

tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exist for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) Any changes resulting from this rule should be effective as soon as practicable because the Washington potato shipping season began in July; (2) the Committee unanimously recommended these changes at a public meeting and all interested parties had an opportunity to provide input; (3) handlers are aware of this action and want to take advantage of this relaxation as soon as possible; and (4) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 946

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 946 is amended as follows:

PART 946—IRISH POTATOES GROWN IN WASHINGTON

■ 1. The authority citation for 7 CFR part 946 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 946.336, paragraph (c)(1) is revised to read as follows:

§ 946.336 Handling regulation.

* * * * *

(c) *Pack and marking:*

(1) *Domestic:* Potatoes packed in cartons shall be either:

(i) U.S. No. 1 grade or better, except that potatoes which fail to meet the U.S. No. 1 grade only because of internal defects may be shipped without regard to this requirement provided the lot contains no more than 10 percent damage by any internal defect or combination of internal defects but not more than 5 percent serious damage by any internal defect or combination of internal defects.

(ii) U.S. No. 2 grade, provided the cartons are permanently and conspicuously marked as to grade. This marking requirement does not apply to cartons containing potatoes meeting the requirements of (c)(1)(i).

* * * * *

Dated: September 6, 2005.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. 05–17964 Filed 9–9–05; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NE–17–AD; Amendment 39–14265; AD 2005–01–15R1]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc RB211 Trent 875, 877, 884, 884B, 892, 892B, and 895 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is revising an existing airworthiness directive (AD) for Rolls-Royce plc (RR) RB211 Trent 875, 877, 884, 884B, 892, 892B, and 895 series turbofan engines with certain part number (P/N) low pressure compressor (LPC) fan blades installed. That AD currently requires initial and repetitive ultrasonic inspections of the fan blade dovetail roots and defines a specific terminating action to the repetitive blade inspection requirements. This AD requires the same actions but clarifies the terminating action. We are issuing this AD to prevent multiple LPC fan blade failures due to cracks, which could result in uncontained engine failure and possible damage to the airplane.

DATES: This AD becomes effective October 17, 2005. The Director of the Federal Register previously approved the incorporation by reference of certain publications listed in the regulations as of January 28, 2005 (70 FR 2336, January 13, 2005).

ADDRESSES: Contact Rolls-Royce plc, P.O. Box 31, Derby DE24 6BJ, UK; telephone 44 (0) 1332 242424; fax 44 (0) 1332 249936, for the service information identified in this AD.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA. You may examine the service information, 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: On January 3, 2005, we issued AD 2005–01–15, Amendment 39–13940 (70 FR 2336, January 13, 2005). That AD superseded AD 2002–11–08, Amendment 39–12769 (67 FR 38852 June 6, 2002). AD 2005–01–15 requires initial and repetitive ultrasonic inspections of the fan blade dovetail roots, and defines a specific terminating action to the repetitive blade inspection requirements. That AD was the result of a report of a cracked fan blade found before the blade reached the initial inspection threshold of AD 2002–11–08. That AD also reduced the repetitive inspection compliance time due to potential breakdown of blade coating and lubrication on certain blades. Those conditions, if not corrected, could result in uncontained engine failure and possible damage to the airplane.

Actions Since We Issued AD 2005–01–15

Since we issued AD 2005–01–15, we received a comment from an operator requesting that we clarify the terminating action in that AD. As that AD is currently written, you must install LPC fan blades in complete sets to comply with the terminating action. Our intent is that all blades must be replaced with blades that meet the replacement criteria to qualify as terminating action, but not necessarily replaced as a complete set. In response to the comment, we published a proposed AD in the **Federal Register** on March 9, 2005 (70 FR 11585). That action proposed to require initial and repetitive ultrasonic inspections of the fan blade dovetail roots, and to clarify a specific terminating action to the repetitive blade inspection requirements.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We received no comments on the proposal or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 350 RR RB211 Trent 875, 877, 884, 884B, 892, 892B, and 895 series turbofan engines of the affected design in the worldwide fleet. We estimate that 90 engines installed on airplanes of U.S. registry will be affected by this AD. We also estimate that it would take about 8 work hours per engine to perform the inspections, and about 260 work hours per engine to perform the terminating action. The average labor rate is \$65 per work hour. Based on these figures, we estimate the total cost of the AD to U.S. operators to be \$1,567,800.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
- (3) 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.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2001-NE-17-AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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. The FAA amends § 39.13 by removing Amendment 39-13940 (70 FR 2336, January 13, 2005), and by adding the following new airworthiness directive, Amendment 39-14265:

2005-01-15R1 Rolls-Royce plc:

Amendment 39-14265. Docket No. 2001-NE-17-AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective October 17, 2005.

