

Cost Impact

The FAA estimates that 240 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$8 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$30,720, or \$128 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that 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) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part

39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Empresa Brasileira De Aeronautica S.A. (Embraer): Docket 2000–NM–121–AD.

Applicability: Model EMB–120 series airplanes, serial numbers 120003, 120004, 120006 through 120308 inclusive, 120310, 120312 through 120314 inclusive, 120316 through 120323 inclusive, and 120325 through 120330 inclusive; certificated in any category.

Note 1: 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 (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 overheating of the wire between certain circuit breakers, which could result in smoke emissions in the cockpit, accomplish the following:

(a) At the next scheduled maintenance inspection ("A"-check), but no later than 400 flight hours after the effective date of this AD: Replace the existing wire between circuit breakers 0304 and 0358 with a wire coded W200–1063–12, in accordance with EMBRAER Service Bulletin 120–30–0028, dated August 25, 1997.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, 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.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

Special Flight Permits

(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.

Note 3: The subject of this AD is addressed in Brazilian airworthiness directive 97–11–01, dated November 25, 1997.

Issued in Renton, Washington, on July 25, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 00–19263 Filed 7–28–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–134–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 747 series airplanes. This proposal would require inspections to detect cracking of the front spar web of the wing, and corrective action, if necessary. This action is necessary to detect and correct fatigue cracking of the front spar web, which could result in fuel leaking onto an engine and a consequent fire. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by September 14, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–134–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–134–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must

be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tamara Anderson, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2771; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-134-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-134-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The FAA has received a report indicating that an operator found a 24-inch-long crack in the front spar web of the right wing of a Boeing Model 747 series airplane. Metallurgical analysis of the cracked web section indicated that three cracks initiated from a hole common to a rib post located on the front spar at front spar station inboard (FSSI) 656. The initiation and propagation of the cracking have been attributed to fatigue. This condition, if not corrected, could result in fuel leaking onto an engine and a consequent fire.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 747-57A2311, dated January 27, 2000, which describes procedures for various repetitive external inspections to detect cracking of the front spar web of the wing. The inspections include:

- A detailed visual inspection to detect cracking of the front spar web between the seal rib at FSSI 628 and the rib post at FSSI 684;
- An ultrasonic inspection to detect cracking of the web behind the front spar stiffeners and for horizontal cracks in the web under the upper and lower chords between FSSI 628 and FSSI 684; and
- A high frequency eddy current (HFEC) inspection to detect vertical cracks in the web near the vertical flanges of the upper and lower chords.

The alert service bulletin also describes procedures for an optional web inspection that can be performed in lieu of the external web inspections. The optional inspection necessitates less access than the external inspection when the fuel tanks are already being accessed for other reasons, and is intended to provide an alternative method of inspection. The optional method includes:

- Detailed visual inspections from inside the fuel tank to detect cracks of the aft side of the web, and from outside the fuel tank to detect cracks between the upper and lower chords at the wing station (WS) 642 rib post;
- Ultrasonic inspections from outside the fuel tank to detect horizontal cracks in the web between the rib post and the

upper and lower chords at the WS 642 rib post, and to detect cracks in the web behind the front spar stiffener at FSSI 628; and,

- An HFEC inspection to detect vertical cracks in the web near the vertical flanges of the upper and lower chords at the WS 642 rib post.

Accomplishment of the actions specified in the alert service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the alert service bulletin described previously, except as discussed below.

Differences Between Alert Service Bulletin and This Proposed AD

Operators should note that, although the alert service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, 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.

Cost Impact

There are approximately 478 airplanes of the affected design in the worldwide fleet. The FAA estimates that 97 airplanes of U.S. registry would be affected by this proposed AD.

The external inspections that are one option for compliance with this proposed AD would take approximately 48 work hours per airplane (not including access and close-up), at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed external inspections on U.S. operators is estimated to be \$2,880 per airplane, per inspection cycle.

In lieu of accomplishment of the external inspections, this proposed AD would provide for an optional web inspection that would take approximately 50 work hours per airplane, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed optional web inspection on U.S. operators is estimated to be \$3,000 per airplane, per inspection cycle.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that 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) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2000–NM–134–AD.

Applicability: Model 747 series airplanes, as listed in Boeing Alert Service Bulletin 747–57A2311, dated January 27, 2000; certificated in any category.

Note 1: 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 (c) 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 fatigue cracking of the front spar web of the wing, which could result in fuel leaking onto an engine and a consequent fire, accomplish the following:

Repetitive Inspections

(a) At the later of the times specified in paragraphs (a)(1) and (a)(2) of this AD, perform the Part 1 external web inspection—including detailed visual, ultrasonic, and high frequency eddy current (HFEC) inspections—to detect cracking of the front spar web of the wing, in accordance with Boeing Alert Service Bulletin 747–57A2311, dated January 27, 2000. In lieu of the Part 1 external web inspection, accomplishment of the Part 2 optional web inspection to detect cracking—which also includes detailed visual, ultrasonic, and HFEC inspections—in accordance with Boeing Alert Service Bulletin 747–57A2311, dated January 27, 2000, is acceptable for compliance with this paragraph. Repeat the inspections thereafter at intervals not to exceed 2,000 flight cycles.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

(1) Prior to the accumulation of 13,000 total flight cycles or 30,000 total flight hours, whichever occurs first.

(2) Within 18 months after the effective date of this AD.

Repair

(b) If any cracking is detected during any inspection required by paragraph (a) of this AD, prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), 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 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 approval letter must specifically reference this AD.

Alternative Methods of Compliance

(c) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

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

Special Flight Permits

(d) 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.

Issued in Renton, Washington, on July 25, 2000.

Donald L. Riggins,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–19267 Filed 7–28–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D–0785]

Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "Developing Medical Imaging Drugs and Biological Products." FDA has revised the draft guidance issued on October 14, 1998, in response to comments from industry and other interested persons. The revised draft guidance is intended to assist developers of drug and biological products used for medical imaging in conducting the clinical investigations of, and submitting various types of applications for, such products. The revised draft guidance also provides