

Aerospatiale Modification 01392 has not been installed, certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes 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 reduced structural integrity of the airplane resulting from fatigue cracking of the windshield frame structure, accomplish the following:

(a) Prior to the accumulation of 24,000 total flight cycles, or within 60 days after the effective date of this AD, whichever occurs later: Inspect to detect cracking of the windshield frame structure in accordance with Operation Description (B—Inspection) of the Accomplishment Instructions of Aerospatiale Service Bulletin ATR42-53-

0093, Revision 1, or ATR42-53-0094, Revision 2, both dated February 19, 1996.

(1) If the inspection reveals no crack, or reveals cracking that does not exceed the specifications listed in Figure 6, Sheet 1, of Service Bulletin ATR42-53-0093, Revision 1, dated February 19, 1996: Prior to further flight, modify the windshield frame structure in accordance with either service bulletin.

(2) If the inspection reveals any crack that exceeds the specifications in Figure 6, Sheet 1, of Service Bulletin ATR42-53-0093, Revision 1, dated February 19, 1996, but does not exceed the cut-out areas specified in Figure 7, Sheet 1, of Service Bulletin ATR42-53-0094, Revision 2, dated February 19, 1996: Prior to further flight, modify the windshield frame structure in accordance with Service Bulletin 42-53-0094, Revision 2, dated February 19, 1996.

(3) If the inspection reveals any crack that exceeds the cut-out areas specified in Figure 7, Sheet 1, of Service Bulletin ATR42-53-0094, Revision 2, dated February 19, 1996: Prior to further flight, modify the windshield frame structure in accordance with a method approved by the Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate.

**Note 2:** Accomplishment of the modifications specified in ATR Service Bulletin ATR42-53-0093, Revision 1, or ATR42-53-0094, Revision 2, both dated

February 19, 1996, is not equivalent to accomplishment of Aerospatiale Modification 01392. Therefore the ATR42 Time Limits Document inspection items with "PRE MOD 1392" effectivity are still applicable for airplanes modified by either of the previously described service bulletins.

(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, International Branch, ANM-116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

(c) 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.

(d) The actions shall be done in accordance with the following Aerospatiale Service Bulletins, which contain the specified effective pages:

Service bulletin referenced and date	Page number shown on page	Revision level shown on page	Date shown on page
ATR42-53-0093, Revision 1, February 19, 1996 .....	1-4, 13 .....	1 .....	February 19, 1996.
	5-12, 14-41 .....	Original .....	April 26, 1995.
ATR42-53-0094, Revision 2, February 19, 1996 .....	1, 2, 8, 9, 16, 18, 39, 40, 48, 53, 54 .....	2 .....	February 19, 1996.
	3, 4, 7, 10-15, 17, 19-24, 26, 27, 29-32, 34-38, 47, 55, 56.	1 .....	May 29, 1995.
	5, 6, 25, 28, 33, 41-46, 49-52 .....	Original .....	April 24, 1995

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Note 4:** The subject of this AD is addressed in French airworthiness directive 95-126-061(B), dated June 21, 1995.

(e) This amendment becomes effective on June 3, 1998.

Issued in Renton, Washington, on April 21, 1998.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 98-11068 Filed 4-28-98; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 96-NM-59-AD; Amendment 39-10504; AD 98-09-23]

RIN 2120-AA64

#### Airworthiness Directives; Lockheed Model L-1011 Series Airplanes Equipped With Rolls Royce Model RB211-22B Engines

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD), applicable to certain Lockheed Model L-1011 series airplanes, that currently requires various modifications and corrective actions to prevent a potential fire hazard caused by heat damage to the flex fuel feed line from an undetected

gearbox fire. In lieu of the various modifications and corrective actions, that AD also provides for an optional terminating action (i.e., installation of a vent air tube in the gear compartment and thickened gearbox housings) for another existing AD. For airplanes on which that optional terminating action has been accomplished, this amendment requires accomplishment of the various modifications and corrective actions. This amendment is prompted by a report indicating that, due to bearing failure, an in-flight fire occurred on an airplane on which a thickened gearbox housing was installed. The actions specified by this AD are intended to detect and correct bearing failure, which could lead to a fire in the gearbox.

