

Rules and Regulations

Federal Register

Vol. 84, No. 71

Friday, April 12, 2019

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC-2017-0151]

RIN 3150-AK07

Reactor Vessel Material Surveillance Program; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory basis; availability; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a document that published in the **Federal Register** (FR) on April 3, 2019, regarding the availability of a regulatory basis to support a rulemaking that would amend the NRC's regulations for the light-water power reactor vessel material surveillance programs. This action is necessary to correct the ADAMS accession number for the regulatory basis.

DATES: The correction is effective April 12, 2019.

ADDRESSES: Please refer to Docket ID NRC-2017-0151 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0151. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/>

adams.html. To begin the search, 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.

- **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:

Stewart Schneider, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-4123; email: Stewart.Schneider@nrc.gov.

SUPPLEMENTARY INFORMATION:

Correction

In FR Rule Doc. 2019-06418, appearing on page 12876 in the April 3, 2019, **Federal Register**, in the second bullet in the second column on page 12876, correct the ADAMS Accession No. "ML18057A005" to read "ML19038A477".

Dated at Rockville, Maryland, this 9th day of April, 2019.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019-07282 Filed 4-11-19; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-1236; Product Identifier 2017-SW-136-AD; Amendment 39-19613; AD 2019-07-02]

RIN 2120-AA64

Airworthiness Directives; Robinson Helicopter Company Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Robinson Helicopter Company

(Robinson Helicopter) Model R66 helicopters. This AD requires inspecting the oil tank outlet's fitting color. If the fitting is blue, this AD requires replacing the tank with an oil tank that lacks a blue fitting. This AD also requires determining the revision letter on the ink stamp, and installing an oil tank angle based on that determination. This AD was prompted by reports of broken oil tank internal baffles. The actions of this AD are intended to correct an unsafe condition on these products.

DATES: This AD is effective May 17, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of May 17, 2019.

ADDRESSES: For service information identified in this final rule, contact Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505; telephone (310) 539-0508; fax (310) 539-5198; or at <http://www.robinsonheli.com/servelib.htm>. You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1236.

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-2017-1236; 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 AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations (phone: 800-647-5527) 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:

Danny Nguyen, Aerospace Engineer, Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California

90712; telephone (562) 627-5247; email danny.nguyen@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

On September 21, 2018, at 83 FR 47848, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Robinson Helicopter Model R66 helicopters, serial numbers 0003 through 0789, 0791, 0794 and 0796. The NPRM proposed to require, within 100 hours time-in-service (TIS), inspecting the oil tank outlet fitting color and replacing the tank before further flight if the fitting is blue. The NPRM also proposed to require determining the revision letter of the G689-1 oil tank assembly identification ink stamp and then installing G805-1 angle if the identification ink stamp is followed by revision letter F, G, H, or I, or by revision letter J with no yellow dot near the ink stamp. For revision letter J, a yellow dot indicates that the angle has been pre-installed and that no further action would be necessary. If the identification ink stamp is followed by a revision letter K, the NPRM proposed no further action would be necessary.

The NPRM was prompted by report of broken oil tank internal baffles caused by vibration. The proposed requirements were intended to prevent a broken baffle inside an oil tank, which could result in loss of oil pressure and oil flow to the engine, leading to engine failure and subsequent forced landing of the helicopter.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of the same type design and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information Under 14 CFR Part 51

We reviewed Robinson Helicopter R66 Service Bulletin SB-21A, Revision A, dated June 6, 2017, which specifies installing an angle in the tank outlet to prevent a failed baffle from blocking the outlet.

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.

Differences Between This AD and the Service Information

The service information specifies performing the corrective actions within the next 100 hours TIS or by July 31, 2017, whichever comes first. This AD requires the actions within 100 hours TIS.

Costs of Compliance

We estimate that this AD affects 265 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Labor costs average \$85 a work-hour.

The cost for identifying the oil tank assembly identification ink stamp and outlet fitting color is minimal. Inserting a G805-1 angle requires about 1 work-hour and parts cost about \$17 for an estimated cost of \$102 per helicopter.

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

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 that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under 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 an economic evaluation of the estimated costs to comply with this 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.

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):

2019-07-02 Robinson Helicopter Company:
Amendment 39-19613; Docket No. FAA-2017-1236; Product Identifier 2017-SW-136-AD.

(a) Applicability

This AD applies to Robinson Helicopter Company Model R66 helicopters, serial numbers 0003 through 0789, 0791, 0794 and 0796, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as broken baffle inside an oil tank. This condition could result in loss of oil pressure and oil flow to the engine, leading to engine failure and subsequent forced landing of the helicopter.

