Proposed Rules

Federal Register
Vol. 65, No. 62
Thursday, March 30, 2000

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–CE–20–AD]

RIN 2120–AA64

Airworthiness Directives; The New Piper Aircraft, Inc. PA–42 Series 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 certain The New Piper Aircraft, Inc. (Piper) PA–42 series airplanes. The proposed AD requires that you revise the Airplane Flight Manual (AFM) to include requirements for activation of the airframe pneumatic deicing boots. The proposed AD is the result of reports of in-flight incidents and an accident that occurred in icing conditions where the airframe pneumatic deicing boots were not activated. The actions specified by the proposed AD are intended to assure that flightcrews have the information necessary to activate the pneumatic wing and tail deicing boots at the first signs of ice accumulation. Without this information, flightcrews could experience reduced controllability of the aircraft due to adverse aerodynamic effects of ice adhering to the airplane prior to the first deicing cycle.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this rule on or before June 2, 2000.

ADDRESSES: Submit comments in triplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–CE–20–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

FOR FURTHER INFORMATION CONTACT: John P. Dow, Sr., Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 426–6932; facsimile: (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments in triplicate to the address specified under the caption **ADDRESSES.**The FAA will consider all comments received on or before the closing date. We may amend the proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of the proposed AD action and determining whether we need to take additional rulemaking action.

The FAA is re-examining the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on whether the style of this document is clearer, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at *http://www.plainlanguage.gov*.

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might suggest a need to modify the rule. You may examine all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of the proposed AD.

If you want us to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 2000–CE–20–AD.'' We will date stamp and mail the postcard back to you.

Discussion

What events have caused this AD? On January 9, 1997, an Empresa Brazileira de Aeronautica, S.A. (EMBRAER) Model EMB–120RT series airplane was involved in an uncommanded roll excursion and consequent rapid descent that resulted in an accident near Monroe, Michigan. The post-accident investigation conducted by the National Transportation Safety Board (NTSB) concluded that the airplane had accumulated a thin, rough layer of ice on its lifting surfaces. That accumulation of ice, in combination with the slowing of the airplane to an airspeed inappropriate for the icing conditions in which the airplane was flying, resulted in loss of control that was not corrected before the airplane impacted the ground. The NTSB also concluded that the flight crew did not activate the wing and tail pneumatic deicing boots. An NTSB recommendation related to this accident requested that FAA mandate that pneumatic deicing boots be turned on as soon as the airplane enters icing conditions.

We reviewed the icing-related incident history of certain airplanes and we determined that icing incidents may have occurred because pneumatic deicing boots were not activated at the first evidence of ice accretion. As a result, the handling qualities or the controllability of the airplane may have been reduced due to the accumulated ice. That factor was present in the accident discussed previously and, as such, constitutes an unsafe condition.

Based on the incidents above, we initiated AD action against several make and model airplanes, including The New Piper Aircraft, Inc. (Piper) PA–31 series airplanes (Docket No. 99–CE–49–AD). The AD's required revising the Airplane Flight Manual (AFM) to include requirements for activation of the airframe pneumatic deicing boots.

Comments received on Docket No. 99–CE–49–AD indicated that the proposed actions should also apply to Piper PA–42 series airplanes. Rather than hold up the AD on the Piper PA–31 series airplanes, we decided to initiate a separate AD action (NPRM) for the Piper Models PA–42, PA42–720, PA42–720R, and PA42–1000 airplanes.

What are the consequences if the condition is not corrected? This condition, if not corrected, could lead to

reduced controllability of the aircraft due to adverse aerodynamic effects of ice adhering to the airplane prior to the first deicing cycle.

The FAA's Determination and an Explanation of the Provisions of the Proposed AD

What has FAA decided? After examining the circumstances and reviewing all available information related to the incidents described above, we have determined that:

—an unsafe condition referenced in this document exists or could develop on other Piper PA–42 series airplanes of the same type design; and

—AD action should be taken in order to prevent reduced controllability of the aircraft due to adverse aerodynamic effects of ice adhering to the airplane prior to the first deicing cycle.

What does this AD require? The proposed AD requires you to revise the Limitations Section of the AFM to include requirements for activation of pneumatic deicing boots at the first indication of ice accumulation on the airplane.

Cost Impact

How many airplanes does the proposed AD impact? We estimate that 120 airplanes in the U.S. registry would be affected by the proposed AD.

What is the cost impact of the initial inspection on owners/operators of the affected airplanes? We estimate that it would take approximately 1 workhour per airplane to accomplish the proposed AFM revisions. Accomplishing the proposed AFM revision requirements of this NPRM may be performed by the owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), and must be entered into the aircraft records showing compliance with the proposed AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9). The only cost impact of the proposed AD is the time it would take each owner/operator of the affected airplanes to insert the information into the AFM.

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

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 14 CFR part 39 of the Federal Aviation Regulations 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:

The New Piper Aircraft, Inc.: Docket No. 2000–CE–20–AD.

(a) *What airplanes are affected by this AD?* Models PA–42, PA–42–720, PA–42–720R, and PA–42–1000 airplanes, all serial numbers, that are:

(1) Equipped with pneumatic deicing boots; and

(2) Certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes on the U.S. Register. The AD does not apply to your airplane if it is not equipped with pneumatic de-icing boots.