**DATES:** Effective June 3, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 3, 1998.

**ADDRESSES:** The service information referenced in this AD may be obtained from Lockheed Aeronautical Systems Support Company (LASSC), Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30080. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Thomas B. Peters, Aerospace Engineer, Systems and Flight Test Branch, ACE-116A, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone (770) 703-6063; fax (770) 703-6097.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 87-07-10, amendment 39-5597 (52 FR 10736, April 3, 1987), which is applicable to certain Lockheed Model L-1011 series airplanes, equipped with Rolls Royce Model RB211-22B engines, was published in the **Federal Register** on July 18, 1997 (62 FR 38491). That action proposed to continue to require various modifications and corrective actions to prevent a potential fire hazard caused by heat damage to the flex fuel feed line from an undetected gearbox fire. In lieu of the various modifications and corrective actions, that action also provided for an optional terminating action (i.e., installation of a vent air tube in the gear compartment and thickened gearbox housings) for another existing AD. For airplanes on which the optional terminating action has been accomplished, that action proposed to require accomplishment of the various modifications and corrective actions.

#### Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposed rule.

The Air Transport Association (ATA) of America, on behalf of one of its members, requests that any alternative method of compliance approved

previously for compliance with paragraphs (a) and (b) of AD 87-07-10 be approved as an alternative method of compliance for this proposed AD. The FAA concurs with the commenter's request. Paragraph (e) of this final rule has been revised to indicate that any approval of an alternative method of compliance that was granted previously for AD 87-07-10 is approved as an alternative method of compliance with the requirements of paragraphs (a) and (b) of this AD.

The ATA, on behalf of another commenter, states that the proposed AD is unnecessary. The commenter notes that the proposal is somewhat redundant in that it only eliminates an alternative method of compliance with AD 87-07-10. The commenter further states that neither AD 87-07-10 nor the proposed AD does anything to address the basic problem, which is failure of accessory gearbox bearings. According to the commenter, several enhancements have been made over the years to prevent bearing failures, which, if unnoticed by available monitoring methods (chip detectors), could result in fires. The commenter believes that proper management of the chip detector monitoring and improvements available to upgrade the accessory gearbox bearings make the proposed AD and contemplated breather temperature sensors unnecessary. Last, the commenter notes that the latest gearbox fires did not occur in an RB211-22B-style gearbox.

The FAA does not concur that issuance of this AD is unnecessary. The commenter is correct in noting that the latest gearbox fires did not occur in an RB211-22B-style gearbox. Rather, fires have occurred in engines with the thicker, RB211-524-style gearbox housings. In light of this more recent service experience, it is evident that the installation of the thicker gearbox housings is not, in itself, sufficient to eliminate the unsafe condition addressed in AD 87-07-10. Therefore, AD 87-07-10 is being superseded to eliminate the installation of those gearbox housings, without further action, as an approved method of compliance.

The commenter is also correct in noting that the basic problem is failure of accessory gearbox bearings. There are, however, no known means to completely eliminate the possibility that such bearings could fail and precipitate fires. It is, therefore, necessary to ensure that any fire that does occur in the gearbox housing can be detected in a timely manner. Compliance with the requirements of this AD will ensure that, in the event such a fire does occur,

the flight crew can take corrective action, i.e., engine shutdown and discharge of the fire suppression system, on a timely basis.

#### Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

#### Cost Impact

There are approximately 130 Lockheed Model L-1011 series airplanes equipped with Rolls Royce Model RB211-22B engines of the affected design in the worldwide fleet. The FAA estimates that 76 airplanes of U.S. registry will be affected by this AD.

