TABLE 2—COMPLIANCE	TIMES FOR	REDETITIVE	INSPECTION INTERVAL
TABLE Z—COMPLIANCE	LIMES FOR	DEPETITIVE	INSPECTION INTERVAL

Model	Repetitive inspection interval	
A310–203, A310–204, A310-221, and A310–222 airplanes	Within 1,700 flight cycles or 3,500 flight hours, whichever occurs first. Within 1,600 flight cycles or 4,600 flight hours, whichever occurs first.	
'LR' A310-304, A310-322, A310-324, and A310-325 long range airplanes.	Within 1,200 flight cycles or 6,100 flight hours, whichever occurs first.	

- (4) If any crack is found during any inspection required by paragraph (f)(1) or (f)(3) of this AD, before further flight, repair in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A310–57–2096, dated May 6, 2008. Instead, for previously repaired areas, continue the inspection in accordance with the procedures specified in paragraph (g) of this AD.
- (5) After each inspection required by this AD, submit an inspection report in accordance with Airbus Mandatory Service Bulletin A310–57–2096, dated May 6, 2008; at the times specified in paragraphs (f)(5)(i) or (f)(5)(ii) of this AD, as applicable.
- (i) If the inspection was done after the effective date of this AD: Submit the report within 30 days after the inspection.
- (ii) If the inspection was accomplished prior to the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

#### FAA AD Differences

**Note 1:** This AD differs from the MCAI and/or service information as follows: No differences.

#### Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227-2125; fax (425) 227-1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office.

- (2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.
- (3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection

requirements and has assigned OMB Control Number 2120–0056.

#### **Related Information**

(h) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2008– 0211, dated December 4, 2008; and Airbus Mandatory Service Bulletin A310–57–2096, dated May 6, 2008, for related information.

Issued in Renton, Washington, on August 17, 2009.

#### Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–20352 Filed 8–24–09; 8:45 am] **BILLING CODE 4910–13–P** 

#### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 39

[Docket No. FAA-2009-0718; Directorate Identifier 2009-NM-025-AD]

#### RIN 2120-AA64

# Airworthiness Directives; Boeing Model 747 Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for all Boeing Model 747 airplanes. This proposed AD would require one-time detailed and high frequency eddy current inspections for cracks in the wing and horizontal stabilizer side-ofbody joints and the fuselage skin circumferential splices, and repair if necessary. This proposed AD would also require, for certain airplanes, repetitive detailed inspections for cracks of the fuselage skin circumferential splices, and repair if necessary. This proposed AD results from Boeing analysis indicating that the wing and horizontal stabilizer side-of-body joints, and the fuselage skin circumferential splices are susceptible to fatigue cracking due to high cyclic loads on the airplane. We are proposing this AD to detect and correct fatigue cracking at multiple adjacent locations in the subject areas, which could connect to

form large cracks and result in reduced structural integrity leading to rapid decompression and consequent loss of control of the airplane.

**DATES:** We must receive comments on this proposed AD by October 9, 2009. **ADDRESSES:** You may send comments by

any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.
  - Fax: 202-493-2251.
- Mail: U.S. Department of Transportation, Docket Operations, M— 30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M—30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, Washington 98124-2207; telephone 206-544-5000, extension 1, fax 206-766-5680; e-mail me.boecom@boeing.com; Internet https://www.myboeingfleet.com. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221 or 425-227-1152.

# **Examining the AD Docket**

You may examine the AD docket on the Internet at http://www.regulations.gov; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Ivan Li, Aerospace Engineer, Airframe

Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590.

#### SUPPLEMENTARY INFORMATION:

#### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the ADDRESSES section. Include "Docket No. FAA-2009-0718; Directorate Identifier 2009-NM-025-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to http://www.regulations.gov, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

#### Discussion

Boeing analysis indicates that the wing and horizontal stabilizer side-of-body joints and the fuselage skin circumferential splices on Model 747 airplanes are susceptible to fatigue cracking due to high cyclic loads on the airplane. This condition, if not corrected, could result in reduced structural integrity leading to rapid decompression and consequent loss of control of the airplane.

#### **Related Rulemaking**

On March 24, 2004, we issued AD 2004-07-22, amendment 39-13566 (69 FR 18250, April 7, 2004), for all Boeing Model 747 series airplanes. (A correction of AD AD 2004-07-22 was issued on December 26, 2007 (73 FR 1052, January 7, 2008), to clarify the AD applicability.) That AD supersedes two existing ADs which require that the maintenance inspection program be revised to include inspections that will give no less than the required damage tolerance rating for each structural significant item, and repair of cracked structure. That AD also requires additional and expanded inspections, and repair of cracked structure. That AD resulted from a structural re-evaluation that identified additional structural elements where, if damage were to occur, supplemental inspections may be required for timely detection of fatigue cracking. We issued that AD to ensure the continued structural integrity of the

entire fleet of Model 747 series airplanes.