(c) Effective Date

This AD becomes effective May 17, 2019.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 100 hours time-in-service:

- (1) Visually inspect the oil tank outlet fitting color to determine if it is blue. If the fitting is blue, before further flight, replace the tank with an oil tank that does not have a blue fitting.
- (2) Locate the G689-1 oil tank assembly identification ink stamp on the top surface of the oil tank, and determine the revision letter.
 - (i) If the identification ink stamp is followed by a revision letter F, G, H, or I unless previously installed, install a G805-1 angle as follows:

(A) Drain the engine oil and disconnect the F723-1 line assembly from the tank fitting at the firewall, using as reference Figure 1 of Robinson Helicopter Company R66 Service Bulletin SB-21A, Revision A, dated June 6, 2017.

(B) Pinch the flanges of G805-1 angle at the minimum required to enable insertion, and insert the angle in the oil tank outlet fitting until the angle snaps in place.

(C) Connect the F723-1 line assembly to the tank fitting. Special torque nut to 675 in.-lb. Torque stripe the fitting.

(ii) If the identification ink stamp is followed by a revision letter J, determine if there is a yellow dot near the ink stamp. A yellow dot indicates that the angle has been pre-installed and that no further action is required by this AD. If there is not a yellow dot near the ink stamp, install a G805-1 angle by following the procedures in paragraphs (e)(2)(i)(A) through (e)(2)(i)(C) of this AD.

(iii) If the identification ink stamp is followed by a revision letter K, no further action is required by this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Danny Nguyen, Aerospace Engineer, Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627-5247; email 9-ANM-LAACO-AMOC-REQUESTS@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 7910, Engine Oil Storage (Airframe Furnished).

(h) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Robinson Helicopter Company R66 Service Bulletin SB-21A, Revision A, dated June 6, 2017.

(ii) [Reserved]

(3) For Robinson Helicopter Company service information identified in this AD, contact Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505; telephone (310) 539-0508; fax (310) 539-5198; or at <http://www.robinsonheli.com/servelib.htm>.

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For

information on the availability of this material at the FAA, call (817) 222-5110.

(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, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on March 26, 2019.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019-07177 Filed 4-11-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA-2016-N-0124 (formerly part of Docket No. FDA-1975-N-0012)]

RIN 0910-AH97

Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; finding of ineligibility for inclusion in final monograph.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this final action establishing that certain active ingredients used in nonprescription (also known as over-the-counter (OTC)) consumer antiseptic products intended for use without water (referred to throughout as consumer antiseptic rubs or consumer rubs) are not eligible for evaluation under the OTC Drug Review for use in consumer antiseptic rubs. Drug products containing these ineligible active ingredients will require approval under a new drug application (NDA) or abbreviated new drug application (ANDA) prior to marketing. FDA is issuing this final action after considering the recommendations of the Nonprescription Drugs Advisory Committee (NDAC), public comments on the Agency's notices of proposed rulemaking, and all data and information on OTC consumer antiseptic rub products that have come to the Agency's attention. This final action finalizes the 1994 tentative final monograph (TFM) for OTC consumer antiseptic rub drug products that

published in the **Federal Register** of June 17, 1994 (the 1994 TFM), as amended by the proposed rule published in the **Federal Register** (FR) of June 30, 2016 (2016 Consumer Antiseptic Rub proposed rule).

DATES: Effective April 13, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule, into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Anita Kumar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5445, Silver Spring, MD 20993-0002, 301-796-1032.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose of the Final Rule
 - B. Summary of the Major Provisions of the Final Rule
 - C. Costs and Benefits
- II. Table of Abbreviations/Commonly Used Acronyms in This Document
- III. Introduction
 - A. Terminology Used in the OTC Drug Review Regulations
 - B. Topical Antiseptics and Scope of Document
- IV. Background
 - A. Significant Rulemakings Relevant to This Document
 - B. Public Meetings Relevant to This Document
 - C. Eligibility for the OTC Drug Review
 - D. Updated Statistical Analysis for Efficacy
- V. Comments on the Proposed Rule and FDA Response
 - A. Introduction
 - B. General Comments on the Proposed Rule and FDA Response
 - C. Comments on Effectiveness and FDA Response
 - D. Comments on Safety and FDA Response
 - E. Comments on the Preliminary Regulatory Impact Analysis and FDA Response
- VI. Effective Date
- VII. Economic Analysis of Impacts
 - A. Introduction
 - B. Summary of Costs and Benefits
 - C. Summary of Regulatory Flexibility Analysis
- VIII. Paperwork Reduction Act of 1995
- IX. Analysis of Environmental Impact
- X. Consultation and Coordination With Indian Tribal Governments
- XI. Federalism
- XII. References