The actions that are currently required by AD 87-07-10 take approximately 3 work hours per engine (3 engines per airplane) to accomplish, at an average labor rate of \$60 per work hour. Required parts for Walter Kidde systems will cost approximately \$2,100 per engine. Required parts for Graviner systems will cost approximately \$8,100 per engine. Based on these figures, the cost impact of the installation currently required by AD 87-07-10 on U.S. operators is estimated to be \$6,840 per airplane (for Walter Kidde systems) or \$24,840 per airplane (for Graviner systems).

The required modification will take approximately 6 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$10,000 per airplane. Based on these figures, the cost impact on U.S. operators of the modification required by this AD is estimated to be \$787,360, or \$10,360 per airplane.

The introduction of a vent air tube will take approximately 3 work hours per engine (3 engines per airplane) to accomplish, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$500 per engine. Based on these figures, the cost impact on U.S. operators of the introduction of a vent air tube required by this AD is estimated to be \$155,040, or \$2,040 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

**Regulatory Impact**

The regulations adopted herein will 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, 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 39-5597 (52 FR

10736, April 3, 1987), and by adding a new airworthiness directive (AD), amendment 39-10504, to read as follows:

**98-09-23 Lockheed:** Amendment 39-10504. Docket 96-NM-59-AD. Supersedes AD 87-07-10, Amendment 39-5597.

**Applicability:** Model L-1011 series airplanes equipped with Rolls Royce RB211-22B engines, certificated in any category.

**Note 1:** If an operator has accomplished the requirements of paragraphs (a) and (b) of this AD on any affected airplane and, subsequently, installs a different Model RB211-22B engine on that airplane, the airplane and all installed engines are still subject to the requirements of this AD.

**Note 2:** This AD applies to each airplane 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 airplanes 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 (e) 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 detect and correct bearing failure, which could lead to a fire in the gearbox, accomplish the following:

(a) Within 8,000 flight hours or 30 months after May 8, 1987 (the effective date of AD 87-07-10, amendment 39-5597), whichever occurs first, accomplish the procedures specified in the Accomplishment Instructions of the service bulletins listed in paragraphs (a)(1) and (a)(2) of this AD.

(1) Lockheed Service Bulletin 093-26-036, dated April 1, 1986, *Installation of Fire Detector Segment*; and

(2) Lockheed Service Bulletin 093-71-067, Revision 1, dated April 1, 1986, *Gearbox Breather Duct Modification*.

(b) Within 8,000 flight hours or 30 months after May 8, 1987, whichever occurs first, accomplish the procedures specified in the Accomplishment Instructions of the service

bulletins listed in paragraphs (b)(1) and (b)(2) of this AD.

(1) Rolls Royce Service Bulletin RB.211-72-4666, Revision 3, dated October 14, 1977, *Introduction of Vent Air Tube in Gear Compartment*; and

(2) Rolls Royce Service Bulletin RB.211-72-8138, dated March 21, 1986, *Installation of Additional No. 7 Fire Sensor*.

(c) For airplanes on which Rolls Royce Service Bulletin RB.211-72-4666, Revision 3, dated October 14, 1977, and Rolls Royce Service Bulletin RB.211-72-3878, Revision 3, dated June 25, 1976, have been accomplished in accordance with paragraph C. of AD 87-07-10: Within 48 months or 16,000 flight hours after the effective date of this AD, whichever occurs first, accomplish the actions specified in paragraphs (a) and (b) of this AD.

(d) Accomplishment of the requirements of paragraphs (a) and (b) of this AD; or accomplishment of the requirements of paragraph (c) of this AD; constitutes terminating action for the requirements of AD 85-09-03, amendment 39-5056. The AFM limitations required by AD 85-09-03 may be removed following accomplishment of the terminating action.

(e)(1) 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, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

(2) Alternative methods of compliance, approved previously in accordance with AD 87-07-10, amendment 39-5597, are approved as alternative methods of compliance with paragraphs (a) and (b) of this AD.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(f) 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 airplane to a location where the requirements of this AD can be accomplished.

