

Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. NCUA has determined that the proposed amendment does not constitute a significant regulatory action for the purposes of the Executive Order.

List of Subjects in 12 CFR Part 701

Credit unions, Senior executive officials.

By the National Credit Union Administration Board on October 26, 1998.

Becky Baker,

Secretary of the Board.

For the reasons set forth in the preamble, it is proposed that 12 CFR part 701 be amended as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, and 1789. Section 701.6 is also authorized by 31 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 et seq., 42 U.S.C. 1861 and 42 U.S.C. 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

2. Section 701.14 is amended as follows:

- a. Revise the introductory text of paragraph (b)(3) and add paragraph (b)(4).
- b. Revise paragraph (c)(2).
- c. Amend paragraph (d)(1) by adding two new sentences after the first sentence and by removing the last three sentences and adding five sentences.

The revisions and additions to § 701.14 read as follows:

§ 701.14 Change in official or senior executive officer in credit unions that are newly chartered or are in troubled condition.

* * * * *

(b) * * *

(3) Except as provided in paragraph (4) of this section for corporate credit unions, “troubled condition” means any insured credit union that has one or a combination of the following conditions:

* * * * *

(4) In the case of a corporate credit union, *troubled condition* means any insured corporate credit union that has one or a combination of the following conditions:

(i) Has been assigned:

(A) A 4 or 5 Corporate Risk Information System (CRIS) rating in either the Financial Risk or Risk Management composites by NCUA for a federal corporate credit union, or

(B) An equivalent 4 or 5 CAMEL composite rating by the state supervisor in the case of a federally insured, state-chartered corporate credit union, or an equivalent 4 or 5 CRIS rating in either the Financial Risk or Risk Management composites by the state supervisor in the case of a federally insured, state-chartered corporate credit union in those states that have adopted the CRIS system, or

(C) A 4 or 5 CRIS rating in either the Financial Risk or Risk Management composites by NCUA based on core workpapers received from the state supervisor in the case of a federally insured, state-chartered credit union in a state that does not use either the CAMEL or CRIS systems. In this case, the state supervisor will be notified in writing by the Director of the Office of Corporate Credit Unions that the corporate credit union has been designated by NCUA as a troubled institution;

* * * * *

(c) * * *

(2) The credit union meets the definition of troubled condition as set forth in paragraph (b) (3) or (4) of this section.

* * * * *

(d) *Procedures for notice of proposed change in official or senior executive officer.—*(1) *Filing and acceptance.*

* * * In the case of a corporate credit union, notice shall be filed with the Director of the Office of Corporate Credit Unions. Additional references herein to Regional Director will, for corporate credit unions, mean the Director of the Office of Corporate Credit Unions. * * * Within ten business days the Regional Director will review the notice and determine whether the notice is complete. If the notice is not complete, the Regional Director can request additional information. The credit union will receive written notification of the date that the notice is deemed complete and ready for processing. Within 30 calendar days from the date a notice is deemed complete, the Regional Director will send a written notification to the individual and the credit union of disapproval or approval of the proposed official or employee. If the Regional Director fails to issue a written notification within 30 calendar days, the

individual is considered approved and service may begin.

* * * * *

[FR Doc. 98–29196 Filed 11–4–98; 8:45 am]

BILLING CODE 7535–01–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–66–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney PW4000 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This proposal would require revisions to the Time Limits Section (TLS) of the manufacturer’s Engine Manuals (EMs) for Pratt & Whitney (PW) PW4000 series turbofan engines to include required enhanced inspection of selected critical life-limited parts at each piece-part exposure. This proposal would also require an air carrier’s approved continuous airworthiness maintenance program to incorporate these inspection procedures. Air carriers with an approved continuous airworthiness maintenance program would be allowed to either maintain the records showing the current status of the inspections using the record keeping system specified in the air carrier’s maintenance manual, or establish an acceptable alternate method of record keeping. This proposal is prompted by an FAA study of in-service events involving uncontained failures of critical rotating engine parts which indicated the need for improved inspections. The improved inspections are needed to identify those critical rotating parts with conditions, that if allowed to continue in service, could result in uncontained failures. The actions specified by this proposed AD are intended to prevent critical life-limited rotating engine part failure, which could result in an uncontained engine failure and damage to the airplane.