On January 29, 2004, we issued AD 2004-03-09, amendment 39-13453 (69 FR 6542, February 11, 2004), for all Boeing Model 747–100, 747–100B, 747– 100B SUD, 747-200B, 747-200F, 747-200C, 747-300, 747SR, and 747SP series airplanes. That AD requires repetitive inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, and repair if necessary. That AD also provides for an optional modification that, if accomplished, terminates the repetitive inspection requirement, but would necessitate eventual post-modification inspections. We issued that AD to find and fix fatigue cracking of structure near and common to the upper chord and splice fittings of the rear spar of the wing, which could result in loss of structural integrity of the airplane.

#### **Relevant Service Information**

We have reviewed Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008. The service bulletin describes procedures for one-time detailed and open-hole high frequency eddy current (HFEC) inspections for cracks in the wing side-of-body (SOB) joint upper and lower surfaces; one-time detailed and open-hole HFEC inspections for cracks in the horizontal stabilizer SOB joint; one-time surface and open-hole HFEC inspections for cracks of the fuselage skin circumferential splices; as applicable; and repair if necessary. The service bulletin also describes procedures, for certain airplanes, for repetitive detailed inspections for cracks of the fuselage skin circumferential splices. The service bulletin also allows surface HFEC inspections as an option for doing certain open-hole HFEC inspections for cracks in the horizontal stabilizer SOB joint surfaces. For airplanes on which any crack is found during any inspection, the procedures include reporting the crack finding to Boeing and contacting Boeing for repair data, and repairing before further flight.

The compliance times for the inspections are as follows:

• For Groups 1 through 5 airplanes, for the detailed inspection of the fuselage skin circumferential splices: Before the accumulation of 25,000 total flight cycles, or within 1 year after the date on the service bulletin, whichever occurs later. For airplanes on which no crack is found, the inspection is repeated within 6,000 flight cycles after the initial inspection, and thereafter at intervals not to exceed 6,000 flight cycles.

- For Groups 1 through 3 airplanes, for the detailed and open-hole HFEC inspections of the wing SOB joint upper and lower surfaces; detailed and openhole HFEC inspections of the horizontal stabilizer SOB joint; and surface and open-hole HFEC inspections of the fuselage skin circumferential splices are to be done at the later of the following times: Before the accumulation of 30,000 total flight cycles or 115,000 total flight hours (whichever occurs first), or within 1 year after the date on the service bulletin. The service bulletin also specifies that operators do not accomplish the inspections until the airplane has accumulated at least either 28,500 total flight cycles or 110,000 total flight hours.
- For Groups 4 through 6 airplanes for the detailed and open-hole HFEC inspections of the wing SOB joint upper and lower surfaces; detailed and openhole HFEC inspections of the horizontal stabilizer SOB joint; and surface and open-hole HFEC inspections of the fuselage skin circumferential splices are to be done at the later of the following times: Before the accumulation of 30.000 total flight cycles or 135.000 total flight hours (whichever occurs first), or within 1 year after the date on the service bulletin. The service bulletin also specifies that operators should not accomplish the inspections until the airplane has accumulated at least either 28,500 total flight cycles or 130,000 total flight hours.

# FAA's Determination and Requirements of This Proposed AD

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Difference Between the Proposed AD and Service Information."

# Difference Between the Proposed AD and Service Information

The service bulletin specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

• Using a method that we approve; or

• Using data that meet the certification basis of the airplane, and that have been approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization

Organization whom we have authorized to make those findings.

#### **Interim Action**

We consider this proposed AD interim action. If final action is later identified, we might consider further rulemaking then.

### **Costs of Compliance**

We estimate that this proposed AD would affect 165 airplanes of U.S. registry. We also estimate that it would take 2,604 work-hours per product to comply with this proposed AD. The average labor rate is \$80 per work-hour. Based on these figures, we estimate the cost of this proposed AD to the U.S. operators to be \$34,372,800, or \$208,320 per product.

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

#### Regulatory Findings

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

For the reasons discussed above, I certify 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. 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.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

### List of Subjects in 14 CFR Part 39

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

#### The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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 adding the following new AD:

Boeing: Docket No. FAA-2009-0718; Directorate Identifier 2009-NM-025-AD.

#### **Comments Due Date**

(a) We must receive comments by October 9, 2009.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to all Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes, certificated in any category.

### Subject

(d) Air Transport Association (ATA) of America Code 51: Standard practices/ structures.

### **Unsafe Condition**

(e) This AD results from a Boeing analysis indicating that the wing and horizontal stabilizer side-of-body joints, and the fuselage skin circumferential splices are susceptible to fatigue cracking due to high cyclic loads on the airplane. The Federal Aviation Administration is issuing this AD to detect and correct fatigue cracking at multiple adjacent locations in the subject areas, which could connect to form large cracks and result in reduced structural integrity leading to rapid decompression and consequent loss of control of the airplane.