(g) The actions shall be done in accordance with the following service bulletins, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
Lockheed Service Bulletin 093-26-036, April 1, 1986.	1-7 .....	Original ....	April 1, 1986.
Lockheed Service Bulletin 093-71-067, Revision 1, April 1, 1986.	1-7, 9-11 .....	1 .....	April 1, 1986.
	8 .....	Original ....	February 5, 1986.
Rolls Royce Service Bulletin RB.211-72-8138, March 21, 1986.	1-34 .....	Original ....	March 21, 1986.

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
Rolls Royce Service Bulletin RB.211-72-4666, Revision 3, October 14, 1977.	1 .....	3 .....	October 14, 1977.
	2-6, 6A, 7-10 .....	2 .....	August 26, 1977.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Lockheed Aeronautical Systems Support Company (LASSC), Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30080. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, Suite 450, Atlanta, Georgia 30349; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on June 3, 1998.

Issued in Renton, Washington, on April 21, 1998.

**Gary L. Killion,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 98-11088 Filed 4-28-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 892

[Docket No. 96N-0320]

#### Radiology Devices; Classifications for Five Medical Image Management Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying five radiology devices that provide functions related to medical image communication, storage, processing, and display into class I (general controls) or class II (special controls). The medical image storage device and medical image communications device are classified into class I, and they are exempted from the requirement of premarket notification when they do not use irreversible compression. The medical image digitizer, the medical image hardcopy device, and the picture archiving and communications system are classified into class II. These actions

are being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

**EFFECTIVE DATE:** May 29, 1998.

#### FOR FURTHER INFORMATION CONTACT:

Loren A. Zaremba, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of December 2, 1996 (61 FR 63769), FDA issued a proposed rule to classify five medical image management devices into class I or class II. The medical image storage device and medical image communications device were proposed to be classified into class I, and exempted from the requirement of premarket notification when they do not use irreversible compression. The medical image digitizer, medical image hardcopy device, and picture archiving and communications system were proposed to be classified into class II. FDA provided for interested persons to submit written comments on the proposal by March 3, 1997.

##### II. Response to Comments

The agency received six comments responding to the proposed rule. These comments were submitted by a law firm, two manufacturers of medical image management devices, two medical professional organizations, and a medical device manufacturers' association.

1. One comment expressed concern that exempting medical image storage devices from the requirement of premarket notification would encourage less experienced manufacturers to use the marketplace as a testing ground for their new products. This comment stated that the medical image management industry needs guidance from FDA on material choices, labeling, and quality assurance issues. The comment also suggested that FDA consider adopting minimum standards relating to specifications, device compatibility, lifetime, and labeling.

FDA agrees that the integrity of medical image storage devices is important in health care. The agency does not believe, however, that premarket notification is necessary to ensure the safety and effectiveness of these products. The agency believes that other general controls, particularly the good manufacturing practices requirements (part 820) (21 CFR part 820)), which include controls on production, packaging, labeling, and recordkeeping, are sufficient to provide reasonable assurance of their safety and effectiveness. On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). Section 206(a)(2) of FDAMA added sections 510(l) and 510(m) to the act (21 U.S.C. 360(l) and (m)). Section 510(l) of the act provides that a premarket notification is not required for a class I device, unless the device is intended for a use that is of substantial importance in preventing impairment of human health or the device presents a potential unreasonable risk of illness or injury. Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements if FDA determines that a premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that the medical image storage device and the medical image communications device do not require premarket notifications in accordance with the criteria in section 510(l) of the act. Also, FDA has determined that the medical image digitizer, the medical image hardcopy device, and the picture archiving and communication system require premarket notification in order to provide reasonable assurance of their safety and effectiveness. The class II devices in this rule will be subject to the design control requirements in part 820, while the class I devices will be exempt from the design control requirements in accordance with § 820.30. FDA believes that design controls are not necessary for class I devices in this rule. To provide guidance to the industry, FDA will continue to participate in the activities of voluntary standards organizations in the development of recommendations relating to materials