

subject to the requirements of this AD. For engines 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 as indicated, unless already done.

To prevent rotary fuel pump leaks, which could result in an engine failure, engine fire, and damage to or loss of the aircraft, accomplish the following:

(a) If the Lear/Romec part number (P/N) on rotary fuel pumps, series RG9080, RG9570, or RG17980 has an "/M" suffix, the pump has been modified, and no further action is required.

(b) If the P/N does not have an "/M" suffix, perform initial and follow-up torque check inspections of pump relief valve attaching screws in accordance with the Accomplishment Instructions of Lycoming Service Bulletin (SB) No. 529B, dated June 10, 2002, as follows:

(1) Within 10 hours time-in-service (TIS), or 30 days after the effective date of this AD, whichever occurs first, perform the initial torque check inspection. If the torque does not meet the specifications in Lycoming SB No. 529B, dated June 10, 2002, tighten screws to the required torque in accordance with that SB.

(2) Perform follow-up torque check inspections at 50 hour intervals TIS, or 6 months since the previous torque check inspection, whichever occurs first. If the torque does not meet the specification in Lycoming SB No. 529B, dated June 10, 2002, during this follow-up inspection, tighten screws to the required torque in accordance with that SB.

(3) Continue the follow-up torque check inspections required by paragraph (a)(2) of this AD until:

(i) The accumulation of 100 hours TIS since the inspection with the torque remaining within the SB specification; or

(ii) The torque meets the SB specification during the initial inspection and a subsequent inspection taking place after accumulating an additional 50 hours TIS also meets the SB specification.

(4) After the accumulation of 100 hours TIS since the inspection with the torque remaining within the SB specification; visually inspect the pump at 50-hour intervals until the pump is replaced with a modified pump (with the "/M" after the part number).

(c) Replacement of a rotary fuel pump series RG9080, RG9570, or RG17980, with an unmodified pump (without the "/M" after the part number) requires repeating the initial and follow-up inspections in accordance with paragraph (b) of this AD.

Optional Terminating Action

(d) Replacement of a rotary fuel pump series RG9080, RG9570, or RG17980, with a

modified pump (with the "/M" after the part number) constitutes terminating action for the inspection requirements specified in paragraphs (b)(1) through (b)(4) of this AD.

Alternative Methods of Compliance

(e) 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). Operators must submit their request 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 airworthiness directive, if any, may be obtained from the New York ACO.

Special Flight Permits

(f) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the inspection requirements of this AD can be done.

Issued in Burlington, Massachusetts, on December 5, 2002.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002-NM-73-AD]

RIN 2120-AA64

Airworthiness Directives; Aerospatiale Model ATR42-500 Series Airplanes, and Model ATR72-102, -202, -212, and -212A Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR42-500 series airplanes, and Model ATR72-102, -202, -212, and -212A series airplanes. This proposal would require replacement of insulation blankets constructed of metallized polyethyleneterephthalate (MPET) located from sections 11 through 16 of the fuselage with new insulation blankets constructed of Terul 18™. This proposal is prompted by reports of in-flight and ground fires on certain airplanes manufactured with insulation

blankets constructed of MPET, which may contribute to the spread of a fire when ignition occurs from small ignition sources such as electrical arcing or sparking. The action specified by the proposed AD is intended to ensure that insulation blankets constructed of MPET are removed from the fuselage. Such insulation blankets could propagate a small fire that is the result of an otherwise harmless electrical arc and could lead to a much larger fire. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by January 13, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2002-NM-73-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2002-NM-73-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2125; fax (425) 227-1149.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue.

For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2002-NM-73-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. 2002-NM-73-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Aerospatiale Model ATR42-500 series airplanes, and Model ATR72-102, -202, -212, and -212A series airplanes. The DGAC advises that it has received reports of fires initiated by an electrical short circuit behind a sidewall, in which the flammability characteristics of thermal/acoustical insulation material constructed of metallized polyethyleneteraphthalate (MPET) may have been a contributing factor.

Although reported incidents have not occurred on ATR airplane models, the DGAC has issued French airworthiness directives 2001-635-061(B) and 2001-636-088(B), both dated December 26, 2001, in order to assure the continued airworthiness of Aerospatiale Model ATR42-500 series airplanes, and Model

ATR72-102, -202, -212, and -212A series airplanes in France.

Insulation blankets constructed of MPET that are installed in the fuselage, if not removed, could propagate a small fire that is the result of an otherwise harmless electrical arc and could lead to a much larger fire.

