, during a later inspection of the bracket, a crack was found through the bearing boss.

Relevant Service Information

We reviewed Cessna Aircraft Company Single Engine Service Bulletin SEB04–1, dated April 26, 2004, and Single Engine Service Bulletin SEB04–01, Revision 1, dated October 3, 2012. The service information describes procedures for:

- Inspecting P/N 0322709 and P/N 0322709–1 inboard aileron hinge brackets for cracks or corrosion; and
- Replacing any bracket found cracked or corroded with a bracket that is FAA-approved and made from aluminum.

Revision 1 of the service information adds casting numbers for the parts to be inspected and clarifies the inspection.

FAA’s Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all requirements of AD 2004–21–08 (69 FR 62396, October 26, 2004) while requiring future compliance following a revised service bulletin that clarifies the casting numbers and part numbers to be inspected.

Change to Existing AD

This proposed AD would retain all requirements of AD 2004–21–08 (69 FR 62396, October 26, 2004). Since AD 2004–21–08 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 2004–21–08	Corresponding requirement in this proposed AD
paragraph (e)(1) paragraph (e)(2) paragraph (e)(3)	paragraph (h) paragraph (i) paragraph (j)

Costs of Compliance

We estimate that this proposed AD affects 643 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection of the affected inboard aileron hinge brackets for cracks or corrosion.	1 work-hour × \$85 per hour = \$85	Not Applicable	\$85	1,180 airplanes × \$85 = \$54,655.

The new requirements of this proposed AD add no additional economic burden.

We estimate the following costs to do any necessary replacements that would be required based on the results of the

proposed inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement of left-hand (LH) brackets	3 work-hours × \$85 per hour = \$255	\$1,999	\$2,254
Replacement of right-hand (RH) brackets	3 work-hours × \$85 per hour = \$255	1,592	1,847
Replacement of LH and RH brackets	6 work-hours × \$85 per hour = \$510	4,101	4,611

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 have 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 that the 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 removing airworthiness directive (AD) 2004–21–08, Amendment 39–13828 (69 FR 62396, October 26, 2004), and adding the following new AD:

Cessna Aircraft Company: Docket No. FAA–2012–18033; Directorate Identifier 2004–CE–16–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by February 22, 2013.

(b) Affected ADs

This AD revises AD 2004–21–08, Amendment 39–13828.

(c) Applicability

This AD affects Models 190, 195 (L–126A,B,C), 195A, and 195B airplanes, all serial numbers, that are:

- (1) Certificated in any category; and
- (2) Equipped with at least one part number (P/N) 0322709 or P/N 0322709–1 inboard aileron hinge bracket.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 2710, Aileron Control System.

(e) Unsafe Condition

This AD was prompted by reports of confusion between the casting number on the aileron hinge bracket and the part number called out in the AD. We are issuing this AD to correct the unsafe condition on these products.

(f) Compliance

Comply with this AD at the times specified following the procedures in Cessna Aircraft Company Single Engine Service Bulletin SEB04–01, Revision 1, dated October 3, 2012, unless already done.

(g) Credit for Actions Accomplished in Accordance With Previous Service Information

This paragraph provides credit for the actions required by paragraphs (h), (i), and (j) of this AD, if the actions were performed before the effective date of this AD using Cessna Aircraft Company Single Engine Service Bulletin SEB04–1, dated April 26, 2004. All actions performed after the effective date of this AD will be required following Cessna Aircraft Company Single Engine Service Bulletin SEB04–01, Revision 1, dated October 3, 2012.

(h) Inspect Each P/N 0322709 and P/N 0322709-1 Inboard Aileron Hinge Bracket or Any Other Bracket Made From Magnesium for Cracks or Corrosion

Within the next 100 hours time-in-service (TIS) after November 30, 2004 (the effective date retained from AD 2004-21-08, Amendment 39-13828 (69 FR 62396, October 26, 2004)), and repetitively thereafter at intervals not to exceed 100 hours TIS until each bracket is replaced with aluminum, inspect each P/N 0322709 and P/N 0322709-1 inboard aileron hinge bracket or any other bracket made from magnesium for cracks or corrosion.

(i) Replace Any Cracked or Corroded Inboard Aileron Hinge Bracket

Before further flight after any inspection where any cracked or corroded bracket is found, replace any cracked or corroded inboard aileron hinge.

(1) If replacement is with an FAA-approved bracket made from magnesium, do the 100-hour TIS interval repetitive inspections as required in paragraph (h) of this AD.

(2) If replacement is with an FAA-approved bracket that is made from aluminum, then no further inspections are necessary. These can be Cessna parts or non-Cessna parts.

(j) Terminating Action for the Repetitive Inspections

(1) As terminating action for the repetitive inspections, you may replace all inboard aileron hinge brackets with FAA-approved brackets that are made from aluminum (as specified in paragraph (i)(2) of this AD) regardless if any corrosion or crack is found.

(2) You may do this replacement at any time, but you must replace any corroded or cracked bracket before further flight after the applicable inspection where any corrosion or crack is found.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita Aircraft Certification Office (ACO), 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 ACO, send it to the attention of the person identified in the Related Information section of this AD.

(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.

(3) All AMOCs approved for AD 2004-21-08 (69 FR 62396, October 26, 2004) are approved for this AD.

(l) Related Information

(1) For more information about this AD, contact Gary Park, Aerospace Engineer, Wichita ACO, FAA, 1801 Airport Road, Wichita, KS 67209; phone: (316) 946-4123; fax: (316) 946-4107; email: gary.park@faa.gov.

(2) For service information identified in this AD, contact Cessna Aircraft Company, Customer Service, P.O. Box 7706, Wichita, KS 67277; telephone: (316) 517-5800; fax: (316) 517-7271; email: customercare@cessna.textron.com; Internet: <http://www.cessnasupport.com>. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on December 31, 2012.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013-00069 Filed 1-7-13; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868 and 870

[Docket No. FDA-2012-N-1174]

Anesthesiology Devices; Reclassification of Membrane Lung for Long-Term Pulmonary Support; Redesignation as Extracorporeal Circuit and Accessories for Long-Term Pulmonary/Cardiac Support

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: On its own initiative, based on new information, the Food and Drug Administration (FDA) is proposing to reclassify membrane lung devices for long-term pulmonary support, a preamendments class III device, into class II (special controls) for conditions where imminent death is threatened by cardiopulmonary failure in neonates and infants or where cardiopulmonary failure results in the inability to separate from cardiopulmonary bypass following cardiac surgery. A membrane lung for long-term pulmonary support refers to the oxygenator component of an extracorporeal circuit used during long-term procedures, commonly referred to as extracorporeal membrane oxygenation (ECMO). Because circuit components used with the oxygenator are to be subject to the same regulatory controls, all of the device components used in an ECMO procedure are being considered in the scope of this proposed order, and the title and identification of the regulation will be revised accordingly to include extracorporeal circuit and accessories for long-term pulmonary/cardiac support.

DATES: Submit either electronic or written comments on this proposed order by April 8, 2013. See section XI of this document for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-1174, 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 way:

- *Mail/Hand delivery/Courier (for paper or CD-ROM 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 the Agency name and Docket No. FDA-2012-N-1174 for this order. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1666, Silver Spring, MD 20993, 301-796-6380, angela.krueger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act of 2004 (Pub. L. 108-