

The FAA estimates that 19 receivers in the U.S. registry would be affected by the proposed AD, that it would take approximately 2 workhours per receiver to accomplish the proposed action, and that the average labor rate is approximately \$60 an hour. The manufacturer is not charging the owner/operator for exchanging the navigation receiver unit and is allowing 2 workhours of labor to be claimed by the owners/operators to accomplish the proposed action. Based on these figures, there is no cost impact of the proposed AD on U.S. operators. The FAA has no way of determining if any of the affected airplanes have the navigation receiver with Modification 20 installed.

The compliance time of this AD is presented in calendar time instead of hours time-in-service (TIS). The FAA has determined that a calendar time compliance is the most desirable method because of the wide range of fleet usage. Therefore, to ensure that the above-referenced condition is detected and corrected on all airplanes within a reasonable period of time without inadvertently grounding any airplanes, a compliance schedule based upon

calendar time instead of hours TIS is required.

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 action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed 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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

AlliedSignal Inc.: Docket No. 95-CE-91-AD.

Applicability: VHF Navigation Receivers with the following model, part numbers, computer software, and modifications that do not have Modification 20 installed on but not limited to Learjet Model 31A, Fokker Model F27-50, and British Aerospace Model ATP airplanes, certificated in any category.

Model	King part No.	Software ID	Modification
VN-411B	066-1101-00	06	18 and 19.
VN-411B	066-1101-31	00	00 and 19.
VN-411B	066-1101-40	00	00 and 19.
VN-411B	066-1101-50	00	00 and 19.

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 (d) 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 within the next 90 calendar days after the effective date of this AD or upon replacement or repair of any affected AlliedSignal VHF Navigation Receiver, whichever occurs first, unless already accomplished.

To prevent VHF navigation receiver interference from FM radio station broadcast frequencies, which could cause distortion of the navigation audio and deflection of the desired flight path of the airplane during

landing operations, possibly resulting in loss of the airplane, accomplish the following:

(a) Remove any navigation receiver that does not have Modification 20 installed and return the unit to an AlliedSignal Bendix/King service center in accordance with AlliedSignal Bendix/King Service Bulletin (SB) VN 411B-20, dated January 1996.

(b) Replace the navigation receiver with one that has Modification 20 installed by an AlliedSignal Bendix/King service center in accordance with AlliedSignal Bendix/King SB VN 411B-20, dated January 1996.

(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.

(d) An Alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add

comments and then send it to the Manager, Wichita Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita Aircraft Certification Office.

(e) All persons affected by this directive may obtain copies of the document referred to herein upon request to AlliedSignal, General Aviation Avionics, 400 North Rogers Road, Olathe, Kansas 66062-1212; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on June 4, 1996.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-14693 Filed 6-10-96; 8:45 am]

BILLING CODE 4910-13-P

14 CFR Part 39**[Docket No. 95-CE-85-AD]****RIN 2120-AA64****Airworthiness Directives: Pilatus Aircraft Ltd., Model PC-6 Airplanes****AGENCY:** Federal Aviation Administration, DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to Pilatus Aircraft Ltd. (Pilatus) Model PC-6 airplanes. The proposed action would require inspecting for loose or sheared rivets in the hinge brackets on the horizontal stabilizer and inspecting for incorrect spacing tolerance of the hinge brackets. If the rivets are found loose or sheared, the proposed AD would require replacing the rivets and also re-positioning the hinge brackets, if found incorrectly spaced. Several reports of rivets shearing on the hinge brackets prompted the proposed action. The actions specified in this proposed AD are intended to prevent structural failure of the hinge bracket on the horizontal stabilizer, which could result in partial or complete loss of control of the horizontal stabilizer and loss of control of the airplane.

DATES: Comments must be received on or before August 14, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95-CE-85-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Pilatus Aircraft Ltd., CH-6370 Stans, Switzerland. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Roman T. Gabrys, Project Officer, Small Airplane Directorate, Aircraft Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone (816) 426-6932; facsimile (816) 426-2169.

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 should 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 that summarizes 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 No. 95-CE-85-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, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95-CE-85-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Federal Office for Civil Aviation (FOCA), which is the airworthiness authority for Switzerland, recently notified the FAA that an unsafe condition may exist on certain Pilatus Model PC-6 airplanes. The FOCA has received several reports of sheared or loose rivets in the hinge bracket that attaches the horizontal stabilizer to the fuselage. Investigation reveals that preloads in the hinge bracket flanges may exist due to tightness of the fit of the spacer, or in certain instances, the hinge bracket is not positioned or spaced correctly. This condition can substantially affect the load carrying capability of these brackets, thus causing the rivets to shear or loosen, which could lead to structural failure of the horizontal stabilizer.