Affected ADs

(b) This AD revises AD 2005-01-15, Amendment 39-13940.

Applicability: (c) This AD applies to Rolls-Royce plc (RR) RB211 Trent 875, 877, 884, 884B, 892, 892B, and 895 series turbofan engines with low pressure compressor (LPC) fan blades, part numbers (P/Ns) FK30838, FK30840, FK30842, FW12960, FW12961, FW12962, and FW13175, installed. These engines are installed on, but not limited to, Boeing Company 777 series airplanes.

Unsafe Condition

(d) This AD revision results from a request by an operator to clarify the terminating action in AD 2005-01-15. We are issuing this AD to prevent multiple LPC fan blade failures due to cracks, which could result in uncontained engine failure and possible damage to the airplane.

Compliance: (e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

(f) Ultrasonic-inspect and disposition the dovetail roots of LPC fan blades, P/Ns FK30838, FK30840, FK30842, FW12960, FW12961, FW12962, and FW13175, that are removed from the engine, using 3.A.(1) through 3.A.(5) or, for blades that are not removed from the engine, using 3.B.(1) through 3.B.(5) of the Accomplishment Instructions of RR Alert Service Bulletin (ASB) No. RB.211-72-AD344, Revision 7, dated March 12, 2004, as follows:

(1) For blades P/Ns FK30838, FK30840, and FK30842, that have not been relubricated during any interval exceeding 600 cycles-since-new (CSN) or 600 cycles-since-rework (CSR) using either RR ASB No. RB.211-72-AD344 or Service Bulletin (SB) No. RB.211-72-D347, inspect as specified in paragraph (f) of this AD and within the compliance times specified in the following Table 1:

TABLE 1.—COMPLIANCE TIMES FOR BLADES P/Ns FK30838, FK30840, AND FK30842

Engine series	Boeing 777 series	Airplane maximum gross weight (times 1,000 pounds)	Initial inspection CSN	Repetitive inspection (cycles-since-last-inspection) (CSLI)
(i) -884B, -892	-300	(A) 660 and 632.5	600	80
		(B) 580	2,000	600
(ii) -884, 884, -892, -892B, and -895	-200	(A) 632.5 and 648	1,200	100
		(B) 656	600	80
		(C) 555	2,000	600
(iii) -875	-200	535	2,000	600
(iv) -877	-200	545	2,000	600

(2) For blades P/Ns FK30838, FK30840, and FK30842, that have been relubricated at intervals not exceeding 600 CSN or 600 CSR

using either RR ASB No. RB.211-72-AD344 or SB No. RB.211-72-D347, inspect as specified in paragraph (f) of this AD and

within the compliance times specified in the following Table 2:

TABLE 2.—COMPLIANCE TIMES FOR BLADES P/Ns FK30838, FK30840, AND FK30842

Engine series	Boeing 777 series	Airplane maximum gross weight (times 1,000 pounds)	Initial inspection CSN	Repetitive inspection CSLI
(i) -884B, 892	-300	(A) 660 and 632.5	600	80

TABLE 2.—COMPLIANCE TIMES FOR BLADES P/Ns FK30838, FK30840, AND FK30842—Continued

Engine series	Boeing 777 series	Airplane maximum gross weight (times 1,000 pounds)	Initial inspection CSN	Repetitive inspection CSLI
(ii) -884, -892, -892B, and -895	-200	(B) 580 (A) 632.5 and 648 (B) 656 (C) 555	2,400 1,200 600 2,400	600 100 80 600
(iii) -875	-200	535	2,400	600
(iv) -877	-200	545	2,400	600

(3) For blades P/Ns FW12960, FW12961, FW12962, and FW13175, either new or reworked to that configuration at greater than 600 CSN or since previous rework, or that

have not been relubricated during any interval exceeding 600 CSN or 600 CSR using either RR ASB No. RB.211-72-AD344 or SB No. RB.211-72-D347 requirements, inspect

as specified in paragraph (f) of this AD and within the compliance times specified in the following

TABLE 3.—COMPLIANCE TIMES FOR BLADES P/Ns FW12960, FW12961, FW12962, AND FW13175

Engine series	Boeing 777 series	Airplane maximum gross weight (times 1,000 pounds)	Initial inspection CSN	Repetitive inspection CSLI
(i) -884B, -892	-300	(A) 660 and 632.5 (B) 580	600 2,000	100 600
(ii) -884B, -892, -892B, and -895	-200	(A) 632.5 and 648 (B) 656 (C) 555	1,200 600 2,000	125 100 600
(iii) -875	-200	535	2,000	600
(iii) -877	-200	545	2,000	600

