Proposed Rules

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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. 2001–NE–06–AD]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B Series Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to adopt a new airworthiness directive (AD) that is applicable to Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B series turboshaft engines. This proposal would require the insertion of a sleeve in the attachment boss of the compressor bleed valve. This proposal is prompted by several cases of contained centrifugal compressor impeller blade ruptures that have occurred in service. The actions specified by the proposed AD are intended to prevent acoustic excitation of the centrifugal compressor impeller blades resulting in contained compressor impeller blade ruptures and power loss that could lead to an uncommanded in-flight shutdown.

DATES: Comments must be received by November 5, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–NE–06–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: *9-ane-adcomment@faa.gov.* Comments sent via the Internet must contain the docket number in the subject line. Comments may be inspected at this location between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The service information referenced in the proposed rule may be obtained from Turbomeca S.A, Turbomeca S.A., 64511 Bordes Cedex, France; telephone 33 05 59 64 40 00, fax 33 05 59 64 60 80.

FOR FURTHER INFORMATION CONTACT: Glorianne Niebuhr, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7132; fax (781) 238–7199.

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 action 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 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 2001–NE–06–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–NE–06–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

The Direction Generale de L'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B series turboshaft engines. The DGAC advises that several cases of contained centrifugal compressor impeller blade ruptures caused by acoustic excitation of the blades have occurred in service. This excitation may lead to initiation of cracks on the blades resulting in contained compressor impeller blade ruptures and power loss that could lead to an uncommanded inflight shutdown. To reduce the level of acoustic vibration of the compressor blades, a coupling effect must be removed. This is accomplished by distributing the symmetry by insertion of a metal sleeve. The actions specified by the proposed AD are intended to prevent acoustic excitation of the centrifugal compressor impeller blades resulting in contained compressor impeller blade ruptures and power loss that could lead to an uncommanded in-flight shutdown.

Manufacturer's Service Information

Turbomeca S.A. has issued Service Bulletin (SB) No. 292 72 2054, dated September 20, 1999, and SB No. 292 72 0261, dated September 20, 1999, that provide instructions for the removal of the compresser bleed valve, installation of the sleeve, and reinstallation of the compresser bleed valve. The DGAC classified these SB's as mandatory and issued AD's No. 1999–391(A) and 1999–392(A), dated October 6, 1999, in order to ensure the airworthiness of these Turbomeca S.A. engines in France.

Bilateral Agreement Information

This engine model is manufactured in France and is the 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.

Proposed Requirements of This AD

Since an unsafe condition has been identified that is likely to exist or develop on other Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B series turboshaft engines of the same type design that are used on rotocraft registered in the United States, the proposed AD would require insertion of a sleeve in the attachment boss of the compresser bleed valve. The actions would be required to be accomplished in accordance with the SB's described previously.

Economic Impact

There are approximately 1,406 engines of the affected design in the worldwide fleet. The FAA estimates that 476 engines installed on aircraft of U.S. registry would be affected by this proposed AD. The FAA also estimates that it would take approximately 0.5 work hours per engine to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $430 per engine. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $218,960.

Regulatory Impact

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

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:

Turbomeca S.A.: Docket No. 2001–NE–06–AD.

Applicability

This airworthiness directive (AD) is applicable to Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B series turboshaft engines. These engines are installed on, but not limited to, Eurocopter France AS350B1, AS350B2, AS350B3; Astar 350D, Fennic AD550U2 and Sikorsky S–76A and S–76C series helicopters.

Note 1: This AD applies to each engine 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 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 (b) 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

Compliance with this AD is required within 30 days after the effective date of this AD, unless already done. To prevent acoustic excitation of the centrifugal compressor impeller blades resulting in contained blade ruptures and power loss that could lead to an uncommanded in-flight shutdown, do the following:

(a) Remove the compressor bleed valve, install the sleeve at the bottom of the boss attachment and install the valve as follows:

(1) For Arriel 2S1 and –2B engines in accordance with Paragraph 2.B. and 2.C. of Turbomeca S.A. Service Bulletin (SB) No. 292 72 2054, dated September 20, 1999.

(2) For Arriel 1D, –1D1, –1S, and –1S1 engines in accordance with Paragraph 2.B. and 2.C. of Turbomeca S.A. SB No. 292 72 0261, dated September 20, 1999.

Alternative Methods of Compliance

(b) 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, Engine Certification Office (ECO). Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(c) 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 helicopter to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Direction Generale de L'Aviation Civile (DGAC) Airworthiness Directives No. 1999–391(A) and 1999–392 (A), dated October 6, 1999.

Issued in Burlington, Massachusetts, on August 28, 2001.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–22313 Filed 9–5–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 99P–1864]

Orthopedic and Rehabilitation Devices: Reclassification of the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint from class III (premarket approval) to class II (special controls). The agency is also proposing to revise the device identification. This reclassification is based upon new information regarding the device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association. The agency is also publishing the recommendation of the Orthopedic and Rehabilitation Devices Panel (the Panel) regarding the