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:

Rolls-Royce Corporation: Docket No. 2000–NE–27–AD.

Applicability: This airworthiness directive is applicable to Rolls-Royce Corporation (formerly Allison Engine Company) models AE 2100A and AE 2100C engines with high pressure turbine (HPT) wheel 23050912 installed; AE 2100A engine with turbine wheel 23063462-serial number (S/N) MM14062 installed; AE 2100D3 and AE 3007A, AE 3007A1/1, AE 3007A1/2, AE 3007A1/3, AE 3007A1, AE 3007A1P, AE 3007A3 and AE 3007C with HPT second stage wheels with S/Ns before MM183060. These engines are installed on but not limited to Embraer (EMB) 145 and 135, Cessna Citation 750, and Industi Pesawat Terbang Nusantara (IPTN) N–250 airplanes.

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 (f) 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 the requirements of this AD is required as indicated, unless already.

To detect and prevent early development of cracks due to low cycle fatigue of the high pressure turbine (HPT) 2nd stage wheel in the aft bore face that can lead to wheel failure power loss, and possible damage to the airplane, do the following:

One-time Inspection

(a) Perform a one-time acid etch inspection to the 2nd stage high pressure turbine wheel in accordance with the Accomplishment Instructions contained in the following Rolls-Royce Alert Service Bulletins:

TABLE 1.—APPLICABLE ALERT SERVICE BULLETINS

AE models	Rolls-Royce service bulletin
AE 2100A	AE 2100A–A–72–234, Revision 2, dated October 13, 2000.
AE2100C	AE 2100C–A–72–183, Revision 2, dated October 13, 2000.
AE2100D3	AE 2100D3–A–72–179, Revision 2, dated October 13, 2000.
AE3007A	AE 3007A–A–72–179, Revision 2, dated October 17, 2000.
AE3007C	AE 3007C–A–72–153, Revision 2, dated October 17, 2000.

(b) Perform these inspections according to the following compliance times:

TABLE 2.—INSPECTION COMPLIANCE TIMES

Models	With turbine wheel	Mandatory
(1) AE2100A, AE2100C	23050912	Before 4800 cycles since new (CSN).
(2) AE2100A	23063462–S/N MM 14062	Before 4800 CSN.
(3) AE2100D3	23050912	Before 3200 CSN.
(4) All other AE2100A, AE2100C, and AE2100D3.	23069592, 23063462, 23064822, 23070673, 23065892, 23069116, 233064473, 23064474, 23068072 with S/N's MM183060 and before..	Next shop visit.
(5) All AE3007A, AE3007A1/1, AE 3007A1/2, AE 3007A1/3, AE 3007A1, AE3007A1P, AE3007A3, and AE3007C series engines.	23063462, 23065892, 23069116, 23069592, 23069438, with S/N MM183060 and before..	Next shop visit.

(c) If cracks are discovered, replace the turbine wheel with a serviceable part.

(d) The next shop visit is defined as whenever the engine is removed and sent to a maintenance center for inspection or repair.

(e) A serviceable part is defined as any turbine wheel with a serial number greater than MM183060, or less than MM183060, that has undergone an acid etch inspection and has been determined to have no cracks.

Alternative Methods of Compliance

(f) 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, Chicago Aircraft 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, Chicago Aircraft 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 Chicago Aircraft Certification Office.

Ferry Flights

(g) 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 December 1, 2000.

David A. Downey,

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

[FR Doc. 00–31613 Filed 12–11–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–71–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney JT8D series 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 Pratt

& Whitney (PW) JT8D series turbofan engines. This proposal would require removing certain 2nd stage compressor disks, specified by serial number, from service. This proposal is prompted by a report from PW of a number of JT8D engine 2nd stage compressor disks that were delivered to the field with potential machining damage to the tie rod, counterweight, and pin holes. The actions specified by the proposed AD are intended to prevent rupture of the 2nd stage compressor disk caused by machining damage, which could result in an uncontained engine failure and damage to the airplane.

DATES: Comments must be received by February 12, 2001.

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–71–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 Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–6600, fax (860) 565–4503. 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: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175; 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 98–ANE–71–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. 98–ANE–71–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

Pratt & Whitney (PW) notified the Federal Aviation Administration (FAA) of the possibility of machining damage in the holes of five hundred twenty-three 2nd stage compressor disks, part number (P/N) 745902, P/N 790832, and P/N 807502. Machining damage may have resulted in distorted microstructure in the tie rod, counterweight, and pin holes. Increased stress due to the distorted microstructure could cause cracks that propagate through the disk. This condition, if not corrected, could result in rupture of the 2nd stage compressor disk caused by machining damage, which could result in an uncontained engine failure and damage to the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved the technical content of JT8D Alert Service Bulletin (ASB) JT8D A6336, Revision 1, dated June 29, 1999, that lists the serial numbers (SN's) of certain 2nd stage compressor disks, P/N 745902, P/N 790832, and P/N 807502, and describes procedures replacing the disk if it is listed by SN in the ASB.

Explanation of Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, this AD is being proposed to prevent rupture of the 2nd stage compressor disk caused by machining damage, which could result in an uncontained engine failure and damage to the airplane. This proposed AD would require removal of 2nd stage compressor disks, P/N 745902, P/N 790832, and P/N 807502, before accumulating 2,000 cycles-since-new if the SN is listed in the ASB. The compliance time was established based on the safety concerns and the life management analysis. The actions would be required to be accomplished in accordance with the ASB described previously.

Cost Impact

There are approximately 110 engines of the affected design in the worldwide fleet. The FAA estimates that 60 engines, installed on airplanes of U.S. registry, would be affected by this proposed AD, that it would take approximately 48 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. The prorated cost of the unusable life of a 2nd stage disk is $30,000. The manufacturer has informed the FAA that it may pay the cost of the disk, which may lower the cost to operators. Based on these figures, the FAA estimates the total cost impact of the proposed AD on U.S. operators to be $1,972,800.

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:

Pratt & Whitney: Docket No. 98–ANE–71-AD.

Applicability: JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A,–11, –15, –15A, –17, –17A, –17R, and –17AR series turbofan engines with 2nd stage compressor disks, part number (P/N) 745902, P/N 790832, and P/N 807502, installed. These engines are installed on, but not limited to Boeing 727 series airplanes, Boeing 737–100 and –200 series airplanes and McDonnell Douglas DC–9 series airplanes.

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 (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: Required as indicated, unless accomplished previously.

To prevent a rupture of the 2nd stage compressor disk, caused by machining damage, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

Removal of Disk

(a) Remove from service 2nd stage compressor disks, P/N 745902, P/N 790832, and P/N 807502, identified by serial number in the Accomplishment Instructions of JT8D Alert Service Bulletin (ASB) JT8D A6336, Revision 1, dated June 29, 1999, prior to accumulating 2,000 cycles since new.

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

Issued in Burlington, Massachusetts, on December 5, 2000.

Diane S. Romanosky,

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

[FR Doc. 00–31614 Filed 12–11–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 660

[Docket No. 00N–1586]

Revision to Requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations applicable to microbiological controls for licensed Anti-Human Globulin (AHG) and Blood Grouping Reagents (BGR). FDA is proposing to remove the requirements that the products be sterile. FDA is taking this action because the requirement that these products be sterile is not necessary for the products to be safe, pure, and potent. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. FDA is taking this action final because the proposed changes are noncontroversial and FDA anticipates that it will receive no significant adverse comment.

DATES: Submit written comments on or before February 26, 2001.

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.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment.

An adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not subjects of significant adverse comments.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on