

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

[Docket No. 98-NM-70-AD]

RIN 2120-AA64

Airworthiness Directives; de Havilland Model DHC-8-100, -200, and -300 Series Airplanes**AGENCY:** Federal Aviation Administration, DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to revise an existing airworthiness directive (AD), applicable to certain de Havilland Model DHC-8-100, -200, and -300 series airplanes, that currently requires modification of the attitude and heading reference systems (AHRS). That AD was prompted by a report of loss of power to both AHRS's during flight due to a faulty terminal block to which the signal ground for the AHRS's is connected. The actions specified by that AD are intended to prevent simultaneous power loss to both AHRS's, which could result in reduced controllability of the airplane. This action would reduce the applicability of the existing AD.

DATES: Comments must be received by July 16, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 98-NM-70-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: Luciano Castracane, Aerospace Engineer, Systems and Equipment Branch, ANE-172, FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York

11581; telephone (516) 256-7535; fax (516) 568-2716.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 98-NM-70-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 98-NM-70-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

On September 19, 1997, the FAA issued AD 97-20-10, amendment 39-10147 (62 FR 50861, September 29, 1997), applicable to certain de Havilland Model DHC-8-100, -200, and -300 series airplanes, to require modification of the attitude and heading reference systems (AHRS). That action was prompted by a report of loss of power to both AHRS's during flight due to a faulty terminal block to which the signal ground for the AHRS's are connected. The requirements of that AD are intended to prevent simultaneous power loss to both AHRS's, which could result in reduced controllability of the airplane.

Actions Since Issuance of Previous Rule

Since issuance of that AD, the Transport Canada Aviation (TCA), which is the airworthiness authority for Canada, has issued Canadian airworthiness directive CF-97-01R2, dated August 13, 1997. This revision supersedes Canadian airworthiness directive CF-97-01R1, dated February 3, 1997, which was referenced in AD 97-20-10 as the parallel Canadian airworthiness directive for AD 97-20-10. The only change effected by CF-97-01R2 is to reduce the list of affected airplanes to serial numbers 3 through 472 inclusive. The effectivity listing of CF-97-01R2 limits accomplishment of the modification of the AHRS to those airplanes on which the modification was not accomplished in production.

FAA's Conclusions

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCA has kept the FAA informed of the situation described above. The FAA has examined the findings of the TCA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would revise AD 97-20-10 to continue to require modification of the AHRS. The proposed AD also would reduce the applicability of that AD to airplanes having serial numbers 3 through 472 inclusive.

Cost Impact

The FAA estimates that 167 de Havilland Model DHC-8-100, -200, and -300 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$10 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$41,750, or \$250 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that 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); and (3) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing amendment 39-10147 (62 FR 50861, September 29, 1997), and by adding a new airworthiness directive (AD), to read as follows:

De Havilland, Inc.: Docket 98-NM-70-AD. Revises AD 97-20-10, Amendment 39-10147.

Applicability: Model DHC-8-100, -200, and -300 series airplanes, serial numbers 3

through 472 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent simultaneous power loss to both attitude and heading reference systems (AHRS), which could result in reduced controllability of the airplane, accomplish the following:

(a) Within 400 hours time-in-service after November 3, 1997 (the effective date of AD 97-20-10, amendment 39-10147), modify the AHRS's, in accordance with Bombardier Alert Service Bulletin S.B. A8-34-117, Revision 'C', dated February 14, 1997.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF-97-01R2, dated August 13, 1997.

Issued in Renton, Washington, on June 9, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. 98N-0361]

Administrative Practices and Procedures; Internal Agency Review of Decisions; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations governing the review of agency decisions by inserting a statement that sponsors, applicants, or manufacturers of drugs (including biologics) or devices may request review of a scientific controversy by an appropriate scientific advisory panel, or an advisory committee. The agency is taking this action to clarify the availability of review of scientific controversies by such advisory panels or committees. This proposed rule is a companion document to a direct final rule published elsewhere in this issue of the **Federal Register**. If FDA receives any significant adverse comment, the direct final rule will be withdrawn, and the comments will be considered in the development of a final rule using usual notice and comment rulemaking based on this proposed rule.

DATES: Comments must be received on or before August 31, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Suzanne M. O'Shea, Office of the Chief Mediator and Ombudsman (HF-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3390.

SUPPLEMENTARY INFORMATION:

I. Discussion

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). Section 404 of FDAMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by adding a new provision, Dispute Resolution (section 562 of the act (21 U.S.C. 360bbb-1)). Under the dispute resolution provision, FDA is to determine the existence of procedures