

(TCCA); or De Havilland Aircraft of Canada Limited's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF-2009-29R4, dated October 1, 2021, for related information. This MCAI may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2022-0143.

(2) For more information about this AD, contact Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7300; fax 516-794-5531; email 9-avs-nyaco-cos@faa.gov.

(3) For service information identified in this AD, contact De Havilland Aircraft of Canada Limited, Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416-375-4000; fax 416-375-4539; email thd@dehavilland.com; internet <https://dehavilland.com>. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

Issued on February 15, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022-03718 Filed 2-22-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2022-0146; Project Identifier AD-2021-00449-R]

RIN 2120-AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020-26-13, which applies to certain Sikorsky Aircraft Corporation (Sikorsky) Model S-92A helicopters. AD 2020-26-13 requires establishing the life limit for certain part-numbered horizontal stabilizer root fittings FWD (forward root fittings) and certain part-numbered stabilizer strut fittings. AD 2020-26-13 also requires repetitively inspecting certain parts, and depending on the inspection results, removing parts from

service. Finally AD 2020-26-13 prohibits installing certain stabilizer assemblies on any helicopter. Since the FAA issued AD 2020-26-13, the manufacturer notified the FAA that due to an error in the service information, certain part numbers in AD 2020-26-13 are incorrect. Also, the FAA determined that additional inspections are required to address the unsafe condition. This proposed AD would retain certain requirements and the prohibition for installing certain stabilizer assemblies on any helicopter from AD 2020-26-13 and would correct certain part numbers and require additional repetitive inspections. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by April 11, 2022.

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 <https://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 NPRM, contact Sikorsky's Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611, United States; phone: (800) 946-4337; email: wcs_cust_service_eng.gr-sik@lmco.com; website: www.sikorsky360.com. You may view this service information at the 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.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2022-0146; 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 NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Dorie Resnik, Aerospace Engineer, Aviation Safety Section, Boston ACO

Branch, Compliance & Airworthiness Division, 1200 District Avenue, Burlington, MA 01803; telephone (781) 238-7693; email 9-AVS-AIR-BACO-COS@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2022-0146; Project Identifier AD-2021-00449-R" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dorie Resnik, Aerospace Engineer, Aviation Safety Section, Boston ACO Branch, Compliance & Airworthiness Division, 1200 District Avenue, Burlington, MA 01803; telephone (781) 238-7693; email 9-AVS-AIR-BACO-COS@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2020–26–13, Amendment 39–21368 (85 FR 84201, December 28, 2020) (AD 2020–26–13) for Sikorsky Model S–92A helicopters with forward root fitting part number (P/N) 92209–07111–101 or 92070–20125–101; or stabilizer strut fitting P/N 92209–07404–041, 92209–07403–041, or 92070–20117–041 installed on horizontal stabilizer assembly (stabilizer assembly) P/N 92070–20117–045, 92070–20117–046, 92070–20125–041, 92070–20125–042, 92070–20125–043, 92070–20125–044, 92205–07400–043, or 92205–07400–045. AD 2020–26–13 was prompted by seven incidents of fatigue cracking in forward root fittings. Fatigue cracking in a forward root fitting degrades the load path and increases the load on other assembly parts, particularly at the aft horizontal stabilizer attachment points; therefore AD 2020–26–13 requires determining the total hours time-in-service (TIS) of the forward root fitting and the stabilizer strut fitting, establishing a life limit of 7,900 total hours TIS for certain part-numbered forward root fittings, and establishing a life limit of 19,100 total hours TIS for certain stabilizer strut fittings. For certain part-numbered stabilizer strut fittings, AD 2020–26–13 also requires repetitive inspections of certain parts of an affected stabilizer strut assembly. The FAA issued AD 2020–26–13 to prevent a forward root fitting from remaining in service beyond its life limit and to detect fatigue cracking in a forward root fitting and prevent increased load and stress cracking in the stabilizer root fitting aft.

