

(a) Applicability

This AD applies to Model AS350B3 helicopters with a dual hydraulic system installed, certificated in any category.

Note 1 to paragraph (a) of this AD: The dual hydraulic system for Model AS350B3 helicopters is referred to as Airbus modification OP 3082 or OP 3346.

(b) Unsafe Condition

This AD defines the unsafe condition as lack of hydraulic pressure in a tail rotor (T/R) hydraulic system. This condition could result in loss of T/R flight control and subsequent loss of control of the helicopter.

(c) Affected ADs

This AD supersedes AD 2015–22–53, Amendment 39–18331 (80 FR 74982, December 1, 2015).

(d) Comments Due Date

We must receive comments by November 7, 2017.

(e) 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.

(f) Required Actions

(1) Before further flight, insert a copy of this AD into the rotorcraft flight manual, Section 4 Normal Operating Procedures, or make pen and ink changes to the preflight and post-flight procedures as follows:

(i) Stop performing the yaw load compensator check (ACCU TST switch) during preflight procedures, and instead perform the yaw load compensator check during post-flight procedures after rotor shut-down.

(ii) The yaw servo hydraulic switch (collective switch) must be in the “ON” (forward) position before takeoff.

Note 2 to paragraph (f)(1)(ii) of this AD: The yaw servo hydraulic switch is also called the hydraulic pressure switch or hydraulic cut off switch in various Airbus Helicopters rotorcraft flight manuals.

(2) Within 350 hours time-in-service:

(i) Install a timer relay for the yaw servo hydraulic switch (collective switch) by following the Accomplishment Instructions, paragraph 3.B.2.b.1, 3.B.2.b.2, 3.B.2.b.3, 3.B.2.b.4, 3.B.2.b.5, or 3.B.2.b.6, as applicable to the configuration of your helicopter, of Airbus Helicopters Service Bulletin (SB) No. AS350–67.00.64, Revision 0, dated February 25, 2015 (AS350–67.00.64). If your helicopter has an automatic pilot system, also comply with paragraph 3.B.2.b.7 of AS350–67.00.64.

(ii) Install an indicator light on the caution and warning panel by following the Accomplishment Instructions, paragraph 3.B.2.c.1 or 3.B.2.c.2, as applicable to the configuration of your helicopter, of AS350–67.00.64.

(iii) Replace the bistable ACCU TST button on the control panel with a monostable button as depicted in Figure 1 or Figure 3, as applicable to the configuration of your helicopter, of Airbus Helicopters SB No. AS350–67.00.65, Revision 0, dated August 25, 2016.

(3) After the effective date of this AD, do not install a bistable ACCU TST button on any helicopter.

(g) Special Flight Permits

A special flight permit may be issued for paragraph (f)(2) of this AD only.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, FAA, may approve AMOCs for this AD. Send your proposal to: George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email 9-ASW-FTW-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.

(i) Additional Information

(1) Airbus Helicopters SB No. AS350–67.00.66, Revision 1, dated October 22, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html. 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.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2016–0220, dated November 4, 2016. You may view the EASA AD on the Internet at <http://www.regulations.gov> in the AD Docket.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 2910, Main Hydraulic System.

Issued in Fort Worth, Texas, on August 29, 2017.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2017–18973 Filed 9–7–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2017–0867; Product Identifier 2017–CE–021–AD]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Viking Air Limited Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracking found in the wing rear spar web at the wing station where the flap outboard hinge is attached. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by October 23, 2017.

ADDRESSES: You may send comments 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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663–8444; fax: (250) 656–0673; email:

technical.support@vikingair.com;

Internet: <http://www.vikingair.com/support/service-bulletins>. You may review this referenced service

information at the FAA, Policy and Innovation Division, 901 Locust, Kansas

City, Missouri 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> by searching for and locating Docket No. FAA-2017-0867; 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 (telephone (800) 647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7329; fax: (516) 794-5531; email: aziz.ahmed@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-2017-0867; Product Identifier 2017-CE-021-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

The Transport Canada, which is the aviation authority for Canada, has issued AD Number CF-2017-17, dated May 18, 2017 (referred to after this as "the MCAI"), to correct an unsafe condition for all Viking Air Limited Models DHC-2 Mk. I, DHC-2 Mk. II, and DHC-2 Mk. III airplanes and was based on mandatory continuing airworthiness information originated by an aviation authority of another country. The MCAI states:

It was reported that a crack was found in the wing rear spar web, part number C2W1007, at wing station 123.5 where the flap outboard hinge is attached. An aileron hinge bracket has also been found cracked. Viking Air Ltd. analysis shows that similar cracks may develop on the wing rear spar web and flap/aileron hinge arm support brackets at the other flap/aileron hinge attachment locations.

Undetected cracking of the wing rear spar or flap/aileron hinge bracket may lead to the failure of the component with consequent loss of aeroplane control.

The MCAI requires inspecting the left-hand and right-hand wing rear spar and the flap/aileron hinge air support brackets for cracks, damage, or discrepancy and repairing or replacing any cracked, damaged, or discrepant parts. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0867.

Related Service Information Under 1 CFR Part 51

Viking Air Limited has issued DHC-2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017. The service information describes procedures for inspecting the left-hand and right-hand wing rear spars, the flap/aileron hinge brackets, and the exterior store support bracket for cracks, damage, and discrepancies and specifies repairing or replacing any cracked, damaged, or discrepant parts. 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 of this NPRM.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Interim Action

We consider this proposed AD interim action. The inspection report required by this proposed AD allows us to obtain better information into the nature, cause, and extent of the damage to the wing rear spars and flap/aileron hinge arm support brackets and to develop final action to address the unsafe condition. Once final action has been identified, we may consider further rulemaking.

