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-2016-5443; Directorate Identifier 2016-SW-021-AD]

RIN 2120-AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking

(NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This proposed AD would require installing an engine flame detector bracket assembly and harness assembly. This proposed AD is prompted by reports of false fire warnings. The proposed actions are intended to prevent the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 27, 2017. **ADDRESSES:** You may send comments by any of the following methods:

- Federal eRulemaking Docket: Go to http://www.regulations.gov. Follow the online instructions for sending your comments electronically.
 - Fax: 202-493-2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- Hand Delivery: Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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–2016– 5443; 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 economic 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 service information identified in this proposed rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-Winged-S or 203–416–4299; email wcs_cust_service_eng.gr-sik@lmco.com. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT:

Kristopher Greer, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email kristopher.greer@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring

expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We propose to adopt a new AD for Sikorsky Model S–92A helicopters with serial numbers 920006 through 920298. This proposed AD would require installing a No. 2 engine outboard flame detector bracket assembly (bracket) and a No. 2 engine flame detector harness assembly (harness), if not already installed or if the bracket was not installed before the harness. This proposed AD is prompted by reports received by Sikorsky of false fire indications from the No. 2 engine outboard flame detectors. Sikorsky attributed the root cause of the false fire warnings to micro pin fretting at the bayonet connection between the sensor and wire harness. Sikorsky consequently developed a new harness to increase stability and reduce the component wear. The proposed actions are intended to prevent a false fire indication, which could lead to an unnecessary emergency landing or ditching.

FAA's Determination

We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Related Service Information Under 1 CFR Part 51

We reviewed Sikorsky S–92 Customer Service Notice 92–094, Revision B, dated June 14, 2016, which provides procedures for installing harness part number (P/N) 92310–04201–041.

We also reviewed Sikorsky Special Service Instructions No. 92–107, Revision G, dated February 25, 2016, (SSI No. 92–107) which specifies installing new brackets, P/N 92070–30033–011, 92070–30033–014, and 92070–30033–015, to increase the stability of the No. 2 engine outboard flame detector.

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.

Other Related Service Information

We reviewed Sikorsky S–92 Alert Service Bulletin (ASB) 92–26–006, Basic Issue, dated February 25, 2016. This service information provides instructions for installing a new bracket by complying with SSI No. 92–107.

We also reviewed S–92 ASB 92–26–007, Basic Issue, dated June 14, 2016. This service information specifies installing harness P/N 92310–04201–041 after or concurrently with the new bracket.

Proposed AD Requirements

This proposed AD would require installing a bracket and a harness, if not already installed or if the bracket was not installed before the harness, in accordance with Sikorsky service information.

Costs of Compliance

We estimate that this proposed AD would affect 50 helicopters of U.S. Registry and that labor costs average \$85 per work-hour. Based on these estimates, we expect that installing a new bracket and harness would require 15.25 work hours for a labor cost of about \$1,296. Parts would cost \$100 for a total cost of about \$1,396 per helicopter and \$69,800 for the U.S. fleet.

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, 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 to the extent that it justifies making a regulatory distinction; 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 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 airworthiness directive (AD):

Sikorsky Aircraft Corporation: Docket No. FAA–2016–5443; Directorate Identifier 2016–SW–021–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters, serial numbers 920006 through 920298, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a false fire warning. This condition could result in an unnecessary emergency landing or ditching.

(c) Comments Due Date

We must receive comments by February 27, 2017.

(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 180 hours time-in-service:

- (1) For helicopters with a No. 2 engine outboard flame detector bracket assembly (bracket) (either part number (P/N) 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and with a No. 2 engine flame detector harness assembly (harness) P/N 92310–04201–041 installed: If the harness was installed before the bracket, replace the harness.
- (2) For helicopters with a bracket (either P/N 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and without a harness P/N 92310–04201–041 installed: remove the harness and install harness P/N 92310–04201–041 by following the Accomplishment Instructions, section 3.C.1, of Sikorsky S–92 Customer Service Notice 92–094, Revision B, dated June 14, 2016 (CSN 92–094).
- (3) For helicopters without a bracket (either P/N 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and with a harness P/N 92310–04201–041 installed:
- (i) Install a bracket P/N 92070–30033–014 by following the Instructions, paragraph D, of Sikorsky Special Service Instructions No. 92– 107, Revision G, dated February 25, 2016 (SSI 92–107).
 - (ii) Replace the harness.
- (4) For helicopters without a bracket (either P/N 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and without a harness P/N 92310–04201–041 installed:
- (i) Install a bracket P/N 92070-30033-014 by following the Instructions, paragraph D, of SSI 92-107.
- (ii) Remove the harness and install harness P/N 92310–04201–041 by following the Accomplishment Instructions, section 3.C.1, of CSN 92–094.

(f) Alternative Methods of Compliance (AMOC)

- (1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Kristopher Greer, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email kristopher.greer@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) Additional Information

Sikorsky S–92 Alert Service Bulletin 92–26–006, Basic Issue, dated February 25, 2016, and Sikorsky S–92 Alert Service Bulletin 92–26–007, Basic Issue, dated June 14, 2016, which are not incorporated by reference, contain additional information about the subject of this proposed rule. For service information identified in this proposed rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–

Winged—S or 203–416–4299; email wcs_cust_service_eng.gr-sik@lmco.com. You may review a copy of information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 2612, Fire Detection.

Issued in Fort Worth, Texas, on December 7, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–30051 Filed 12–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2012-D-1002]

Questions and Answers Regarding Food Facility Registration (Seventh Edition); Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." The revised draft guidance supersedes the version of the food facility registration draft guidance that we announced on November 8, 2016. When finalized, this guidance is intended to provide updated information relating to the food facility registration requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the revised draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the revised draft guidance by March 27, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to http:// 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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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—2012—D—1002 for the revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• 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 http:// www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/ regulatoryinformation/dockets/ default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of the draft guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Courtney Buchanan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2487.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." The revised draft guidance supersedes the version of the food facility registration draft guidance that we announced on November 8, 2016 (81 FR 78526). We are issuing the revised draft guidance consistent with our good guidance practices regulation (21 CFR