

DATES: Continue to submit comments on or before January 31, 2000.

ADDRESSES: Comments should be mailed to Jane Palsgrove Butler, Associate Administrator for Financial Assistance, Small Business Administration, 409 Third Street, S.W., Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Jane Palsgrove Butler, Associate Administrator for Financial Assistance, (202) 205-6490.

SUPPLEMENTARY INFORMATION: On November 8, 1999, SBA published a proposed rule to amend the regulations governing Certified Development Companies ("CDCs") (64 FR 60735). The original comment period closes on December 8, 1999. SBA is extending the comment period for 60 days.

SBA will also plan a public hearing on this proposed rule and will publish in the **Federal Register** a Notice providing further information on the public hearing.

Dated: November 24, 1999.

Jane Palsgrove Butler,

Associate Administrator for Financial Assistance.

[FR Doc. 99-31214 Filed 11-30-99; 8:45 am]

BILLING CODE 8025-01-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NE-42-AD]

RIN 2120-AA64

Airworthiness Directives; Turbomeca Arrius 1A Series Turboshaft Engines

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 Turbomeca Arrius 1A and series turboshaft engines. This proposal would require installation of module TU63, which provides a separate supply of fuel for one of the 10 main injectors of the fuel injection system. This proposal is prompted by reports of unexpected power loss during test flights. The actions specified by the proposed AD are intended to prevent unexpected power loss, which could result in an uncommanded in-flight engine shutdown, autorotation, and forced landing.

DATES: Comments must be received by January 31, 2000.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-NE-42-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may also be submitted to the Rules Docket by using the following Internet address: "9-ane-adcomment@faa.gov". Comments may be inspected at this location between 8:00 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, 40220 Tarnos, France; telephone +33 05 59 64 40 00, fax +33 05 59 64 60 80. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

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.

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 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 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 notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 99-NE-42-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, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-NE-42-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 Federal Aviation Administration (FAA) that an unsafe condition may exist on Turbomeca Arrius 1A series turboshaft engines. The DGAC advises that they have received reports of unexpected power loss during test flights. This power loss is due to lack of fuel supply to the main fuel injectors during low fuel flow conditions. The power loss occurred during a very quick decrease of power consumption caused by displacing collective pitch of the helicopter to minimum stop, for example, during a "quick stop." This condition, if not corrected, could result in unexpected power loss, which could result in an uncommanded in-flight engine shutdown, autorotation, and forced landing.

Service Information

Turbomeca has issued Service Bulletin (SB) No. 319 72 0016, Revision 1, dated December 22, 1997, that specifies procedures for installing module TU63, which provides a separate supply of fuel for one of the 10 main injectors of the fuel injection system. The DGAC classified this SB as mandatory and issued Airworthiness Directive (AD) 98-200(A), dated May 20, 1998, in order to assure the airworthiness of these engines in France.

Bilateral Airworthiness Agreement

This engine model is manufactured in France and is type certificated for operation in the United States under the provisions of § 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 Actions

Since an unsafe condition has been identified that is likely to exist or develop on other engines of the same type design registered in the United States, the proposed AD would require installation of module TU63, at the earliest of the following: the next shop visit after the effective date of this AD, 120 cycles-in-service after the effective date of this AD, or within 30 days after the effective date of this AD. The actions would be required to be accomplished in accordance with the SB described previously.

Economic Analysis

There are approximately 100 engines of the affected design in the worldwide fleet. The FAA estimates that 9 engines installed on aircraft of US registry would be affected by this proposed AD, that it would take approximately 1 work hour per engine to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$5,500.00 per engine. Based on these figures, the total cost impact of the proposed AD on US operators is estimated to be \$ 50,040. The manufacturer has advised the DGAC that they may provide module TU63 at no cost to the operator, thereby substantially reducing the cost impact of this proposed rule.

Regulatory Impact

This proposal does not have federalism implications, as defined in Executive Order No. 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 proposal.

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: Docket No. 99-NE-42-AD.

Applicability: Turbomeca Arrius 1A series turboshaft engines, installed on but not limited to Ecureuil AD355 series helicopters.

Note 1: This airworthiness directive (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 (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 prevent unexpected power loss, which could result in an uncommanded in-flight engine shutdown, autorotation, and forced landing, accomplish the following:

Installation of Module TU63

(a) Install module TU63 in accordance with the Instructions for Incorporation of Turbomeca Service Bulletin (SB) No. 319 72 0016, Revision 1, dated December 22, 1997, at the earliest of the following after the effective date of this AD:

- The next shop visit, or
- Within 120 cycles-in-service, or
- Within 30 days.

Definition

(b) For the purpose of this AD, a shop visit is defined as whenever the engine is removed from the helicopter for maintenance.

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, Engine

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

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

Ferry Flights

(d) 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 requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on October 24, 1999.

David A. Downey,

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

[FR Doc. 99-31171 Filed 11-30-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 99N-1852]

RIN 0910-AB83

Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the status reports section of the postmarketing annual reporting requirements for drug and biological products, and to require applicants to submit annual status reports for certain postmarketing studies of licensed biological products. This proposed rule would describe the types of postmarketing studies covered by these status reports, the information to be included in the reports, and the type of information that FDA would consider appropriate for public disclosure. The agency is taking this action to implement section 130 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments on the proposed rule by February 14, 2000. Submit written comments on the information collection provisions by January 3, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch