replacement of the existing retaining bolt of the attendant seat lap belt with a new bolt and a washer. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

There are approximately 55 double flight attendant seats installed on 35 Boeing Model 767 series airplanes of the affected design in the worldwide fleet. Each of these airplanes has 1 or 2 seats. The FAA estimates that 40 double flight attendant seats installed on 20 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per seat to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $1 per seat. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $61 per seat.

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.

Regulatory Impact

The regulations proposed herein would 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 96–NM–206–AD.

Applicability: Model 767 series airplanes, as listed in Boeing Service Bulletin 767–25–0217, dated January 13, 1994; equipped with a seat base assembly having part number 414T2025; 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 ensure that a washer between the bolt head and bushing is installed in the restraint anchor configuration of the double flight attendants seats that are wall mounted, accomplish the following:

(a) Within 90 days after the effective date of this AD, replace the existing retaining bolt of the attendant seat lap belt with a new bolt and a washer, in accordance with Boeing Service Bulletin 767–25–0217, dated January 13, 1994.

(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, Seattle Aircraft Certification Office (ACO), FAA, Transport 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, Seattle ACO.

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

(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.

Issued in Renton, Washington, on May 30, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–14770 Filed 6–5–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–50–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200 and –300 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 767–200 and –300 series airplanes. This proposal would require a one-time inspection for worn or broken wire bundles in the ceiling above the main passenger door and repair, if necessary; and relocation of the wire bundles to prevent chafing. This proposal is prompted by a report indicating that the opening of the main passenger door caused the door liner and a ceiling panel to chafe and ultimately break a wire installed in this area. The actions specified by the proposed AD are intended to prevent these wires from becoming worn or breaking, which could lead to the failure of several systems, such as the fuel shutoff valves that allow the flight crew to stop the flow of fuel in the event of an engine fire.

DATES: Comments must be received by July 17, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–50–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.

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: Stephen Oshiro, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (425) 227–2793; 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.

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 97–NM–50–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–103, Attention: Rules Docket No. 97–NM–50–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received a report indicating that a broken wire was detected in the ceiling above the main passenger door on a Boeing Model 767 series airplane. An investigation revealed that the opening of this door causes the upper liner of the door and the moveable ceiling panel in this area to chafe wire bundles, which can lead to worn and broken wires.

Because these wires are connected to such safety systems as the fuel shutoff valves for the engines, oxygen deployment for passengers, emergency lighting, passenger signs, and the signal for emergency evacuation, worn or broken wires can cause one or more of these systems to fail. Such failure of the fuel shutoff valves, for example, would prevent the flight crew from stopping the flow of fuel to the engines in the event of a fire.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 767–33–0052, Revision 1, dated December 8, 1994, which describes procedures for a one-time inspection to detect worn or broken wires in the wire bundles located above the main passenger door; repair of any worn or broken wires; and relocation of these wire bundles inboard of this door. Such relocation of the wire bundles will prevent worn or broken wires due to chafing by the upper liner of the door or the moveable ceiling panel.

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 a one-time inspection to detect worn or broken wires in the wire bundles located above the main passenger door; repair of any worn or broken wires; and relocation of the wire bundles inboard of this door. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

There are approximately 403 Boeing Model 767–200 and –300 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 142 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 1 work hour per airplane to accomplish the proposed inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed inspection on U.S. operators is estimated to be $8,520, or $60 per airplane.

It would take approximately 57 work hours per airplane to accomplish the proposed relocation of the wire bundles, at an average labor rate of $60 per work hour. Required parts would cost approximately $200 per airplane. Based on these figures, the cost impact of the proposed relocation of the wire bundles on U.S. operators is estimated to be $514,040, or $3,620 per airplane.

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 AD were not adopted.

Regulatory Impact

The regulations proposed herein would 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 97–NM–50–AD.

Applicability: Model 767–200 and –300 series airplanes; as listed in Boeing Service Bulletin 767–33–0052, Revision 1, dated

December 8, 1994; 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 wires in the area above the main passenger door from becoming worn or breaking, which could lead to the failure of several systems, such as the fuel shutoff valves that allow the flight crew to stop the flow of fuel in the event of an engine fire, accomplish the following:

(a) Within 12 months after the effective date of this AD, conduct a one-time inspection to detect worn or broken wires in the wire bundles installed above the main passenger door, in accordance with Boeing Service Bulletin 767–33–0052, Revision 1, dated December 8, 1994. Prior to further flight, repair any worn or broken wires and relocate the wire bundles inboard of this door, in accordance with the service bulletin. Thereafter, no further action is required by this AD.

Note 2: Inspection; repair, if necessary; and relocation of the wire bundles accomplished prior to the effective date of this AD in accordance with Boeing Service Bulletin 767–33–0052, dated April 2, 1992, is considered acceptable for compliance with the requirements of paragraph (a) of this AD.

(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, Seattle Aircraft Certification Office (ACO), FAA, Transport 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, 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.

(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.

Issued in Renton, Washington, on May 30, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–14771 Filed 6–5–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 95N–0342]

Export Requirements for Medical Devices; Withdrawal of Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a proposed rule that appeared in the **Federal Register** of November 27, 1995 (60 FR 58308). The proposed rule would have amended FDA's regulations for exporting devices for investigational use. FDA is withdrawing the proposed rule because recent statutory changes have made the rulemaking unnecessary.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–827–3380.

SUPPLEMENTARY INFORMATION: At present, two statutory provisions in the Federal Food, Drug, and Cosmetic Act (the act) govern the export of devices that are not approved for marketing in the United States.

The first provision, at section 801(e)(2) of the act (21 U.S.C. 381(e)(2)), became law as part of the Medical Device Amendments Act of 1976 (Pub. L. 94–295) and required FDA approval of certain exports of unapproved devices. The second provision, section 802 of the act (21 U.S.C. 382), was the result of the FDA Export Reform and Enhancement Act of 1996 (Pub. L. 104–134, and amended by Pub. L. 104–180) (Export Act of 1996).

Before the latter provision became law, FDA had undertaken a program to streamline the requirements for the exportation of unapproved devices under section 801(e) of the act. FDA issued a proposed rule to simplify the agency's export approval process for certain unapproved devices (60 FR 58308). The proposed rule was intended, in part, to respond to concerns in the device industry that the statutory requirement of FDA approval of device exports may undermine a firm's ability to compete in international markets and may represent an unnecessary regulatory barrier. (It should be emphasized, however, that FDA's approval times for device export applications have decreased significantly, from an average of 91 days per request in 1992, to 10 days in 1995, and further decreased to 8 days in fiscal year 1996.) The proposed rule was also intended to implement part of the President's and Vice-President's ''National Performance Review'' pertaining to the exportation of unapproved devices (as announced in an April, 1995 report entitled, ''Reinventing Drug and Device Regulations''). Under the National Performance Review initiative, the agency would permit the export of unapproved devices to certain advanced industrialized countries without prior FDA review and approval, provided that the device complied with the importing country's laws. The report also stated that the Administration would seek the necessary legislative changes and would consult Congress on the appropriate list of advanced industrialized countries.

The report also stated that FDA would initiate administrative changes to permit exports to countries that are not on the list of advanced industrialized countries ''if the exporter has an Investigational Device Exemption (IDE) permitting testing on humans in the United States, the importing country has given FDA a letter providing blanket approval for IDE-type devices, and the device is in compliance with the importing country's laws.'' Consequently, FDA proposed to amend 21 CFR 812.18 to state that a person who wishes to export an investigational device subject to part 812 (21 CFR part 812) (investigational devices) must comply with the requirements at section 801(e)(1) of the act, but that, for purposes of section 801(e)(2) of the act, prior FDA approval would be unnecessary if the investigational device to be exported is the subject of an approved IDE (including nonsignificant risk devices which, under FDA regulations, are considered to have an approved IDE) and ''will be marketed or used in clinical trials in the foreign country for the same intended use as that in the approved IDE and is to be exported to a country that has expressed its approval of the importation of investigational devices'' that are the subject of an approved IDE. The proposed rule also stated that, if the device is the subject of an approved IDE and has received a ''CE'' mark from the European Union (EU), the device may be exported to any country in the European Economic Area (EEA).

The proposed rule also would have FDA make available a list of countries that have approved the importation of investigational devices that are the subjects of approved IDE's. Additionally, the proposal would require prior FDA approval to export an