Pilatus Aircraft Ltd. has issued service bulletin (SB) PC-6 165, dated February 7, 1994, which specifies procedures for inspecting for sheared or loose rivets, replacing any sheared or loose rivets

with new rivets, and checking the spacing tolerance of the hinge brackets.

FOCA classified this service bulletin as mandatory and has issued airworthiness directive (AD) HB 94-086, dated June 4, 1994, in order to ensure the continued airworthiness of these airplanes in Switzerland.

This airplane model is manufactured in Switzerland and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement between Switzerland and the United States. Pursuant to this bilateral airworthiness agreement, the Switzerland FOCA has kept the FAA informed of the situation described above. The FAA has examined the findings of the Switzerland FOCA, 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.

After examining the circumstances and reviewing all available information related to the incidents described above, the FAA has determined that AD action should be taken to prevent a reduction in the structural integrity of the hinge bracket and tailplane, which could result in partial or complete loss of control of the horizontal stabilizer and loss of control of the airplane.

Since an unsafe condition has been identified that is likely to exist or develop in other Pilatus Model PC-6 airplanes of the same type design registered in the United States, the proposed AD would require the following:

- Inspecting the hinge brackets attached to the fuselage for loose or sheared rivets,
- Inspecting the hinge brackets for correct spacing tolerance and positioning,
- Removing the brackets and adjusting any incorrect spacing or positioning, and
- Replacing any loose or sheared rivets with new rivets.

The FAA estimates that one airplane in the U.S. registry would be affected by the proposed AD, that it would take less than 1 workhour per airplane to accomplish the proposed actions, and that the average labor rate is approximately \$60 an hour. Based on these figures, the total cost impact of the proposed AD for the only U.S. operator is estimated to be \$60. This is the cost of the inspection only and does not include the cost for replacing any loose rivets, if found. This figure is based on the assumption that the affected owner/

operator of the affected airplane has not performed the inspection or modification.

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 action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); 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 has been placed 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 adding a new airworthiness directive (AD) to read as follows:

Pilatus Aircraft Ltd.: Docket No. 95-CE-85-AD.

Applicability: Model PC-6 Airplanes (serial numbers 825 through 892).

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 (e) 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 within the next 75 hours time-in-service (TIS), after the effective date of this AD, unless already accomplished.

Note 2: The compliance time required in this AD takes precedence over the compliance time in Pilatus Service Bulletin PC-6 165, dated February 7, 1994.

To prevent structural failure of the hinge bracket on the horizontal stabilizer, which could result in partial or complete loss of control of the horizontal stabilizer and loss of control of the airplane, accomplish the following:

(a) Inspect the hinge brackets on the horizontal stabilizer for sheared or loose rivets in accordance with paragraph 2.A. in the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus Service Bulletin (SB) PC-6 165, dated February 7, 1994.

(b) Inspect the spacing tolerance of the hinge bracket in accordance with paragraph 2.C. in the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus SB PC-6 165, dated February 7, 1994.

(c) If there are loose or sheared rivets or if the bracket spacing is out of the spacing tolerance, prior to further flight, modify the position and space tolerance of the hinge brackets and replace any loose or sheared rivets in accordance with paragraph 2.D. in the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus SB PC-6 165, dated February 7, 1994.

(d) 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.

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to Pilatus Aircraft Ltd., CH-6370 Stans, Switzerland; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri.

Issued in Kansas City, Missouri on June 4, 1996.

Henry A. Armstrong,
*Acting Manager, Small Airplane Directorate,
Aircraft Certification Service.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 200, 250, and 310

[Docket No. 96N-0183]

RIN 0910-AA53

Consolidation of Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to consolidate a list of drugs, previously determined by rulemaking to be new drugs, into one section. This document would also remove the sections now providing for these drugs, except for certain information in the regulations that FDA considers to be necessary. This action, which will make the regulations more concise and efficient, is being taken in response to the President's regulatory reinvention initiative (REGO).

DATES: Written comments by August 26, 1996. FDA proposes that any final rule based on this proposal become effective 2 weeks after its date of publication in the Federal Register.

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: Mary E. Catchings, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Introduction

On March 4, 1995, President Clinton issued a memorandum titled "Regulatory Reinvention Initiative." This memorandum, part of the reform of the Federal regulatory system, directed heads of departments and agencies to undertake a page-by-page review of their existing regulations and to eliminate or modify those that are outdated or otherwise in need of reform. FDA has conducted a comprehensive review of