

(ii) If the airload support roller travels beyond the limits specified in the service bulletin, repair in accordance with a method approved by the Manager, Seattle ACO, FAA or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the FAA to make such findings.

(2) For Group III airplanes identified in the service bulletin: Modify the inboard jackscrews of the outboard flap (*i.e.*, replacing the down stop at the inboard jackscrews of the outboard flap) in accordance with Part II of the Accomplishment Instructions of the service bulletin.

(l) For Model 727 airplanes listed in Boeing Service Bulletin 57-72, dated September 21, 1966: Before or at the same time with the requirements of paragraph (h) of this AD, do the actions specified in paragraphs (l)(1) through (l)(4) of this AD.

(1) Chamfer the upper and lower flanges at the aft end of the forelap tracks in accordance with the Accomplishment Instructions of the service bulletin.

(2) Do a standard magnetic particle inspection of the entire forelap tracks for cracks in accordance with the Accomplishment Instructions of the service bulletin. If any crack is detected, before further flight, repair in accordance with a method approved by the Manager, Seattle ACO, FAA or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the FAA to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

(3) Do a general visual inspection of the track rib faces at the front and rear spars to verify if the opening in the spars is flush with or clear of the plane of the rib faces, in accordance with the Accomplishment Instructions of the service bulletin. If the opening is not flush or clear with the plane, before further flight, rework the spar opening in accordance with the Accomplishment Instructions of the service bulletin.

(4) Do a general visual inspection of the head or shank of bolts by securing the forelap links to the forelap tracks to verify if they protrude beyond the edge of the track flange in accordance with the Accomplishment Instructions of the service bulletin. If the head or shank of the bolts protrude beyond the edge of the track flange, before further flight, rework in accordance with the Accomplishment Instructions of the service bulletin.

Note 1: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors.

Stands, ladders, or platforms may be required to gain proximity to the area being checked."

(m) For airplanes other than those identified in the service bulletins specified in paragraphs (j) through (l) of this AD: Before or at the same time with the requirements of paragraph (h) of this AD, do an inspection to verify if any of the parts listed in the "Spares Affected" paragraph of each service bulletin referenced in paragraphs (j) through (l) of this AD are installed on the airplane. If any part identified in that paragraph is found installed, before further flight, do the applicable corrective and investigative action(s) specified in paragraphs (j) through (l) of this AD.

Optional Terminating Actions

(n) Replacement of the two carriage attach fittings on the inboard and outboard foreflaps of each wing with new, improved fittings, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727-57A0135, Revision 3, dated June 27, 2002; and accomplishment of the actions specified in paragraphs (j) through (m) of this AD, as applicable, before or concurrently with the replacement; constitutes terminating action for the requirements of this AD.

Optional Deferral of Inspection

(o) Replacement of the two carriage attach fittings on the inboard and outboard foreflaps of each wing with new fittings having the same part number as the existing fittings, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727-57A0135, Revision 3, dated June 27, 2002; and accomplishment of the actions specified in paragraphs (j) through (m) of this AD, as applicable, before or concurrently with the replacement; defers the next inspection required by paragraph (f) of this AD for 10,000 flight cycles after the replacement. Thereafter, repeat the inspections required by paragraph (f) of this AD at intervals not to exceed 1,000 flight cycles.

Credit for Previously Accomplished Service Bulletins

(p) Installations accomplished before the effective date of this AD in accordance with Boeing Service Bulletin 57-59, dated September 2, 1965; are acceptable for compliance with the requirements of paragraph (j) of this AD.

(q) Inspections and modifications accomplished before the effective date of this AD in accordance with Boeing Service Bulletin 727-27-133, dated October 7, 1971; are acceptable for compliance with the requirements of paragraph (k) of this AD.

Alternative Methods of Compliance (AMOCs)

(r)(1) In accordance with 14 CFR 39.19, the Manager, Seattle ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make those

findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on November 19, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04-26028 Filed 11-23-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2004-19678; Directorate Identifier 2004-NM-62-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 747-400F Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 747-400F series airplanes. This proposed AD would require initial detailed and open-hole high frequency eddy current inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, and repair of any cracking. This proposed AD also would require a preventive modification of the upper deck floor beams, and repetitive inspections for cracking after accomplishing the modification. This proposed AD is prompted by reports of fatigue cracking found on the upper deck floor beam to frame attachment points. We are proposing this AD to prevent fatigue cracks in the upper chord, upper chord strap, and the web of the upper deck floor beams and resultant failure of the floor beams. Failure of a floor beam could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by January 10, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

• **DOT Docket Web site:** Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

• *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

• *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL-401, Washington, DC 20590.