DATES: Comments must be received by February 3, 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–66–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.dot.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.

FOR FURTHER INFORMATION CONTACT:

Peter White, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7128, 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-66-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-66-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

Discussion

A recent FAA study analyzing 15 years of accident data for transport

category airplanes identified several failure mode root causes that can result in serious safety hazards to transport category airplanes. This study identified uncontained failure of critical life-limited rotating engine parts as the leading engine-related safety hazard to airplanes. Uncontained engine failures have resulted from undetected cracks in rotating parts that initiated and propagated to failure. Cracks can originate from causes such as unintended excessive stress from the original design, or they may initiate from stresses induced from material flaws, handling damage, or damage from machining operations. The failure of rotating parts can present a significant safety hazard to the airplanes by release of high energy fragments that could injure passengers or crew by penetration of the cabin, damage flight control surfaces, sever flammable fluid lines, or otherwise compromise the airworthiness of the airplane.

Accordingly, the FAA has developed an intervention strategy to significantly reduce uncontained engine failures. This intervention strategy was developed after consultation with industry and will be used as a model for future initiatives. This intervention strategy is to conduct enhanced, nondestructive inspections of fan disks which could most likely result in a safety hazard to the airplane in the event of a disk fracture. The need for additional rule making is also being considered by the FAA. Future ADs may be issued introducing additional intervention strategies to further reduce or eliminate uncontained engine failures.

Properly focused enhanced inspections require identification of the parts whose failure presents the highest safety hazard to the airplane, identifying the most critical features to inspect on these parts, and utilizing inspection procedures and techniques that improve crack detection. The FAA, with close cooperation of the engine manufacturers, has completed a detailed analysis that identifies the most safety significant parts and features, and the most appropriate inspection methods.

Critical life-limited high energy rotating parts are currently subject to some form of recommended crack inspection when exposed during engine maintenance or disassembly. As a result of this AD, the inspections currently recommended by the manufacturer will become mandatory for those parts listed in the compliance section. Furthermore, the FAA intends that additional mandatory enhanced inspections resulting from this AD serve as an adjunct to the existing inspections. The

FAA has determined that the enhanced inspections will significantly improve the probability of crack detection while the parts are disassembled during maintenance. All mandatory inspections must be conducted in accordance with detailed inspection procedures prescribed in the manufacturer's Engine Cleaning, Inspection, and Repair (CIR) manuals.

Additionally, this AD allows for air carriers operating under the provisions of 14 CFR part 121 with an FAA-approved continuous airworthiness maintenance program, and entities with whom those air carriers make arrangements to perform this maintenance, to verify performance of the enhanced inspections by retaining the maintenance records that include the inspections resulting from this AD, provided that the records include the date and signature of the person performing the maintenance action. These records must be retained with the maintenance records of the part, engine module, or engine until the task is repeated. This will establish a method of record preservation and retrieval typical to those in existing continuous airworthiness maintenance programs. Instructions must be included in an air carrier's maintenance manual providing procedures on how this record preservation and retrieval system will be implemented and integrated into the air carrier's record keeping system.

For engines or engine modules that are approved for return to service by an authorized FAA-certificated entity and that are acquired by an operator after the effective date of this AD, the mandatory enhanced inspections need not be accomplished until the next piece-part opportunity. For example, there is no need for an operator to disassemble to piece-part level an engine or module returned to service by an FAA-certificated facility simply because that engine or module was previously operated by an entity not required to comply with this AD. Furthermore, the FAA intends for operators to perform the enhanced inspections of these parts at the next piece-part opportunity following the initial acquisition, installation, and removal of the part following the effective date of this AD. For piece parts that have not been approved for return to service prior to the effective date of this AD, the FAA does intend that the mandatory enhanced inspections required by this AD be performed before such parts are approved for return to service. Piece parts that have been approved for return to service prior to the effective date of this AD may be installed; however,

enhanced inspection will be required at the next piece-part opportunity.