(c) *What problem does this AD address?* The information necessary to activate the pneumatic wing and tail deicing boots at the first signs of ice accumulation is critical for flight in icing conditions. If we did not take action to include this information, flight crews could experience reduced controllability of the aircraft due to adverse aerodynamic effects of ice adhering to the airplane prior to the first deicing cycle.

(d) *What must I do to address this problem?* To address this problem, you must revise the Limitations Section of FAA-approved Airplane Flight Manual (AFM) to include the following requirements for activation of the ice protection systems. You must accomplish this action within the next 10 calendar days after the effective date of this AD, unless already accomplished. You may insert a copy of this AD in the AFM to accomplish this action:

''• Except for certain phases of flight where the AFM specifies that deicing boots should not be used (*e.g.*, take-off, final approach, and landing), compliance with the following is required.

• Wing and Tail Leading Edge Pneumatic Deicing Boot System, if installed, must be activated:

—At the first sign of ice formation anywhere on the aircraft, or upon annunciation from an ice detector system, whichever occurs first; and

—The system must either be continued to be operated in the automatic cycling mode, if available; or the system must be manually cycled as needed to minimize the ice accretions on the airframe.

• The wing and tail leading edge pneumatic deicing boot system may be deactivated only after:

—Leaving known or observed/detected icing that the flight crew has visually observed on the aircraft or was identified by the on-board sensors; and

—After the airplane is determined to be clear of ice.''

Note: The FAA recommends periodic treatment of deicing boots with approved ice release agents, such as ICEX™, in accordance with the manufacturer's application instructions.

(e) *Can the pilot accomplish the action?* Yes. 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 AFM revisions 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).

(f) *Can I comply with this AD in any other way?* Yes.

(1) You may use an alternative method of compliance or adjust the compliance time if:

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

(ii) 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.

(2) 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)(1) 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.

(g) *Where can I get information about any already-approved alternative methods of compliance?* Contact the Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4121; facsimile: (816) 329–4091.

(h) *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.

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

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–7878 Filed 3–29–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 900

[Docket No. 99N–4578]

RIN 0910–AB98

State Certification of Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement the patient notification provisions of the Mammography Quality Standards Act of 1992 (the MQSA). This action will permit FDA to authorize individual States to certify mammography facilities, to conduct the inspection of the facilities, to enforce the MQSA quality standards, and to administer other related functions. FDA retains oversight responsibility for the activities of the States to which this authority has been delegated and mammography facilities certified by those States must continue to meet the quality standards established by FDA for mammography facilities nationwide. The document proposes procedures for application, approval, evaluation, and withdrawal of approval of States as certification agencies. It also proposes standards to be met by States receiving this authority.

DATES: Submit written comments on the proposed rule by June 28, 2000. Written comments on the information collection requirements should be submitted by May 1, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy A. Taylor, Desk Officer for FDA. The Regulatory Impact Study (RIS) and cost analysis is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ruth A. Fischer, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, FAX 301–594–3306.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA (Public Law 102–539) was enacted on October 27, 1992. The purpose of the legislation was to establish minimum national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all mammography facilities, except facilities of the Department of Veterans Affairs, had to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA. The MQSA replaced a patchwork of Federal, State, and private standards with uniform Federal standards designed to ensure that all women nationwide receive adequate quality mammography services. On October 9, 1998, the Mammography Quality Standards Reauthorization Act (the MQSRA) (Public Law 105–248) was enacted to extend the MQSA through fiscal year 2002.

A. Provisions of the MQSA

The key requirements of MQSA to be met by the facilities in order to receive and maintain their FDA certification include:

(1) Compliance with quality standards for personnel, equipment, quality assurance programs, and reporting and recordkeeping procedures.

(2) Accreditation by private, nonprofit organizations or State agencies that have been approved by FDA as meeting standards established by the agency for accreditation bodies and that continue to pass annual FDA reviews of their activities. As part of the accreditation process, the accreditation body must evaluate for quality actual clinical mammograms from each unit in the facility, and determine that the facility quality standards have been met.

(3) Demonstration of continued compliance with the facility quality standards through annual inspections performed by FDA-certified Federal or State Inspectors.

B. Accomplishments to Date

Interim facility quality standards were published in the **Federal Register** of December 21, 1993 (58 FR 67558), and used as the basis for the initial certification of mammography facilities by October 1, 1994, the date by which mammography facilities had to have an FDA certificate in order to continue lawfully providing mammography services. In the **Federal Register** of October 28, 1997 (62 FR 55852), more comprehensive facility quality standards and accreditation body requirements were published, which became effective on April 28, 1999. Five accreditation bodies, the American College of Radiology (ACR) and the States of Arkansas, California, Iowa, and Texas, have been approved by FDA to accredit mammography facilities. Approximately 250 Federal and State inspectors were trained and certified to conduct the MQSA inspections, and the 5th year of inspections has now begun. The number of certified mammography facilities varies with time but typically is slightly under 10,000.

C. Role of the States

State agencies have played a very important role in the development and implementation of the MQSA program. As already noted, four of the five accreditation bodies are States, thus providing an alternative to the ACR for accreditation of facilities within the borders of the accrediting States. Most of the FDA-certified inspectors are State personnel who, working under contract with FDA, have conducted the great majority of the inspections. FDA currently has contracts for the performance of inspections with 46 States, the District of Columbia, Puerto Rico, and New York City.

MQSA also provides for an even more significant State role in the MQSA program. In accordance with section 354(q) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(q)), States