#### Compliance

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

# **Inspections and Repair if Necessary**

(g) Except as provided by paragraphs (h) and (i) of this AD: At the applicable times specified in paragraph 1.E. of Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008, do one-time inspections for cracks in the wing and horizontal stabilizer side-of-

body joints, and the fuselage skin circumferential splices; do detailed inspections, as applicable, for cracks of the fuselage skin circumferential splices; and do all applicable repairs before further flight, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008, except as provided by paragraphs (j) and (k) of this AD. As applicable, repeat the detailed inspection for cracks of the fuselage skin circumferential splices, at the applicable times specified in paragraph 1.E. of Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008.

# **Exceptions to Compliance Times**

- (h) Where Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008, specifies a compliance time after "\* \* \* the date on this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.
- (i) Where Note (a) of Table 2 of paragraph 1.E. of Boeing Alert Service Bulletin 747 51A2060, dated October 30, 2008, specifies that if a certain modification was done then certain inspections may be deferred "until the post modification inspection period as given in Service Bulletin 747-57Â2314," this AD allows, for airplanes on which the modification specified in Boeing Service Bulletin 747-57A2314 has been done, deferring the inspections specified in Part 2 of paragraph 3.B., of the Work Instructions of Boeing Alert Service Bulletin 747-51A2060, dated October 30, 2008, until the applicable post-modification inspection intervals required by paragraph (e) of AD 2004-03-09, amendment 39-13453.

# **Exception to Part 4 Actions**

(j) For Group 6 airplanes identified in Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008: Do the inspections specified in Part 4 of paragraph 3.B. of the Work Instructions of Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008, in accordance with the procedures specified in paragraph (m) of this AD.

#### **Exception to Corrective Actions**

(k) If any crack is found during any inspection required by this AD, and Boeing Alert Service Bulletin 747–51A2060, dated October 30, 2008, specifies to contact Boeing for appropriate action: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

# **Reporting Requirement**

(l) At the applicable time specified in paragraph (l)(1) or (l)(2) of this AD, submit a report of positive and negative findings of cracks found during the inspection required by paragraph (g) of this AD to Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207.

Alternatively, operators may submit reports to their Boeing field service representatives. The report must contain, as a minimum, the following information: airplane serial number, flight cycles at time of discovery, location(s) and extent of positive crack findings. Under the provisions of the

Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120–0056.

- (1) If the inspection was done on or before the effective date of this AD: Send the report within 30 days after the effective date of this AD
- (2) If the inspection was done after the effective date of this AD: Send the report within 30 days after the inspection is done.

# Alternative Methods of Compliance (AMOCs)

(m)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Ivan Li, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590; Or, e-mail information to 9–ANM–Seattle–ACO–AMOC–Requests@faa.gov.

- (2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.
- (3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Issued in Renton, Washington, on August 7, 2009.

#### Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. E9–20382 Filed 8–24–09; 8:45 am]

BILLING CODE 4910-13-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Food and Drug Administration

### 21 CFR Part 803

[Docket No. FDA-2008-N-0393] RIN 0910-AF86

# Medical Device Reporting: Electronic Submission Requirements

Correction

In proposed rule document E9–19683 beginning on page 42203 in the issue of

Friday, August 21, 2009 make the following correction:

On page 42204, in the first column, under the **DATES** section, in the first line, "November 19, 2009" should read "Submit written or electronic comments on the proposed rule by November 19, 2009".

[FR Doc. Z9–19683 Filed 8–24–09; 8:45 am]  $\tt BILLING\ CODE\ 1505–01–D$ 

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Food and Drug Administration**

#### 21 CFR Part 866

[Docket No. FDA-2009-N-0344]

# Microbiology Devices; Reclassification of Herpes Simplex Virus Types 1 and 2 Serological Assays

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its device classification regulations by correcting the regulation classifying herpes simplex virus (HSV) serological assays by removing the reference to HSV serological assays other than type 1 and type 2. When reclassifying this device, FDA mistakenly distinguished between HSV serological assays type 1 and type 2 and all other HSV serological assays. At that time, and today, the only preamendments HSV serological assays FDA was aware of were type 1 and type 2, and therefore, the classification of HSV assays other than type 1 and type 2 was incorrect. FDA is correcting the classification of this device to eliminate possible confusion resulting from this error. Elsewhere in this issue of the Federal Register, we are publishing a companion direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event we receive significant adverse comment and withdraw the direct final rule.

**DATES:** Submit written or electronic comments by November 9, 2009.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2009-N-0344, by any of the following methods: *Electronic Submissions* 

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by email. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the ADDRESSES portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

# FOR FURTHER INFORMATION CONTACT:

Scott McFarland, Center for Devices and Radiological Health WO/66, rm. 5543, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6217.

#### SUPPLEMENTARY INFORMATION:

# I. Why Is This Companion Proposed Rule Being Issued?

This proposed rule is a companion to the direct final rule correcting § 866.3305 (21 CFR 866.3305) by removing HSV serological assays other than type 1 and type 2 from the regulation. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. We are publishing the direct final rule because we believe the rule is noncontroversial, and we do not anticipate receiving any significant adverse comments. If no significant