• *By fax:* (202) 493-2251.

• *Hand Delivery:* Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, 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, P.O. Box 3707, Seattle, Washington 98124-2207.

You can examine the contents of this AD docket on the Internet at <http://dms.dot.gov>, or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL-401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Technical information: Ivan Li, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 917-6437; fax (425) 917-6590.

Plain language information: Marcia Walters, marcia.walters@faa.gov.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA-2004-99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004-NM-999-AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2004-19678; Directorate Identifier 2004-NM-62-AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the

proposed AD in light of those comments.

We will post all comments we receive, without change, to <http://dms.dot.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78), or you can visit <http://dms.dot.gov>.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at <http://www.faa.gov/language> and <http://www.plainlanguage.gov>.

Examining the Docket

You can examine the AD docket on the Internet at <http://dms.dot.gov>, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647-5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Related Rulemaking

On January 29, 2004, we issued AD 2004-03-11, amendment 39-13455 (69 FR 5920, February 9, 2004). That AD applies to certain Boeing Model 747-200C and -200F series airplanes, and requires repetitive inspections to find fatigue cracking in the upper chord of the upper deck floor beams, and repair if necessary. For certain airplanes, that AD also provides an optional repair/modification, which defers certain repetitive inspections.

Actions Since Issuance of Previous Rulemaking

Since issuance of AD 2004-03-11, we have received reports indicating that additional fatigue cracking was found on the upper deck floor beam to frame attachment points, on certain Model 747-200F series airplanes. The upper

deck floor beams on certain 747-400F series airplanes are similar to those on the affected 747-200F series airplanes. In light of these reports, we have determined that it is necessary to issue the proposed AD at this time to ensure the continued operating safety of the affected airplane fleet. Therefore, all of these models may be subject to the same unsafe condition. Failure of a floor beam due to fatigue cracking could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 747-53A2443, dated May 9, 2002. The service bulletin describes procedures for a detailed inspection for cracking of the web, upper chord and upper chord strap of body stations 340 through 520 inclusive, of the upper deck floor beams; an open-hole high frequency eddy current (HFEC) inspection for cracking of the fastener holes of the web, upper chord, and upper chord strap; and repair of any cracking. If any cracking is found, the procedures in the service bulletin include repairing the cracking and accomplishing a preventive modification before further flight, or contacting the manufacturer for repair instructions if the cracking exceeds certain limits.

If no cracking is found, the procedures in the service bulletin include two options: Modifying the upper chord of the upper deck floor beams before further flight, or repeating the detailed and open-hole inspections before the accumulation of 20,000 total flight cycles, then accomplishing the preventive modification before further flight. Accomplishing the preventive modification extends the compliance time for the next detailed and open-hole or surface HFEC inspections of the upper deck floor beams to 15,000 flight cycles after accomplishing the modification.

For the post-modification inspection, the service bulletin gives the option of either repeating the detailed and surface HFEC inspections every 1,000 flight cycles, or repeating the detailed and open-hole HFEC inspections every 5,000 flight cycles.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require initial detailed and open-hole HFEC inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, and repair of any cracking. The proposed AD also would require a preventive modification of the upper deck floor beams, and repetitive inspections for cracking after accomplishing the modification. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under "Differences

Between the Alert Service Bulletin and This Proposed AD."

Differences Between the Alert Service Bulletin and This Proposed AD

The service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, but this proposed AD would require the repair of those conditions to be accomplished in accordance with a method approved by the FAA, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

The service bulletin refers to a "detailed visual inspection" for cracking of the web, upper chord, and strap of the upper deck floor beams. We

have determined that the procedures in the service bulletin should be described as a "detailed inspection." Note 1 has been included in this proposed AD to define this type of inspection.

Although the service bulletin does not list a grace period in the compliance times for the initial inspections and the preventive modification, this proposal adds a grace period to those compliance times. We find that such a grace period will keep airplanes from being grounded unnecessarily.

Costs of Compliance

This proposed AD would affect about 53 airplanes worldwide and 13 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD, depending on the airplane configuration:

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of affected U.S.-registered airplanes	Fleet cost
Pre-modification/inspections.	11	\$65	\$0	\$715	13	\$9,295.
Modification/Inspections done during modification.	498 or 524	65	13,554 or 14,874	45,924 or 48,934.	13	597,012 or 636,142.
Post-modification inspections.	66	65	0	4,290, per inspection cycle.	13	55,770.

