§ 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. 98–CE–30–AD.

Applicability: Model PC-7 airplanes, serial numbers MSN 001 through MSN 609, 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 (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 as indicated in the body of this AD, unless already accomplished.

To prevent main landing gear (MLG) or nose landing gear (NLG) failure caused by deterioration of a MLG or NLG leg seal unit, which could result in damage to the airplane or airplane controllability problems during takeoff, landing, or taxi operations, accomplish the following:

- (a) Within the next 100 hours time-inservice after the effective date of this AD, replace the seal unit on both MLG legs and the NLG leg in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus Service Bulletin No. 32–018, dated March 6, 1998.
- (b) As of the effective date of this AD, no person may install a MLG leg or NLG leg that does not have an improved seal unit installed in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus Service Bulletin No. 32–018, dated March 6, 1998.
- (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, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106. 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 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) Questions or technical information related to Pilatus Service Bulletin No. 32– 018, dated March 6, 1998, should be directed to Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 6509; facsimile: +41 41 610 3351. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in Swiss AD HB 98–069, dated March 23, 1998.

Issued in Kansas City, Missouri, on May 21, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–14192 Filed 5–28–98; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-CE-03-AD]

RIN 2120-AA64

Airworthiness Directives; British Aerospace Model B.121 Series 1, 2, and 3 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); Reopening of the comment period.

SUMMARY: This document proposes to revise an earlier proposed airworthiness directive (AD) that would have required the following on certain British Aerospace Model B.121 Series 1, 2, and 3 airplanes: installing an inspection opening in the area of the main spar web, repetitively inspecting the area at the main spar web for cracks and the area of the wing to fuselage attach bolt holes for corrosion, and repairing or replacing any cracked or corroded part. The proposed AD was the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom. Since issuing the NPRM, British Aerospace has developed additional service information to that referenced in the previous proposal to include the installation of nuts of improved design at the wing to fuselage main-spar attachment fittings and the deletion of the inspection of the area of the wing to fuselage attach bolt holes for corrosion. The improved design nuts provide better torque retention than the nuts originally installed. The Federal Aviation Administration (FAA) has determined that the above-referenced changes in the revised service information should be incorporated into the NPRM, and that the comment period for the proposal should be reopened and the public should have additional time to comment. The actions specified by the proposed AD are intended to prevent structural failure of the main spar web area caused by fatigue cracking or separation of the wing caused by loose nuts at the wing to fuselage mainspar attachment fittings, which could result in loss of control of the airplane.

DATES: Comments must be received on or before July 3, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–03–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 British Aerospace (Operations) Limited, British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 479888; facsimile: (01292) 479703. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Roger Chudy, Aerospace Engineer, Small Airplane Directorate, Aircraft Certification Service, 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. 98–CE–03–AD." The postcard will be date stamped and returned to the commenter.

Availability of Supplemental NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–03–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain British Aerospace Model B.121 Series 1, 2, and 3 airplanes was published in the Federal Register as a notice of proposed rulemaking (NPRM) on March 16, 1998 (63 FR 12708). The NPRM proposed to require installing an inspection opening in the area of the main spar web, repetitively inspecting the area at the main spar web for cracks and the area of the wing to fuselage attach bolt holes for corrosion. and repairing or replacing any cracked or corroded part. Accomplishment of the proposed inspections would be required in accordance with British Aerospace PUP Mandatory Service Bulletin No. B121/102, Revision No. 1, Issued April 16, 1997. If necessary, the proposed repair or replacement would be required in accordance with a scheme obtained from the manufacturer through the FAA, Small Airplane Directorate.

The NPRM was the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom.

Interested persons have been 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.

Events Since Issuance of the NPRM

Since issuance of the NPRM, British Aerospace has developed additional service information to that referenced in the previous proposal to include the installation of nuts of improved design at the wing to fuselage main-spar attachment fittings and the deletion of the inspection at the area of the wing to

fuselage attach bolt holes for corrosion. The improved design nuts provide better torque retention than the ones originally installed.

In addition, British Aerospace has reexamined the service history and evaluated reports from the field and has changed the compliance time (that is referenced in the service information) for the inspection opening installation and the initial eddy current inspection to upon the accumulation of 2,000 flying hours.

To incorporate the above changes, British Aerospace has issued the following service bulletins, which supersede British Aerospace PUP Mandatory Service Bulletin No. B121/ 102, Revision No. 1, Issued April 16, 1997:

- —British Aerospace PUP Mandatory Service Bulletin No. B121/106, dated January 12, 1998, which specifies procedures for replacing the nuts (with improved design nuts) at the wing to fuselage main-spar attachment fittings; and
- —British Aerospace PUP Mandatory Service Bulletin No. B121/105, dated January 12, 1998, which specifies procedures for installing an inspection opening in the area of the main spar web, and inspecting the area at the main spar web for cracks. These procedures are basically the same as contained in British Aerospace PUP Mandatory Service Bulletin No. B121/102, Revision No. 1, Issued April 16, 1997.

