

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note: This AD applies to each airplane identified in paragraph (a) of this AD, 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact T.N. Baktha, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946-4155; facsimile: (316) 946-4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Raytheon Mandatory Service Bulletin SB 53-3341, Revision 1, revised May 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201-0085; telephone: (800) 429-5372 or (316) 676-3140. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on February 16, 2001.

Issued in Kansas City, Missouri, on December 22, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-CE-55-AD; Amendment 39-12067; AD 2000-26-17]

RIN 2120-AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Models PC-12 and PC-12/45 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to Pilatus Aircraft Ltd. (Pilatus) Models PC-12 and PC-12/45 airplanes that are equipped with a certain windshield configuration. This AD requires you to incorporate pilot's operating handbook (POH) information that prohibits the operation of the windshield heating system in the "LIGHT" mode, and requires you to modify the windshield deicing system wiring and circuit breakers. You can remove the POH information after accomplishing the modification. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified by this AD are intended to prevent loss of electrical power to the windshield deicing system due to operation in the "LIGHT" mode, which could result in icing of the windshield and loss of control of the airplane.

DATES: This AD becomes effective on February 24, 2001.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of February 24, 2001.

ADDRESSES: You may get the service information referenced in this AD from Pilatus Aircraft Ltd., Customer Liaison Manager, CH-6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 619 6224; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021; telephone: (303) 465-9099; facsimile: (303) 465-6040. You may examine this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-CE-55-AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4141; facsimile: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

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 Models PC-12 and PC-12/45 airplanes. The FOCA reports that the electrical load of the left hand (LH) and right hand (RH) windshields can become too high during flight at cruise altitudes when the "LIGHT" mode is selected on the windshield deicing system. The FOCA references eight instances where prolonged operation of the windshield deicing system in the "LIGHT" mode caused this system to temporarily shut down.

The airplanes involved in the above instances were equipped with part number (P/N) 959.81.10.107 LH and P/N/ 959.81.10.108 RH windshields.

What Are the Consequences if the Condition Is Not Corrected?

Operation of the existing design windshield deicing system in the "LIGHT" position can overload the electrical capacity of the wiring and circuit breakers. This could result in complete electrical power loss to the windshield and icing of the windshield.

Has FAA Taken Any Action to this Point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Pilatus Models PC-12 and PC-12/45 airplanes that are equipped with a certain windshield configuration. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on October 2, 2000 (65 FR 58675). The NPRM proposed to require you to incorporate POH information that would prohibit the operation of the windshield heating system in the "LIGHT" mode, and would require you to modify the windshield deicing system wiring and circuit breakers. You could remove the POH information after accomplishing the modification.

Was the Public Invited To Comment?

Interested persons were afforded an opportunity to participate in the making of this amendment. No comments were

received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

What Is FAA's Final Determination on This Issue?

After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest

require the adoption of the rule as proposed except for minor editorial corrections. We determined that these minor corrections:

- Will not change the meaning of the AD; and
- Will not add any additional burden upon the public than was already proposed.

Cost Impact

How Many Airplanes Does This AD Impact?

We estimate that this AD affects 108 airplanes in the U.S. registry.

What Is the Cost Impact of This AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
18 workhours×\$60 per hour \$1,080	Pilatus will provide free-of-charge.	\$1,080 per airplane	\$116,640.

Compliance Time of This AD

What Is the Compliance Time of This AD?

The compliance time of this AD is as follows:

- Incorporation of the POH temporary revision: "Within the next 30 days after the effective date of this AD;" and
- Modification: "Within the next 12 months after the effective date of this AD."

Why Is the Compliance of This AD in Calendar Time Instead of Hours Time-in-Service (TIS)?

Although loss of electrical power to the windshield deicing system due to operation in the "LIGHT" mode is unsafe during flight, the condition is not a direct result of airplane operation. The chance of this situation occurring is the same for an airplane with 10 hours time-in-service (TIS) as it would be for an airplane with 500 hours TIS. A calendar time for compliance will assure that the unsafe condition is addressed on all airplanes in a reasonable time period.