Regulatory Findings

We have 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 that the 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the ADDRESSES section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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 airworthiness directive (AD):

Boeing: Docket No. FAA-2004-19678; Directorate Identifier 2004-NM-62-AD.

Comments Due Date

- (a) The Federal Aviation Administration (FAA) must receive comments on this AD action by January 10, 2005.

Affected ADs

- (b) None.

Applicability

- (c) This AD applies to Model 747-400F series airplanes, certificated in any category; as listed in Boeing Alert Service Bulletin 747-53A2443, dated May 9, 2002.

Unsafe Condition

- (d) This AD was prompted by reports of fatigue cracking found on the upper deck floor beam to frame attachment points. We are issuing this AD to prevent fatigue cracks in the upper chord, upper chord strap, and web of the upper deck floor beams and the resultant failure of the floor beams. Failure of a floor beam could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of 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.

Service Bulletin Reference

(f) For the purposes of this AD, the term "service bulletin" means the Accomplishment Instructions of Boeing Alert Service Bulletin 747-53A2443, dated May 9, 2002.

Inspections/Repair/Modification

(g) Before the accumulation of 15,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever is later: Accomplish detailed and open-hole high frequency eddy current (HFEC) inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, by doing all the applicable actions in accordance with Part 3.B.1. of the service bulletin.

Note 1: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

(h) If any crack is found during any inspection required by paragraph (g) of this AD: Before further flight, accomplish the actions required by paragraph (h)(1) and (h)(2) of this AD.

(1) Repair in accordance with the service bulletin; except where the service bulletin specifies to contact Boeing for appropriate action, before further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or according to data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

(2) Accomplish the inspections and preventive modification of the floor beams by doing all the actions in accordance with Part 3.B.2. or Part 3.B.3. of the service bulletin, as applicable. If any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

(i) If no crack is found during any inspection required by paragraph (g) of this AD: Accomplish the actions required by either paragraph (i)(1) or (i)(2) of this AD, at the time specified.

(1) Before further flight: Accomplish the inspections and preventive modification of the floor beam by doing all the actions in accordance with Part 3.B.2 or Part 3.B.3. of the service bulletin, as applicable. If the preventive modification is performed concurrently with the inspections required by paragraph (g) of this AD, the upper chord straps must be removed when performing the open-hole HFEC inspection. If any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

(2) Before the accumulation of 20,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever is later: Accomplish the inspections and preventive modification of the upper deck floor beams, by doing all the actions in accordance with Part 3.B.2. or 3.B.3. of the service bulletin, as applicable. If any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

Post-Modification Inspections

(j) Within 15,000 flight cycles after accomplishing the applicable preventive modification required by paragraph (h)(2), (i)(1), or (i)(2) of this AD: Accomplish the inspections required by either paragraph (j)(1) or (j)(2) of this AD; if any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

(1) Accomplish detailed and surface HFEC inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, by doing all the applicable actions in accordance with Part 3.B.4. of the service bulletin. If no crack is found, repeat the inspections at intervals not to exceed 1,000 flight cycles.

(2) Accomplish detailed and open-hole HFEC inspections for cracking of the web, upper chord, and strap of the upper deck floor beams, by doing all the applicable actions in accordance with Part 3.B.5. of the service bulletin. If no crack is found, repeat the inspections at intervals not to exceed 5,000 flight cycles.

Note 2: There is no terminating action currently available for the repetitive inspections required by this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on November 10, 2004.

Ali Bahrami,

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

[FR Doc. 04-26027 Filed 11-23-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 25**

[Docket No. 2004N-0461]

**Environmental Assessment;
Categorical Exclusions**

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of humanitarian device exemptions (HDEs) and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment (EA) nor environmental impact statement (EIS) is required. Regulations issued by the Council on Environmental Quality require that all Federal Agencies assess the environmental impact of their major actions and ensure that the interested and affected public is informed of environmental analyses. FDA is taking this action in accordance with the National Environmental Policy Act (NEPA).

DATES: Submit written or electronic comments on the proposed rule by December 27, 2004. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

ADDRESSES: You may submit comments, identified by 2004N-0461, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

- E-mail: fdadockets@oc.fda.gov. Include [Docket No. 2004N-0461] in the subject line of your e-mail message.

- FAX: 301-827-6870.

- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information