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.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 a new airworthiness directive to read as follows:

2001–25–04 Honeywell International Inc.: Amendment 39–12557. Docket No. 99–NE–17–AD.

Applicability

This airworthiness directive (AD) is applicable to Honeywell International Inc. (formerly AlliedSignal Inc. and Textron Lycoming) Models LTS101–6000A–2 and LTS101–600A–3 turboshaft engines; and LTP101–600A–1A and LTP101–700A–1A turboprop engines with fuel controls with the following part numbers (P/N's) installed:

TABLE 1.—FUEL CONTROL P/N'S

Engine Model No.	Fuel Control P/N
LTS101–600A–2	4–301–098–01, 4–301–098–04, 4–301–098–10, 4–301–098–15.
LTS101–600A–3	4–301–288–01, 4–301–288–04.
LTP101–600A–1A	4–303–023–01, 4–303–023–02, 4–303–023–03, 4–303–023–04.
LTP101–700A–1A	4–303–033–01, 4–303–033–02, 4–303–033–04.

These engines are used on, but not limited to, Aerospatiale AS350 helicopters and Air Tractor AT–302, Page Thrush, Piaggio P.166–DL3, and Riley International R421 airplanes.

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 at the next replacement of the fuel control or within 12 calendar months after the effective date of this AD, whichever occurs first.

To prevent the engine from reducing the fuel flow to minimum flow resulting in an uncommanded power loss:

(a) Remove any fuel control that has one of the P/N's listed in Table 1 of this AD, and replace with a fuel control that does not have one of the part numbers listed in Table 1 of this AD.

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, Los Angles Aircraft Certification Office (LAACO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, LAACO.

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

Special Flight Permits

(c) Special flight permits may be issued in accordance §§ 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.

Effective Date

(d) This amendment becomes effective on January 23, 2002.

Issued in Burlington, Massachusetts, on December 7, 2001.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–30951 Filed 12–18–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NE–46–AD; Amendment 39–12558; AD 2001–25–05]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Corporation (Formerly Allison Engine Company) AE 3007 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), that is applicable to Rolls-Royce Corporation (formerly Allison Engine Company) AE 3007 series turbofan engines. That AD currently requires removal of certain compressor cone shafts from service before exceeding new cyclic life limits and replacement with serviceable parts. This amendment requires increasing the cyclic life limit for certain serial numbers of new compressor cone shafts, part number (P/N) 23070729, that are used on AE3007A1/3 and AE3007A1P engines. This amendment is prompted by recent approved changes in engineering and manufacturing processes for new compressor cone shafts P/N 23070729. The actions specified by this AD are intended to prevent low-cycle fatigue (LCF) failure of cone shafts, which could result in an uncontained engine failure and damage to the airplane.

DATES: Effective date January 23, 2002.

ADDRESSES: The information in this AD may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Michael Downs, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, Small Airplane Directorate, 2300 East Devon Avenue, Des Plaines, IL 60018; telephone: (847) 294–7870, fax: (847) 294–7834.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 2000–09–05, Amendment 39–11714 (65 FR 26121, May 5, 2000), which is applicable to Rolls-Royce Corporation (formerly Allison Engine Company) AE 3007 series turbofan engines was published

in the **Federal Register** on May 25, 2001 (66 FR 28850). That action proposed to require increasing the cyclic life limit for certain serial numbers of new compressor cone shafts, part number (P/N) 23070729, that are used on AE3007A1/3 and AE3007A1P engines.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Economic Analysis

There are approximately 598 Rolls-Royce Corporation (formerly Allison Engine Company) AE 3007 series turbofan engines of the affected design in the worldwide fleet. The FAA estimates that 364 engines installed on airplanes of U.S. registry will be affected by this AD, that it will take approximately 150 work hours per engine to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $3,921 per engine. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $4,703,244.

Regulatory Analysis

This final 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 final rule.

For the reasons discussed above, I certify that this action (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 final evaluation has been prepared for this action and it 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.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 removing Amendment 39–11714 (65 FR 26121, May 5, 2000) and by adding a new airworthiness directive, Amendment 39–12558, to read as follows:

2001–25–05 Rolls-Royce Corporation: Amendment 39–12558. Docket No. 99–NE–46–AD. Supersedes AD 2000–09–05, Amendment 39–11714.

Applicability

This airworthiness directive (AD) is applicable to Rolls-Royce Corporation (formerly Allison Engine Company) models AE 3007A, AE 3007A1, AE 3007A1/1, AE 3007A1/2, AE 3007A1/3, AE 3007A1P, and AE 3007C turbofan engines, with compressor cone shafts, part numbers (P/N's) 23050728 and 23070729, installed. These engines are installed on but not limited to EMBRAER EMB–135 and EMB–145 series and Cessna 750 series airplanes.

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 (h) 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 as indicated, unless already done.

To prevent low-cycle fatigue (LCF) failure of cone shafts, which could result in an uncontained engine failure and damage to the airplane, do the following:

(a) For Rolls-Royce Corporation model AE 3007A engines, remove cone shafts from service prior to accumulating 9,500 cycles-since-new (CSN) and replace with serviceable parts.

(b) For Rolls-Royce Corporation model AE 3007C engines, remove cone shafts from service prior to accumulating 14,500 CSN and replace with serviceable parts.

(c) For Roll-Royce Corporation models AE 3007A1, AE 3007A1/1, and AE 3007A1/2 engines, remove cone shafts from service prior to accumulating 7,500 CSN and replace with serviceable parts.

