

The FAA has reviewed and approved the technical contents of CFE Company Alert Service Bulletin (ASB) No. CFE738-A72-8029, dated October 1, 1998, that describes procedures for dimensional inspections of curvic couplings on certain HPC rotor components.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require a one-time dimensional inspection of the curvic coupling tooth profile of certain HPC rotor components to check for machining mismatches in the curvic coupling, and, if necessary, replacement with serviceable parts. The actions would be required to be accomplished in accordance with the ASB described previously.

There are approximately 146 engines of the affected design in the worldwide fleet. The FAA estimates that 94 engines installed on aircraft of U.S. registry would be affected by this proposed AD, that it would take approximately 300 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 \$18,000 per engine. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$3,384,000.

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 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:

CFE Company: Docket No. 98-ANE-69-AD.

Applicability: CFE Company Model CFE738-1-1B turbofan engines, serial numbers 105106 through 105251, installed on but not limited to the Dassault Aviation Falcon 2000 model aircraft.

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 failure of certain high pressure compressor (HPC) rotor components, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

(a) Perform a one-time dimensional inspection of the curvic coupling tooth profile of certain HPC components, as identified in the table below, for machining mismatches in the curvic coupling, prior to exceeding the specified number of cycles since new, as listed in the table below, in accordance with procedures described in CFE Company Alert Service Bulletin (ASB) CFE738-A72-8029, dated October 1, 1998:

Nomenclature	Part No.	Cycles since new
Stage 4 and 5 Blisk	6079T74P07	2,460
	6079T74P08	3,430
Impeller Shaft	6079T80P05	1,670
	6079T80P04	2,060
Impeller	6079T77P05	2,150
	6079T77P06	2,130

(b) Remove from service any component that is found with a machining mismatch,

and replace with serviceable component parts.

(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.

(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 aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on December 7, 1998.

David A. Downey,

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

[FR Doc. 98-33026 Filed 12-11-98; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-ANE-42-AD]

RIN 2120-AA64

Airworthiness Directives; AlliedSignal Inc. (formerly Textron Lycoming) ALF502R-5 and ALF502R-3A Model Turbofan 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 AlliedSignal Inc. ALF502R-5 and ALF502R-3A model turbofan engines. This proposal would require incorporation of an improved fan core inlet anti-ice system. This proposal is prompted by reports of uncommanded reduction of engine thrust (rollback) and loss of thrust control in icing conditions. The actions specified by the proposed AD are intended to prevent ice accretion on the fan core inlet stator vane surfaces, which can result in engine rollback and loss of thrust control in icing conditions.

DATES: Comments must be received by February 12, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation

Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98-ANE-42-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may also be sent via the Internet using the following address: "9-ad-engineprop@faa.gov". Comments sent via the Internet must contain the docket number in the subject line. Comments may be inspected at this location between 8:00 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 AlliedSignal Engines, Inc., P.O. Box 5218, Phoenix, AZ 85072-2181, telephone (602) 365-2493, fax (602) 365-5577. 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:

Eugene Triozzi, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7148, 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 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 98-ANE-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. 98-ANE-42-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

Discussion

The Federal Aviation Administration (FAA) has received reports of uncommanded reduction of engine thrust (rollback), and loss of thrust control on AlliedSignal Inc. (formerly Textron Lycoming) ALF502R-5 model turbofan engines. 12 rollback events have been recorded to date, which all occurred in icing conditions at altitudes above 26,000 feet, and generally near areas of weather conditions that can be described as the anvil area of thunderstorm clouds. Seven events involved simultaneous rollbacks of multiple engines on the four-engine British Aerospace (BAe) 146 airplane.

The FAA Transport Airplane Directorate (TAD) issued Airworthiness Directive (AD) 94-07-09, effective on April 15, 1994, to require airplane altitude restrictions and operating procedures, to prevent engine rollbacks during flight in icing conditions. Following two additional rollback events during aircraft operation in icing conditions above 26,000 feet, the FAA TAD issued emergency AD 96-14-09 effective on July 2, 1997, to supersede AD 94-07-09. AD 96-14-09 carried over the earlier AD's altitude restrictions, and revised the Aircraft Flight Manual (AFM) airplane operating procedures.

The FAA Engine Certification Office (ECO) has reviewed the results of engine investigations, component icing tests, and in-flight engine icing tests of the present ALF502R-5 engine, which showed that accretion of ice may occur in the ALF502R-5 engine fan core inlet at stator vane surfaces, under specific icing conditions identified as ice crystals, which are likely to be encountered in weather occurring within the approved engine operating envelope. This ice accretion adversely restricts airflow to the engine core, causing rollback, progressing to further ice accretion and worsening rollback severity. This condition, if not corrected, can result in engine rollback and loss of thrust control.