(4) For blades P/Ns FW12960, FW12961, FW12962, and FW13175, either new or reworked to that configuration at fewer than 600 CSN or since previous rework, and that

have been relubricated at intervals not exceeding 600 CSN using either RR ASB No. RB.211-72-AD344 or SB No. RB.211-72-D347, inspect as specified in paragraph (f) of

this AD and within the compliance times specified in the following Table 4:

TABLE 4.—COMPLIANCE TIMES FOR BLADES P/Ns FW12960, FW12961, FW12962, AND FW13175

Engine series	Boeing 777 series	Airplane maximum gross weight (times 1,000 pounds)	Initial inspection CSN	Repetitive inspection CSLI
(i) -884B, -892	-300	(A) 660 and 632.5 (B) 580	600 2,400	100 1,200
(ii) -884, -892, -892B, and -895	-200	(A) 632.5 and 648 (B) 656 (C) 555	2,400 600 2,400	125 100 1,200
(iii) -875	-200	535	2,400	1,200
(iv) -877	-200	545	2,400	600

(g) When engines containing blades P/Ns FK30838, FK30840, FK30842, FW12960, FW12961, FW12962, and FW13175 are moved from one gross weight category to another, the inspection schedule that is applicable to the higher gross weight category must be used.

Terminating Action

(h) As terminating action to the repetitive inspection requirements of this AD, at the next shop visit when the LPC fan blades are removed for repair or overhaul, but no later than December 31, 2009:

(1) Replace LPC fan blades P/Ns FK30838, FK30840, FK30842, FW12960, FW12961, FW12962, or FW13175, with serviceable LPC fan blades.

(2) For the purposes of this AD, serviceable LPC fan blades are blades that feature additional blade root processing

requirements found in RR SB No. RB.211-72-D672, dated February 1, 2002; or are LPC fan blades that feature a full form root profile. Information on full form root profile blades can be found in RR SB No. RB.211-72-D390, RR SB No. RB.211-72-E044, and RR SB No. RB.211-72-E382.

Previous Credit

(i) Previous credit is allowed for initial inspections of fan blades that were done using RR ASB No. RB.211-72-AD344, Revision 4, dated March 15, 2002, Revision 5, dated June 20, 2003, Revision 6, dated February 27, 2004, or Revision 7, dated March 12, 2004, before the effective date of this AD.

Alternative Methods of Compliance

(j) The Manager, Engine Certification Office, has the authority to approve

alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(k) You must use the Rolls-Royce plc service information specified in Table 5 of this AD to perform the blade inspections and replacements required by this AD. The Director of the **Federal Register** approved the incorporation by reference of the documents listed in Table 5 of this AD as of January 28, 2005 (70 FR 2336, January 13, 2005). You can get a copy from Rolls-Royce plc, P.O. Box 31, Derby DE24 6BJ, UK; telephone 44 (0) 1332 242424; fax 44 (0) 1332 249936. You may review copies at the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001-NE-17-AD, 12 New England Executive Park, Burlington, MA; or at the National Archives

and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go

to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Table 5 follows:

TABLE 5.—INCORPORATION BY REFERENCE

Service Bulletin No.	Page	Revision	Date
RB.211-72-AD344 Total Pages: 11	All	7	March 12, 2004.
RB.211-72-AD344, Appendices 1 through 5 Total Pages: 18	All	7	March 12, 2004.
RB.211-72-D672 Total Pages: 24	All	Original	February 1, 2002.

Related Information

(l) Civil Aviation Authority (CAA) airworthiness directive G-2004-0008, dated April 29, 2004, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on September 6, 2005.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.
[FR Doc. 05-17976 Filed 9-9-05; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2005D-0356]

Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Questions and Answers Regarding Establishment and Maintenance of Records.” The guidance responds to various questions raised about the recordkeeping provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency’s implementing regulation, which requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled “Questions and Answers Regarding Establishment and Maintenance of Records” to Denise Beavers (see **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Beavers, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1721.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act (21 U.S.C. 350c). The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation are required to be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business.

The guidance for industry entitled “Questions and Answers Regarding Establishment and Maintenance of Records” responds to questions about the final rule on records. It is intended to help industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a level 1 guidance. The guidance represents the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

public. Consistent with FDA’s good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115(g)(2)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, the final rule requires that covered persons begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and ensure complete implementation of the final rule.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning establishment and maintenance of records in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any