This proposal would require, within the next 30 days after the effective date of this AD, revisions to the Time Limits Section (TLS) of the Engine Manuals for PW4000 series turbofan engines, and, for air carriers, the approved continuous airworthiness maintenance program. Pratt & Whitney, the manufacturer of PW4000 series turbofan engines, used on 14 CFR part 25 airplanes has provided the FAA with a detailed proposal that identifies and prioritizes the critical life-limited rotating engine parts with the highest potential to hazard the airplane in the event of failure, along with instructions for enhanced, focused inspection methods. The enhanced inspections resulting from this AD will be conducted at piece-part opportunity, as defined below in the compliance section, rather than specific time inspection intervals.

There are approximately 1,900 engines of the affected design in the worldwide fleet. The FAA estimates that 450 engines installed on airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 8 work hours for the fan disk inspection. The average labor rate is \$60 per work hour. Based on these figures, and using recent shop visit rate data, the total cost impact of the proposed AD on U.S. operators is estimated to be \$70,000 per year.

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:

Pratt & Whitney: Docket 98-ANE-66-AD.

Applicability: Pratt & Whitney PW4050, PW4052, PW4056, PW4060, PW4060A, PW4062, PW4060C, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, PW4164, PW4168, PW4074, PW4074D, PW4077, PW4077D, PW4084,

PW4084D, and PW4090 series turbofan engines, installed on but not limited to Airbus A300, A310, and A330 series, Boeing 747, 767, 777 series, and McDonnell Douglas MD-11 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 (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 critical life-limited rotating engine part failure, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

(a) Within the next 30 days after the effective date of this AD, revise the manufacturer's Time Limits section of the manufacturer's Engine Manual, Part Numbers (P/Ns) 50A605, 50A443, 51A342, 50A822, 51A751, and 51A345, as applicable, for Pratt & Whitney PW4050, PW4052, PW4056, PW4060, PW4060A, PW4062, PW4060C, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, PW4164, PW4168, PW4074, PW4074D, PW4077, PW4077D, PW4084, PW4084D, and PW4090 series turbofan engines, and for air carrier operations revise the approved continuous airworthiness maintenance program, by adding the following:

"MANDATORY INSPECTIONS

(1) Perform inspections of the following parts at each piece-part opportunity in accordance with the instructions provided in the PW4000 series Engine Cleaning, Inspection, and Repair (CIR) Manuals:

Part nomen	P/N	Manual section	Inspection	CIR manual
Hub, LPC Assembly	50B221 (50B201 Detail)	72-31-07	02	51A357
Hub, LPC Assembly	50B321 (50B301 Detail)	72-31-07	02	51A357
Hub, LPC Assembly	51B321 (51B301 Detail)	72-31-07	02	51A357
Hub, LPC Assembly	52B021 (52B001 Detail)	72-31-07	02	51A357
Hub, LPC Assembly	51B631 (50B601 Detail)	72-31-07	02	51A750
Hub, LPC Assembly	51B821 (51B801 Detail)	72-31-07	02	51A750
Hub, LPC Assembly	52B521 (52B501 Detail)	72-31-07	02	51A750

(2) For the purposes of these mandatory inspections, *piece-part opportunity* means:

(i) The part is considered completely disassembled when done in accordance with the disassembly instructions in the

engine manufacturer's Engine Manual; and

(ii) The part has accumulated more than 100 cycles in service since the last piece-part opportunity inspection, provided that the part was not damaged

or related to the cause for its removal from the engine."

(b) Except as provided in paragraph (c) of this AD, and notwithstanding contrary provisions in section 43.16 of the Federal Aviation Regulations (14 CFR 43.16), these mandatory inspections shall be performed only in accordance with the Time Limits

section of the applicable PW4000 series Engine Manuals.