Actions Since AD 2020–26–13 Was Issued

Since the FAA issued AD 2020–26–13, Sikorsky notified the FAA that incorrect P/Ns are identified in the Applicability and the Required Actions paragraphs of AD 2020–26–13. This NPRM would expand the applicability of AD 2020–26–13 by adding an additional part-numbered stabilizer assembly. This NPRM would correct paragraph (g)(4) of the Required Actions so that the installation of the titanium stabilizer strut fitting P/N 92209–07404–041 is terminating action for the 50-hour TIS inspections of the aluminum stabilizer strut fitting P/N 92070–20117–04 or 92209–07403–041.

Sikorsky also notified the FAA that an additional repetitive inspection of certain parts of the stabilizer strut assembly is required to prevent the unsafe condition; this NPRM includes this repetitive inspection. Additionally, since AD 2020–26–13 was issued,

Sikorsky requested and the FAA approved a global Alternative Method of Compliance (AMOC) to allow only removing parts from service that are cracked, corroded, or have fretting, deformation, or wear rather than require removing the upper and lower support strut rod ends, including lug and conical fitting and both upper and lower attachment fittings on the stabilizer from service. This NPRM incorporates that global AMOC into the proposed requirements.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

This proposed AD would continue to require S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision (TR) 55–33, dated March 24, 2020 (TR 55–33), which the Director of the Federal Register approved for incorporation by reference as of February 1, 2021 (85 FR 84201, December 28, 2020).

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 **ADDRESSES**.

Other Related Service Information

The FAA reviewed S–92 Maintenance Manual SA S92A–AWL–000, TR No. 4–58, dated October 2, 2017 (TR 4–58), and S–92 Maintenance Manual SA S92A–AWL–000, TR No. 4–66 dated November 20, 2019 (TR 4–66). This service information revises Task 4–00–00–200–000, Table 1 Replacement Schedule, dated November 30, 2015. Both TR 4–58 and 4–66 revise the Airworthiness Limitations Schedule by removing certain part-numbered components, introducing new part-numbered components, and establishing replacement intervals and recurring inspections for the forward root fitting and the horizontal stabilizer strut fitting. TR 4–58 also specifies inspecting the horizontal stabilizer and attaching hardware at a recurring interval of 250 hours TIS.

Proposed AD Requirements in This NPRM

This proposed AD would require determining the total hours TIS of the forward root fitting and the stabilizer strut fitting. This proposed AD would also require establishing a life limit of 7,900 total hours TIS for certain part-

numbered forward root fittings and establishing a life limit of 19,100 total hours TIS for stabilizer strut fitting P/N 92070–20117–041. Finally, this proposed AD would require for certain part-numbered stabilizer strut fittings installed, repetitively visually inspecting the following at intervals not to exceed 50 hours TIS:

- The hat bushing and both upper and lower fittings for a crack, corrosion, fretting, deformation, and wear.
- Both upper and lower support strut rod ends, including each lug and conical fitting, and both upper and lower attachment fittings on the stabilizer and pylon, including the bushings, for a crack, corrosion, fretting, deformation, and wear.
- The surface of each Mylar washer P/N 92070–20117–104 on certain stabilizer assemblies.

This proposed AD would also require repetitively inspecting the following at intervals not to exceed 250 hours TIS or one year, whichever occurs first:

- Each stabilizer attachment bolt and barrel nut set for corrosion, a crack, and damage to the threads indicated by uneven threads, missing threads, or cross-threading.
- Each forward root fitting and aft attachment fitting, including inspecting the bolt holes and fastener holes for a crack, wear, and corrosion; or as an alternative to detect any crack, fluorescent penetrant inspecting (FPI) the area.
- Each forward and aft attachment fitting mating surface for wear of the abrasion-resistant Teflon coating and degradation. For the purposes of this inspection, degradation may be indicated by fretting. If there is any wear of the coating or fretting, this proposed AD would require stripping the coating and performing a FPI or eddy current inspection to inspect for a crack. If there is no crack, this proposed AD would require recoating the surfaces.

Depending on the inspection results, this proposed AD would require removing parts from service before further flight.

Finally, this proposed AD would prohibit installing stabilizer assembly P/N 92205–07400–043, 92205–07400–045, and 92205–07400–047 on any helicopter.

Differences Between This Proposed AD and the Service Information

The service information specifies that returning affected parts to a Sikorsky specialist is required; whereas this proposed AD would not include this requirement.