(d) For Rolls-Royce Corporation model AE 3007A1/3 engines:

(1) With compressor cone shafts P/N 23070729, serial number (SN) MM78599, MM78615, MM78632, MM78650, MM78651, MM78652, MM78653, MM78654, MM78655, MM78656, MM78657, MM78658, MM78659, MM78660, MM78661, MM78662, MM78663, MM78665 or higher, remove cone shafts from service prior to accumulating 9,300 CSN and replace with serviceable parts.

(2) With compressor cone shafts P/N 23050728, or P/N 23070729 having other than the S/N's listed in paragraph (d)(1) of this AD, remove cone shafts from service prior to accumulating 3,500 CSN and replace with serviceable parts.

(e) For Rolls-Royce Corporation AE 3007A1P engines:

(1) With compressor cone shafts P/N 23070729, SN MM78599, MM78615, MM78632, MM78650, MM78651, MM78652, MM78653, MM78654, MM78655, MM78656, MM78657, MM78658, MM78659, MM78660, MM78661, MM78662, MM78663, MM78665 or higher, remove cone shafts from service prior to accumulating 7,300 CSN and replace with serviceable parts.

(2) With compressor cone shafts P/N 23050728, or P/N 23070729 having other than the SN's listed in paragraph (e)(1) of this AD, remove cone shafts from service prior to accumulating 2,400 CSN and replace with serviceable parts.

New Life Limits

(f) Paragraphs (a), (b), (c), (d) and (e) of this AD establish new, lower life limits for cone shafts, P/N's 23050728 and 23070729.

(g) Except for the provisions of paragraph (h) of this AD, no cone shafts, P/Ns 23050728 and 23070729, may remain in service exceeding the life limits established in paragraphs (a), (b), (c), (d) and (e) of this AD.

Alternative Methods of Compliance

(h) 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 must 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.

Special Flight Permits

(i) Special flight permits may be issued in accordance §§ 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 done.

Effective Date

(j) This amendment becomes effective on January 23, 2002.

Issued in Burlington, Massachusetts, on December 7, 2001.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–30952 Filed 12–18–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0583]

Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that establishes the notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. These regulations implement recent changes in the statutory requirements applicable to certain exports, and also codify recordkeeping requirements for exports of products that cannot be marketed or sold in the United States generally.

DATES: This rule is effective March 19, 2002.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of April 2, 1999 (64 FR 15994), FDA published a proposed rule to establish notification and recordkeeping requirements for products exported under section 801 or 802 of the Federal Food, Drug, or Cosmetic Act (the act) (21 U.S.C. 381 or 382, respectively) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), as amended by the FDA Export Reform and Enhancement Act (Public Law 104–134, as amended by Public Law 104–180).

The FDA Export Reform and Enhancement Act significantly changed and simplified the export requirements for unapproved human drugs, biological products, devices, and animal drugs. For example, before the law was enacted, most exports of unapproved new drugs could only be made to the 21 countries then identified in section 802 of the act, and these exports were subject to numerous restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new human drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA) and certain other requirements are met (see section 802(b)(1)(A) of the act). Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. (The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.) This provision of section 802 of the act also applies to the export of certain devices that cannot be sold or marketed in the United States.

The FDA Export Reform and Enhancement Act also established recordkeeping and notification requirements. Section 802(g) of the act requires an exporter of a drug or device under section 802(b)(1)(A) of the act to provide a ''simple notification'' to the agency ''identifying the drug or device when the exporter first begins to export such drug or device'' to any of the 25 countries identified in section 802(b)(1)(A) of the act. For exports to other, nonlisted countries, section 802(g) of the act requires the exporter to provide a simple notification ''identifying the drug or device and the country to which such drug or device is being exported.'' This section also requires persons exporting drugs or devices under any provision of section 802 of the act to ''maintain records of all drugs or devices exported and the countries to which they were exported.''

Certain aspects of the proposed rule raised numerous issues. As a result, in the **Federal Register** of June 17, 1999 (64 FR 32442), FDA extended the comment period from June 16, 1999, to July 16, 1999.

FDA received 18 comments on the proposed rule. In addition, the agency received several comments on the export notification and recordkeeping discussions in its draft export guidance document which was published in the **Federal Register** on June 12, 1998 (63 FR 32219, FDA docket number 98D–0307). Drug manufacturers, device manufacturers, device exporters, and food, drug, and device trade associations submitted comments. An animal drug trade association and a biological product company also submitted comments. Because FDA wrote both the proposed rule and the guidance document contemporaneously, the agency considered comments submitted on the proposed rule and related comments submitted on the draft export guidance document when it prepared this final rule.

II. Comments on the Proposed Rule, Including Related Comments Submitted to the Draft Guidance Document

Most comments focused on specific provisions in the proposed rule. However, others made general comments about FDA's export authority or the need for any regulations or addressed other export issues that were not directly related to the proposed rule. A description of the comments, and FDA's responses, follows.

A. General Comments

(Comment 1) Several comments claimed that the proposal was contrary to the letter or intent of the FDA Export Reform and Enhancement Act because it would create ''unnecessary,'' ''cumbersome,'' or ''burdensome'' requirements that would make it more difficult or time-consuming to export products from the United States, place U.S. firms at a competitive disadvantage in global markets, force firms to relocate overseas, or result in lost profits. Some comments said FDA must withdraw the proposal, although others said the agency should significantly revise the proposal to reduce its requirements.

FDA recognizes that the FDA Export Reform and Enhancement Act was designed to facilitate exports of unapproved products from the United States and, through the draft guidance document, proposed rules, and other contacts with individual firms, the agency worked to reduce or eliminate export requirements and facilitate exports. FDA drafted the proposed rule to implement the notification and recordkeeping requirements in section 802 of the act and to establish a single, consistent agency position regarding the types of records it would examine to determine compliance with section