The FAA ECO has reviewed the results of analyses, component tests, and in-flight engine testing of modifications of the ALF502R-5 engine,

to incorporate an improved fan core inlet anti-ice system. These data show the engine modifications to be acceptable to prevent adverse ice accretion and engine rollback in icing conditions. The FAA ECO has reviewed and approved the technical contents of AlliedSignal Inc. Service Bulletin (SB) No. ALF/LF 72-1020, Revision 2, dated September 30, 1998, that describes procedures for installation of the improved fan core inlet anti-ice system. Installation of modified ALF502 engines onto BAe 146 aircraft also requires incorporation of two airframe modifications, contained in BAe Regional Aircraft SB 26-40-01601A, dated March 25, 1998, and SB 71-68-01581A, Revision 1, dated March 25, 1998.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, this proposed AD would require installation of an improved fan core inlet anti-ice system, at the next shop visit, but no later than December 31, 2002.

The compliance end date of not later than December 31, 2002, was determined based on safety analysis considering the projected ALF502R-5 engine fleet rollback rate and projected cumulative unmodified engine operating hours.

The requirement for compliance at next shop visit was determined based upon average engine hourly usage between shop visits, and the corresponding modification incorporation rate assumed by the safety analysis. The shop visit requirement, rather than a specific hourly usage, was intended to allow modifications to occur concurrently with periodic maintenance.

The actions would be required to be accomplished in accordance with the SBs described previously.

The FAA TAD is considering new rulemaking to allow BAe 146-100A, -200A and -300A aircraft, equipped with all four engines modified, to be excluded from the altitude restrictions and operating procedures of AD 96-14-09. To be considered for that exclusion, modifications of the aircraft associated with the engine modifications, changes to limitations placards, and revisions of the AFM, will be required to be accomplished on the aircraft in accordance with the previously mentioned BAe SBs, BAe SB 71-72-30473A, and certain FAA approved AFM revisions.

There are approximately 982 engines of the affected design in the worldwide fleet. The FAA estimates that 100 engines installed on aircraft of U.S.

registry would be affected by this proposed AD, that it would take approximately 30 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 \$75,000 per engine. Based on these figures, the cost impact for incorporation of engine modifications required by the proposed AD on U.S. operators is estimated to be \$7,680,000.

In addition to the above engine modifications, further aircraft modifications specified by BAe SB No. 71-68-01581A, and BAe SB No. 26-40-01601A, Revision 1, are required prior to installation of modified engines onto BAe 146 aircraft. The FAA estimates that 20 aircraft of U.S. registry would be affected by this proposed AD, that it would take approximately 33 work hours per aircraft to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$2,400 per aircraft. Based on these figures, the cost impact for incorporation of aircraft modifications required by the proposed AD on U.S. operators is estimated to be \$87,600.

Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$7,767,600.

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 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:

AlliedSignal Inc.: Docket No. 98-ANE-42-AD.

Applicability: AlliedSignal Inc. (formerly Textron Lycoming) ALF502R-5 and ALF502R-3A model turbofan engines, installed on but not limited to British Aerospace (BAe) 146100A, -200A and -300A series aircraft.

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 uncommanded reduction of engine thrust and loss of thrust control in icing conditions, accomplish the following:

(a) At the next engine shop visit, but not later than December 31, 2002, install an improved fan core inlet anti-ice system in accordance with Accomplishment Instructions, Paragraphs 2.B. through 2.I.(1-4), of AlliedSignal Inc. Service Bulletin (SB) No. ALF/LF 72-1020, Revision 2, dated September 30, 1998. In order to install engines with the required modifications onto BAe 146-100A, -200A and -300A series aircraft, accomplish BAe Regional Aircraft SB No. 2640-01601A, dated March 25, 1998, and BAe Regional Aircraft SB No. 71-68-01581A, Revision 1, dated March 25, 1998.

(b) For the purpose of this AD, an engine shop visit is defined as maintenance that includes separation of either the fan module or the combustor turbine module from the remainder of the engine.

(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, 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.

(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 aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on December 7, 1998.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 98N-0979]

Investigational New Drug Applications; Clinical Holds; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing investigational new drug applications (IND's) for human drug and biological products. This proposed action would amend the IND clinical hold requirements to state that the agency will respond in writing to a sponsor's request that a clinical hold be removed from an investigation within 30-calendar days of the agency's receipt of the request and the sponsor's complete response to the issue(s) that led to the clinical hold. This proposed action is being taken in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). This proposed rule is a companion document to a direct final rule published elsewhere in this issue of the **Federal Register**. If FDA receives any significant adverse comment, the direct final rule will be withdrawn, and the comments will be considered in the development of a final rule using usual notice-and-comment rulemaking based on this proposed rule.