Costs of Compliance

The FAA estimates that this proposed AD would affect 82 helicopters of U.S. registry. Labor costs are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Visually inspecting the stabilizer assembly and attached hardware would take about 3 work-hours for an estimated cost of \$255 per helicopter and \$20,910 for the U.S. fleet per inspection cycle.

If required, replacing a hat bushing and both upper fittings and lower fittings would take about 1 work-hour and parts would cost about \$10,000 for an estimated cost of \$10,085 per replacement.

If required, replacing the upper and lower support strut rod ends, including lug and conical fitting, would take about 1 work-hour and parts would cost about \$10,000 for an estimated cost of \$10,085 per replacement.

If required, replacing Mylar washers would take about 0.5 work-hour and parts would cost about \$76 for an estimated cost of \$119 per replacement.

If required, performing a fluorescent penetrant inspection would take about 3 work-hours for an estimated cost of \$255 per inspection.

If required, replacing a stabilizer assembly would take about 6 work-hours and parts would cost about \$312,000 for an estimated cost of \$312,510 per replacement.

If required, replacing a forward root fitting would take about 10 work-hours and parts would cost about \$25,000 for an estimated cost of \$25,850 per replacement.

If required, replacing a stabilizer strut fitting would take about 10 work-hours and parts would cost about \$10,000 for an estimated cost of \$10,850 per replacement.

If required, replacing a forward root fitting and an aft attachment fitting would take about 20 work-hours and parts would cost about \$50,000 for an estimated cost of \$51,700 per replacement.

If required, removing wear or corrosion and applying corrosion preventative compound would take about 0.5 work-hour and parts would cost a nominal amount for an estimated cost of \$43 per action.

If required, replacing a stabilizer attachment bolt and barrel nut set would take about 1 work-hour and parts would cost about \$500 for an estimated cost of \$585 per replacement.

If required, replacing a fastener would take about 0.1 work-hour and parts would cost a nominal amount for an estimated cost of \$9 per fastener.

If required, removing the abrasion-resistant Teflon coating to inspect each forward and aft attachment fitting mating surface would take about 5 work-hours for an estimated cost of \$425 per inspection.

If required, applying alodine or equivalent and applying abrasion-resistant Teflon coating would take about 5 work hours with minimal parts cost for an estimated cost of \$425 per application.

According to Sikorsky, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all costs in this cost estimate.

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

The FAA 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) Would not affect intrastate aviation in Alaska, and
- (3) Would 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:
- a. Removing Airworthiness Directive AD 2020–26–13, Amendment 39–21368 (85 FR 84201, December 28, 2020); and
 - b. Adding the following new airworthiness directive:

Sikorsky Aircraft Corporation: Docket No. FAA–2022–0146; Project Identifier AD–2021–00449–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by April 11, 2022.

(b) Affected ADs

This AD replaces AD 2020–26–13, Amendment 39–21368 (85 FR 84201, December 28, 2020) (AD 2020–26–13).

(c) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–92A helicopters, certificated in any category, with the following installed: Horizontal stabilizer root fitting FWD (forward root fitting) part number (P/N) 92209–07111–101 or 92070–20125–101; or stabilizer strut fitting P/N 92209–07403–041 or 92070–20117–041 installed on horizontal stabilizer assembly (stabilizer assembly) P/N 92070–20117–045, 92070–20117–046, 92070–20125–041, 92070–20125–042, 92070–20125–043, 92070–20125–044, 92205–07400–043, 92205–07400–045, or 92205–07400–047.

(d) Subject

Joint Aircraft System Component (JASC) Code 5510, Horizontal Stabilizer Structure.

(e) Unsafe Condition

This AD was prompted by incidents of fatigue cracks in a forward root fitting and life limit recalculations for forward root fitting P/N 92209–07111–101 and 92070–20125–101. The FAA is issuing this AD to prevent a forward root fitting from remaining in service beyond its life limit, detect fatigue cracking in a forward root fitting, and prevent increased load and stress cracking in the stabilizer root fitting aft. The unsafe condition, if not addressed, could result in failure of a stabilizer root fitting, separation of the stabilizer assembly from the helicopter,

and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 50 hours time-in-service (TIS) after the effective date of this AD:

(i) Determine the total hours TIS of the forward root fitting P/N 92209-07111-101 or 92070-20125-101. If the total hours TIS of the forward root fitting is unknown, use the total hours TIS of the stabilizer assembly instead.

(A) If the forward root fitting has accumulated 7,900 or more total hours TIS, before further flight, remove the forward root fitting from service.

(B) If the forward root fitting has accumulated less than 7,900 total hours TIS, before exceeding 7,900 total hours TIS, remove the forward root fitting from service.

(ii) Thereafter following paragraph (g)(1)(i) of this AD, remove the forward root fitting from service before accumulating 7,900 total hours TIS.

(iii) For stabilizer assemblies with stabilizer strut fitting P/N 92070-20117-041 installed, perform the following actions:

(A) Determine the total hours TIS of stabilizer strut fitting P/N 92070-20117-041.

(B) If the stabilizer strut fitting has accumulated 19,100 or more total hours TIS, before further flight, remove the stabilizer strut fitting from service.

(C) If the stabilizer strut fitting has accumulated less than 19,100 total hours TIS, before exceeding 19,100 total hours TIS, remove the stabilizer strut fitting from service.

(iv) Thereafter following paragraph (g)(1)(iii) of this AD, remove the stabilizer strut fitting from service before accumulating 19,100 total hours TIS.

(2) For helicopters with stabilizer strut fitting P/N 92070-20117-041 or 92209-07403-041 installed, within 50 hours TIS after the effective date of this AD and thereafter at intervals not to exceed 50 hours TIS:

(i) Remove the support strut and using a cheese cloth (or similar cloth) and isopropyl alcohol, clean the upper and lower support strut rod ends, horizontal stabilizer attachment fitting, and the tail rotor pylon attachment fitting.

(ii) If installed, visually inspect the surface of each Mylar washer P/N 92070-20117-104 (Mylar washer). The surface should be smooth and continuous. If there is any visible damage such as any tear or scrape, remove the Mylar washer from the peelable-ply washer P/N 92070-20117-105 (peelable-ply washer) and remove the Mylar washer from service as follows:

(A) Dampen a low-lint cloth with 3M 6041 adhesive remover and place on the top of the Mylar washer.

(B) Allow the adhesive remover to soften the Mylar washer and peel the Mylar washer back.

(C) Repeat with more solvent until the Mylar washer and adhesive are removed.

(D) Clean the peelable-ply washer with cheese cloth moistened with isopropyl alcohol and adhere a new Mylar washer to the peelable-ply washer.

Note 1 to paragraph (g)(2)(ii): Stabilizer assembly P/Ns 92070-20125-041, 92070-20125-042, 92070-20125-043, and 92070-20125-044 do not utilize the Mylar washer. The inspection of the Mylar washer is not required on helicopters with stabilizer assembly P/N 92070-20125-041, 92070-20125-042, 92070-20125-043, or 92070-20125-044 installed.

(iii) Using a 10X or higher power magnifying glass, a flashlight, and a mirror, visually inspect the hat bushing and both upper fittings and lower fittings for a crack, corrosion, fretting, deformation, and wear. If there is a crack, corrosion, fretting, deformation, or wear on any part, before further flight, remove the part from service.

(iv) Using a 10X or higher power magnifying glass, a flashlight, and a mirror, visually inspect both upper and lower support strut rod ends, including each lug and conical fitting, and both upper and lower attachment fittings on the stabilizer and pylon including the bushings for a crack, corrosion, fretting, deformation, and wear. If there is a crack, corrosion, fretting, deformation, or wear on any part, before further flight, remove the part from service.

(3) Within 250 hours TIS or one year, whichever occurs first after the effective date of this AD, and thereafter at intervals not to exceed 250 hours TIS or one year, whichever occurs first:

(i) Remove the stabilizer assembly and visually inspect each stabilizer attachment bolt and barrel nut set for corrosion, a crack, and damage to the threads. For the purposes of this inspection, damage may be indicated by uneven threads, missing threads, or cross-threading.

(A) If there is corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA-approved procedures.