Regulatory Impact

Does This AD Impact Various Entities?

The regulations adopted herein will 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does This AD Involve a Significant Rule or Regulatory Action?

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) 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 final 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, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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. FAA amends § 39.13 by adding a new AD to read as follows:

2000-26-17 Pilatus Aircraft Ltd.:

Amendment 39-12067; Docket No. 2000-CE-55AD.

(a) *What airplanes are affected by this AD?* This AD affects Models PC-12 and PC-12/45 airplanes, manufacturer serial number (MSN) 101 through MSN 320, that are:

- (1) certificated in any category; and
- (2) equipped with part number (P/N) 959.81.10.107 LH and P/N 959.81.10.108 RH windshields (PPG P/N NP172121-5 LH and NP172121-6 RH or FAA-approved equivalent part numbers).

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent loss of electrical power to the windshield deicing system due to operation in the "LIGHT" mode, which could result in icing of the windshield and loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Action	Compliance Time	Procedures
(1) Insert Temporary Revision No. 21 to PC-12 Pilot's Operating Handbook, Report No. 01973-001, Section 2, Windshield Heater Operation 101-320, Issued: May 19, 2000..	Within the next 30 days after February 24, 2001 (the effective date of this AD), unless already accomplished..	Anyone who holds at least a private pilot certificate, as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), may incorporate the pilot's operating handbook (POH) revision required by this AD. You must make an entry into the aircraft records that shows compliance with this AD, in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

Action	Compliance Time	Procedures
(2) Modify the windshield deicing system wires and circuit breakers. You may remove the POH temporary revision referenced in paragraph (d)(1) of this AD after accomplishing this modification..	Within the next 12 months after February 24, 2001 (the effective date of this AD), unless already accomplished..	In accordance with the modification procedures in the Accomplishment Instructions section of Pilatus Service Bulletin No. 30-006, dated May 22, 2000.
(3) Do not install, on any affected airplane, P/N 959.81.10.107 LH and P/N 959.81.10.108 RH windshields (PPG P/N NP172121-5 LH and NP172121-6 RH or FAA-approved equivalent part numbers), without incorporating the modification required in paragraph (d)(2) of this AD..	As of February 24, 2001 (the effective date of this AD.).	Not applicable.

Note 1: Temporary Revision No. 21 to PC-12 Pilot's Operating Handbook, Report No. 01973-001, Section 2, Windshield Heater Operation 101-320, Issued: May 19, 2000, eliminates the need for Temporary Revision No. 14 in the POH.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

- (1) Your alternative method of compliance provides an equivalent level of safety; and
- (2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 329-4141; facsimile: (816) 329-4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Pilatus Service Bulletin No. 30-006, dated May 22, 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Pilatus Aircraft Ltd., Customer Liaison Manager, CH-6371 Stans, Switzerland; or from Pilatus Business Aircraft Ltd., Product Support

Department, 11755 Airport Way, Broomfield, Colorado 80021. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on February 24, 2001.

Note 3: The subject of this AD is addressed in Swiss AD HB 2000-393, dated September 6, 2000.

Issued in Kansas City, Missouri, on December 22, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01-184 Filed 1-5-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 00N-1634]

Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations governing the public disclosure of written information for consideration by an advisory committee at an advisory committee meeting. This action amends the regulations to state that the written information for consideration by an advisory committee at a committee meeting is available for public disclosure, whenever practicable, before or at the time of the meeting. FDA is taking this action to reflect current FDA policy in conformance with applicable

law. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES: This rule is effective May 23, 2001. Submit written comments by March 26, 2001. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before April 23, 2001, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation notice in the **Federal Register**. If timely significant adverse comments are received, the agency will publish a document of significant adverse comments in the **Federal Register** and withdraw this direct final rule before April 23, 2001.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Discussion

A. Background

Advisory committees provide independent advice and recommendations to FDA on scientific and technical matters related to products regulated by the agency. To assist committee members in preparing to discuss the issues that will be raised at a committee meeting, the agency and, in certain circumstances, affected members of the regulated industry prepare written background materials