Costs of Compliance

We estimate that this proposed AD will affect 140 products of U.S. registry. We also estimate that it would take about 11 work-hours per product to comply with the basic inspection requirements of this proposed AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the basic cost of this proposed AD on U.S. operators to be \$130,900, or \$935 per product.

In addition, the following is an estimate of possible necessary follow-on replacement actions. We have no way of determining the number of products that may need these actions.

Part No.	Left-hand (LH) or right-hand (RH) wing	Description	Number per airplane	Parts cost	Number of work-hours to replace
C2W123A	Both (one per wing).	Hinge bracket LH inboard (flap)/ RH outboard (aileron).	2	\$288 for both	12 for both.
C2W124A	Both (one per wing).	Hinge bracket RH inboard (flap)/ LH outboard (aileron).	2	\$288 for both	12 for both.
C2W143	Both (four per wing).	Hinge bracket, flap and aileron (common part—multiple wing stations (WS)).	8	\$271 for all eight ...	12 for all eight.
C2W143A (Agricultural Option).	Both (one per wing).	Agricultural (optional configuration)—hinge bracket, support arm (IPC PSM 1-2-4 Figure 128, Item 15).	2 (if applies)	\$271 for both	12 for both.
C2W63	LH	Inboard spar, rear spar	\$277	60.
C2W64	RH	Inboard spar, rear spar	\$277	60.

Part No.	Left-hand (LH) or right-hand (RH) wing	Description	Number per airplane	Parts cost	Number of work-hours to replace
C2W155	Both (one per wing).	Intermediate spar	2	\$563 for both	60 for both.
C2W65A	LH	Spar WS 89.16 to WS 170.16	1*	\$835	60.
C2W66A	RH	Spar WS 89.16 to WS 170.16	1*	\$835	60.
C2W67A	LH	Outboard spar, WS 170.16 to WS 245.75.	1*	\$835	60.
C2W68A	RH	Outboard spar, WS 170.16 to WS 245.75.	1*	\$835	60.

* To replace any wing spar section takes 60 work-hours.

To replace all four wing spar sections per wing takes 240 work-hours.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120-0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591. ATTN: Information Collection Clearance Officer, AES-2000.

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes and domestic business jet transport airplanes to the Director of the Policy and Innovation Division.

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 above, 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, 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 adding the following new AD:

Viking Air Limited: Docket No. FAA-2017-0867; Product Identifier 2017-CE-021-AD.

(a) Comments Due Date

We must receive comments by October 23, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Viking Air Limited Models DHC-2 Mk. I, DHC-2 Mk. II, and DHC-2 Mk. III airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 57: Wings.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracking found in the wing rear spar web at the wing station (WS) where the flap outboard hinge is attached. We are issuing this AD to detect and correct cracks in the wing rear spars and the flap/aileron hinge arm support brackets, which could cause these parts to fail. Failure of the wing rear spars and the flap/aileron hinge arm support brackets could result in loss of control.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (5) of this AD:

- (1) Within the next 400 hours time-in-service (TIS) after the effective date of this AD, visually inspect the left-hand and right-hand wing rear spar and flap/aileron hinge arm support brackets following the Accomplishment Instructions of Viking DHC-2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017 (SB V2/0009, Revision A).

(2) For airplanes with agricultural configuration installed (SOO Mod 2/984), within the next 400 hours TIS after the effective date of this AD, inspect the exterior store support arm bracket at wing station (WS) 101.24 following the Accomplishment Instructions of SB V2/0009, Revision A.

(3) If any discrepancies are found during the inspections required in paragraphs (f)(1) and (2) of this AD, before further flight, repair or replace using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Within 30 days after completing the inspections required in paragraphs (f)(1) and (2) of this AD, using the Operator Reply Form on page 7 of SB V2/0009, Revision A, report the inspection results to Viking Air Limited at the address specified in paragraph (h) of this AD.

(5) As of the effective date of this AD, do not install a wing on any airplane affected by this AD unless it has been inspected as specified in paragraph (f)(1) of this AD and paragraph (f)(2) of this AD, as applicable, and is found free of any discrepancies.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7329; fax: (516) 794-5531; email: aziz.ahmed@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements*: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of

information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(h) Related Information

Refer to MCAI Transport Canada AD Number CF-2017-17, dated May 18, 2017, for related information. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0867. For service information related to this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663-8444; fax: (250) 656-0673; email: technical.support@vikingair.com; Internet: <http://www.vikingair.com/support/service-bulletins>. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on August 29, 2017.

Melvin Johnson,

Deputy Director, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2017-18900 Filed 9-7-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2017-N-5092]

Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments and information.

SUMMARY: As part of the implementation of Executive Order 13771 entitled, "Reducing Regulation and Controlling Regulatory Costs," and Executive Order 13777 entitled, "Enforcing the Regulatory Reform Agenda," the Food and Drug Administration (FDA, Agency, or we) is seeking comments and information from interested parties to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction

while allowing us to achieve our public health mission and fulfill statutory obligations. This document relates to the products regulated by the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on this document by December 7, 2017.

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 December 7, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 7, 2017. 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