(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 Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector (PMI), who may add comments and then send it to the 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 airplane to a location where the requirements of this AD can be accomplished.

(e) The records of the mandatory inspections required as a result of revising the Time Limits section of the PW4000 series Engine Manuals and the air carrier's continuous airworthiness maintenance program as provided by paragraph (a) of this AD shall be maintained by FAA-certificated air carriers which have an approved continuous airworthiness maintenance program in accordance with the record keeping system currently specified in their manual required by sections 121.369 of the Federal Aviation Regulations (14 CFR 121.369); or, in lieu of the record showing the current status of each mandatory inspection required by sections 121.380(a)(2)(vi) of the Federal Aviation Regulations (14 CFR 121.380(a)(2)(vi)), certificated air carriers may establish an approved alternate system of record retention that provides a method for preservation and retrieval of the maintenance records that include the inspections resulting from this AD, and include the policy and procedures for implementing this alternate method in the air carrier's maintenance manual required by sections 121.369 (c) of the Federal Aviation Regulations (14 CFR 121.369 (c)); however, the alternate system must be accepted by the appropriate PMI and require the maintenance records be maintained either indefinitely or until the work is repeated.

Note 3: These record keeping requirements apply only to the records used to document the mandatory inspections required as a result of revising the Time Limits section of the PW4000 series Engine Manuals as provided in paragraph (a) of this AD, and do not alter or amend the record keeping requirements for any other AD or regulatory requirement.

Issued in Burlington, Massachusetts, on October 30, 1998.

David A. Downey,

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

[FR Doc. 98-29603 Filed 11-4-98; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 314, and 600

[Docket No. 98N-0750]

RIN 0910-AB42

Electronic Reporting of Postmarketing Adverse Drug Reactions; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering preparing a proposed rule that would require applicants, manufacturers, packers, and distributors of marketed human drugs and licensed biological products to submit postmarketing expedited individual case safety reports and individual case safety reports contained in periodic safety reports to the agency electronically using standardized medical terminology, data elements, and electronic transmission standards recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The proposed rule would help harmonize reporting of postmarketing safety information worldwide and expedite detection of safety problems for marketed drugs, thus enhancing FDA's ability to protect and promote public health. FDA is soliciting comments from interested persons to assist with the development of the proposed rule. The agency is specifically seeking comments on whether exemptions from any electronic safety reporting requirements should be granted to any entity and, if so, the basis on which they should be granted, the cost benefits or burdens of such requirements, and timeframes for implementing the requirements.

DATES: Written information and comments by February 3, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD-7), 5600 Fishers Lane, Rockville, MD 20857, 301-594-5621 (Internet electronic mail: kuchenberg@cder.fda.gov) or Marcel Salive, Center for Biologics Evaluation

and Research (HFM-220), 1401 Rockville Pike, Rockville, MD 20852, 301-827-3974 (Internet electronic mail: salive@cber.fda.gov).

SUPPLEMENTARY INFORMATION:

I. Background

A. International Harmonization

For several years, FDA has cooperated with industry associations and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through ICH, which is facilitating the harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are: the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research at FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization (WHO), the Canadian Therapeutic Products Directorate, and the European Free Trade Area.

One ICH initiative is to harmonize certain safety reporting requirements of the three regions. Through the ICH process, recommendations have been developed regarding the content, format, and reporting frequency for expedited individual case safety reports and periodic safety reports for human drugs and biological products. In the **Federal Register** of March 1, 1995 (60 FR 11284), FDA published an ICH final guidance entitled "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting" (the ICH E2A guidance). In the **Federal Register** of May 19, 1997 (62 FR 27470), FDA published an ICH final guidance entitled "Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs" (the ICH E2C guidance). Under the auspices of ICH, standards for electronic submission of safety information have been developed, as described in the Appendices, including a standard