The FAA's Determination

After examining all information related to the subject described in this document, the FAA has determined that:

- Improved design nuts should be installed at the wing to fuselage mainspar attachment fittings;
- The improved service information should be incorporated into the proposed AD;
- —The compliance time of the proposed inspection opening installation and initial eddy current inspection should be changed to coincide with the service information referenced above; and
- —AD action should be taken to incorporate these changes to prevent structural failure of the main spar web area caused by fatigue cracking or separation of the wing caused by loose nuts at the wing to fuselage main-spar attachment fittings, which could result in loss of control of the airplane.

The Supplemental NPRM

Since installing improved design nuts at the wing to fuselage main-spar attachment fittings proposes actions that go beyond the scope of what was already proposed, the FAA is reopening the comment period to allow the public additional time to comment on this proposed action.

Cost Impact

The FAA estimates that 2 airplanes in the U.S. registry would be affected by the proposed AD; that it would take approximately 37 workhours per airplane to accomplish the proposed initial inspection, inspection opening installation, and improved design nut installations; that the average labor rate is approximately \$60 an hour. There is no cost for the parts to accomplish the proposed replacements. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$4,440, or \$2,220 per airplane. These figures only take into account the cost of the proposed initial inspections, inspection opening installation, and improved design nut installations; and do not take into account the cost of repetitive inspections. The FAA has no way of determining the number of repetitive inspections each owner/operator of the affected airplanes will incur.

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 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:

British Aerospace (Operations) Limited: Docket No. 98–CE–03–AD.

Applicability: Model B.121 Series 1, 2, and 3 airplanes, all serial numbers, 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 (f) 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 in the body of this AD, unless already accomplished.

To prevent structural failure of the main spar web area caused by fatigue cracking or separation of the wing caused by loose nuts at the wing to fuselage main-spar attachment fittings, which could result in loss of control of the airplane, accomplish the following:

(a) Within the next 100 hours time-inservice (TIS) after the effective date of this AD, replace the nuts (with improved design nuts) at the wing to fuselage main-spar attachment fittings in accordance with British Aerospace PUP Mandatory Service Bulletin No. B121/106, dated January 12, 1998.

(b) Upon accumulating 2,000 hours TIS on the main spar or within the next 50 hours TIS, whichever occurs later, install an inspection opening and inspect, using eddy current methods, the area at the main spar web for cracks in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of British Aerospace PUP Mandatory Service Bulletin No. B121/105, dated January 12, 1998.

Note 2: Accomplishing the installation inspection opening and initial eddy current inspection required by this AD in accordance with British Aerospace PUP Mandatory Service Bulletin No. B121/102, Revision No. 1, Issued April 16, 1997, is considered "already accomplished" for the requirements of paragraph (b) of this AD.

- (c) Within 800 hours TIS after the initial inspection required by paragraph (b) of this AD, and thereafter at intervals not to exceed 800 hours TIS, reinspect the area of the main spar web as specified in paragraph (b) of this AD
- (d) If any cracks are found during any inspection required by this AD, prior to further flight, accomplish the following:
- (1) Obtain a repair or replacement scheme from the manufacturer through the FAA, Small Airplane Directorate, at the address specified in paragraph (e) of this AD; and
- (2) Incorporate this scheme and continue to repetitively inspect as required by paragraph (c) of this AD, unless specified differently in the instructions to the repair or replacement
- (e) 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.
- (f) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, Aircraft Certification Service, 1201 Walnut, suite 900, Kansas City, Missouri 64106. 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.

(g) Questions or technical information related to the service information referenced in this document should be directed to British Aerospace (Operations) Limited, British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 479888; facsimile: (01292) 479703. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 4: The subject of this AD is addressed in British AD 005–01–98, not dated.

Issued in Kansas City, Missouri, on May 21, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–14189 Filed 5–28–98; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

Quality System Inspection Technique Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: "Quality System Inspection Technique." The goal of the meeting is to obtain views and opinions from interested parties concerning a proposed new technique for conducting quality system inspections. This proposed technique could eventually replace the technique presently used when FDA conducts quality systems (good manufacturing practices) inspections of medical device manufacturers. The proposed "Quality System Inspection Technique" was developed by a group composed of the Center for Devices and Radiological Health (CDRH) and Office of Regulatory Affairs staff, familiar with the Quality Systems Regulation and present inspectional processes, with input from the medical device industry. This meeting is part of the CDRH's ongoing reengineering effort to develop an inspection program covering the Quality System Regulation that results in more focused and efficient inspections. DATES: The public meeting will be held on Thursday, June 18, 1998, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public meeting will be held at 5600 Fishers Lane, conference rooms D and E, third floor, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information regarding the meeting: Timothy R. Wells, Center for Devices and Radiological Health (HFZ-332), 2094 Gaither Rd., Rockville, MD 20859, 301–594–4616, FAX 301–594–4638, e-mail trw@cdrh.fda.gov.

For information regarding registration or requests for oral presentations: Georgia A. Layloff, Food and Drug Administration, St. Louis Branch Office, 12 Sunnen Dr., suite 122, St. Louis, MO 63143, 314–645–1167, ext. 121, FAX 314–645–2969, e-mail glayloff@ora.fda.gov.

SUPPLEMENTARY INFORMATION: The draft entitled "Quality System Inspection Technique" is posted for comment on the CDRH's World Wide Web (www) home page. The draft document may be