(B) If there is corrosion that exceeds allowable limits, or a crack, or damage to the threads, before further flight, remove the bolt and barrel nut set from service.

(ii) Inspect the forward root fitting and the aft attachment fitting by:

(A) Gaining access to the inside of the horizontal stabilizer.

(B) Using Brulin Cleaner SD 1291 (or equivalent) and a low-lint cloth, remove all traces of sealing compound, oil, and dirt from the stabilizer mounting surfaces.

(C) Using a 10X or higher magnifying glass, inspect for any crack, wear, and corrosion.

(1) If there is a crack, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(2) If there is wear or corrosion that exceeds allowable limits, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(3) If there is wear or corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA-approved procedures.

(D) Visually inspect each attachment fitting bolt hole and fastener hole for a crack, wear, and corrosion.

(1) If there is a crack, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(2) If there is wear or corrosion that exceeds allowable limits, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(3) If there is wear or corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA approved procedures.

(E) Inspect for loose or working fasteners. If there is a loose or working fastener, before further flight, remove the fastener from service.

(iii) As an alternative means to inspect for cracks in paragraphs (g)(3)(i) and (ii) of this AD, perform a florescent penetrate inspection (FPI).

(iv) Visually inspect each forward and aft attachment fitting mating surface for wear of the abrasion-resistant Teflon coating and degradation. For the purposes of this inspection, degradation may be indicated by fretting. Refer to Figure 204, of S-92 Maintenance Manual, SA S92A-AMM-000, Temporary Revision 55-33, Task 55-11-01-210-004, dated March 24, 2020 (TR 55-33), for a depiction of the area to be inspected. For the purposes of this inspection, wear may be indicated by less than 100% coverage of the abrasion-resistant Teflon coating. If there is wear to the abrasion-resistant Teflon coating or degradation, before further flight:

(A) Chemically strip the abrasion-resistant Teflon coating from the entire mounting pad in accordance with paragraph 7.A.(7)(a) of TR 55-33.

(B) FPI or eddy current inspect for a crack. If there is a crack, before further flight, remove the stabilizer assembly from service.

(C) If there is no crack, treat the affected area by applying alodine or equivalent. Apply abrasion-resistant Teflon coating in accordance with paragraphs 7.A.(7)(d) through (e) of TR 55-33.

(4) Installing stabilizer strut fitting P/N 92209-07404-041 is a terminating action for the requirements in paragraph (g)(2) of this AD.

(5) As of the effective date of this AD, do not install stabilizer assembly P/N 92205-07400-043, 92205-07400-045, or 92205-07400-047 on any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO 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 certification office, send it to the attention of the person identified in Related Information.

(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.

(i) Related Information

(1) For more information about this AD, contact Dorie Resnik, Aerospace Engineer, Boston ACO Branch, 1200 District Avenue, Burlington, Massachusetts 01803; telephone 781-238-7693; email 9-AVS-AIR-BACO-COS@faa.gov.

(2) For service information identified in this AD, contact Sikorsky's Engineering Group Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT, 06611, United States; phone: (800) 946-4337; email: wcs_cust_service_eng.gr-sik@lmco.com; website: www.sikorsky360.com. You may view this referenced service information at the 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.

Issued on February 16, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022-03769 Filed 2-22-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 4 and 820

[Docket No. FDA-2021-N-0507]

RIN 0910-AH99

Medical Devices; Quality System Regulation Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation to align more closely with the international consensus standard for devices by converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions (*i.e.*, other countries). We propose to do so through incorporating by reference an international standard specific for device quality management systems set by the International Organization for Standardization (ISO), the 2016 edition of ISO 13485 (ISO 13485). Through this rulemaking we also propose additional requirements to align with existing requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, and make conforming edits to the Code of Federal Regulations (CFR) to clarify the device

CGMP requirements for combination products. This action, if finalized, will continue our efforts to align our regulatory framework with that used by other regulatory authorities to promote consistency in the regulation of devices and provide timelier introduction of safe, effective, high-quality devices for patients.

DATES: Submit either electronic or written comments on the proposed rule by May 24, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by March 25, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 24, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2021-N-0507 for "Medical Devices; Quality System Regulation Amendments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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