Explanation of Relevant Service Information

The manufacturer has issued Avions de Transport Regional Service Bulletin ATR42-25-0134 (for Model ATR42-500 series airplanes); and ATR72-25-1074 (for Model ATR72-102, -202, -212, -212A series airplanes); both dated January 24, 2002. These service bulletins describe procedures for replacing the existing insulation blankets constructed of MPET located from sections 11 through 16 of the fuselage with new, improved insulation blankets constructed of Terul 18™. Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe condition. The DGAC classified these service bulletins as mandatory.

FAA's Conclusions

These airplane models are manufactured in France and are 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, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, 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 require accomplishment of the actions specified in the applicable service bulletin described previously.

Differences Between Proposed Rule and Foreign Airworthiness Directives

The proposed AD would differ from the parallel French airworthiness directives in that it would require accomplishment of the replacement within 5 years after the effective date of this AD. The parallel French

airworthiness directives require accomplishment of the replacement during the next "eight-year calendar check and before May 31, 2009." In developing an appropriate compliance time for this proposed AD, the FAA considered not only the DGAC's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the compliance time mandated in previously issued ADs concerning insulation blankets constructed of MPET installed on other transport category airplanes, and the average utilization of the affected fleet.

The FAA's intent is that the replacement be conducted during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In order to meet the deadline, the FAA expects early planning and anticipates that operators will have to take advantage of every heavy maintenance opportunity. In light of these factors, the FAA finds a 5-year compliance time for completing the required actions to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety. The difference in compliance time has been coordinated with and acknowledged by the DGAC.

Cost Impact

The FAA estimates that 2 Aerospatiale Model ATR42-500 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 500 work hours per airplane to accomplish the proposed replacement, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$50,000 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators of Model ATR42-500 series airplanes is estimated to be \$160,000 or \$80,000 per airplane.

The FAA estimates that 19 Aerospatiale Model ATR72-102, -202, -212, and -212A series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 500 work hours per airplane to accomplish the proposed replacement, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$60,000 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators of Model ATR72-102, -202, -212, and -212A series airplanes is

estimated to be \$1,710,000 or \$90,000 per airplane.

The cost impact figures discussed above are 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

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 proposal would not have federalism implications under Executive Order 13132.

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 adding the following new airworthiness directive:

Aerospatiale: Docket 2002–NM–73–AD.

Applicability: Model ATR42–500 series airplanes, and Model ATR72–102, –202, –212, and –212A series airplanes, certificated in any category; except those airplanes on which ATR Modification 5117 or 5322 (reference Avions de Transport Regional Service Bulletin ATR 42–25–0134, dated January 24, 2002, or Avions de Transport Regional Service Bulletin ATR 72–25–1074, dated January 24, 2002; as applicable) has been installed.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (c) 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 ensure that insulation blankets constructed of metallized polyethyleneteraphthalate (MPET) are removed from the fuselage, to prevent propagation of a fire that is the result of an otherwise harmless electrical arc and could lead to a much larger fire, accomplish the following:

Insulation Blanket Replacement

(a) Within 5 years after the effective date of this AD, replace insulation blankets located from sections 11 through 16 inclusive of the fuselage with new, improved insulation blankets constructed of Terul 18™, in accordance with the Accomplishment Instructions of Avions de Transport Regional Service Bulletin ATR42–25–0134 (for Model ATR42–500 series airplanes); or ATR72–25–1074 (for Model ATR72–102, –202, –212, –212A series airplanes); both dated January 24, 2002; as applicable.

Note 2: Although paragraph (a) of this AD allows up to 5 years for the required replacement, the FAA encourages operators to review their airplanes to assess their individual needs for materials and plan accordingly. The FAA anticipates that operators will accomplish the requirements of this AD at the earliest practicable maintenance opportunity to lessen the burden toward the end of the compliance time.

Part Installation

(b) As of the effective date of this AD, no person shall install an insulation blanket constructed of MPET on any airplane.

Alternative Methods of Compliance

(c) 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, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(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.

Note 4: The subject of this AD is addressed in French airworthiness directives 2001–635–061(B) and 2001–636–088(B), both dated December 26, 2001.

Issued in Renton, Washington, on December 6, 2002.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–31471 Filed 12–12–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. 94N–0418 and 96P–0276]

Medical Devices: Cardiovascular Devices: Reclassification of the Arrhythmia Detector and Alarm

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the arrhythmia detector and alarm from class III (premarket approval) to class II (special controls) based on new information regarding the device. FDA is also proposing to revise the identification of the arrhythmia detector and alarm to separate the automated external defibrillator (AED) from the identification of the arrhythmia detector and alarm. FDA intends to propose the reclassification of the AED at a later time. FDA is taking this action in response to petitions submitted under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe