approximately 1,019 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $20,917 per airplane ($12,888 for all aft door fittings; $8,029 for all forward door fittings). Based on these figures, the cost impact of the proposed replacement of this AD on U.S. operators is estimated to be $9,436,555, or $82,057 per airplane.

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

Regulatory Impact

The regulations 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 removing amendment 39–8500 (58 FR 11190, February 24, 1993), and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 97–NM–47–AD. Supersedes AD 93–02–16, Amendment 39–8500.

Applicability: Model 747 airplanes, line numbers 1 through 200 inclusive; having 7079–T6 aluminum latch support fittings; 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 (d) 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 the cargo door from opening while the airplane is in flight, which could result in rapid decompression of the airplane, accomplish the following:

Restatement of the Requirements of AD 93–02–16

(a) Within 60 days after March 11, 1993 (the effective date of AD 93–02–16, amendment 39–8500), perform a high frequency eddy current (HFEC) inspection to detect cracking on all surfaces of the upper recess in each 7079–T6 aluminum latch support fitting of the cargo doorway, in accordance with Boeing Service Bulletin 747–53A2377, Revision 1, dated January 28, 1993, or Revision 2, dated October 6, 1994. After the effective date of this AD, only Revision 2 of the service bulletin shall be used.

Note 2: Boeing Service Bulletin 747–53A2377, Revision 2, dated October 6, 1994, references Boeing Service Bulletin 747–53–2200, Revision 1, dated November 16, 1979, as an additional source of service information for the replacement of these fittings.

(1) If any cracking is found on any fitting, prior to further flight, replace the cracked fitting with a new 7075–T73 aluminum latch support fitting in accordance with Boeing Service Bulletin 747–53A2377, Revision 1, dated January 28, 1993, or Revision 2, dated October 6, 1994. After the effective date of this AD, only Revision 2 of the service bulletin shall be used.

(2) If no cracking is found on any fitting, repeat the HFEC inspection thereafter at intervals not to exceed 18 months until the requirements of paragraph (b) of this AD are accomplished.

New Requirements of This AD

(b) Within 18 months after the effective date of this AD, replace all 7079–T6 aluminum latch support fittings with new 7075–T73 fittings in accordance with Boeing Service Bulletin 747–53A2377, Revision 2, dated October 6, 1994. Replacement of all latch support fittings constitutes terminating action for the inspection requirements of this AD.

(c) As of the effective date of this AD, no operator shall install any 7079–T6 aluminum latch support fitting of the cargo door on any airplane.

(d) 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.

(e) 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 December 5, 1997.

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–32427 Filed 12–10–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 97N–0427]

RIN 0910–ZA06

Diagnostic X-Ray Equipment Performance Standard; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to propose amendments to the performance standard for diagnostic x-ray systems and their major components. The agency is taking this action to address changes in the technology and use of radiographic and fluoroscopic systems. The agency is issuing this advance notice of proposed rulemaking (ANPRM) in accordance with its policy of early public disclosure of rulemaking activities. The FDA is

soliciting comments and information from interested persons concerning the subject matter of the proposed amendments.

DATES: Submit written comments on the proposed amendments by March 11, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the SUPPLEMENTARY INFORMATION section for electronic access to the summary of concepts for amendments and a summary of the April 8 through 9, 1997, meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). Submit written requests for single copies of the Diagnostic X-Ray Equipment Performance Standard to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request or fax your request to 301–443–8818.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3314, ext. 32.

SUPPLEMENTARY INFORMATION:

I. Background

FDA, under authority conferred by the Public Health Service Act as amended by the Radiation Control for Health and Safety Act (RCHSA) of 1968 (Pub. L. 90–602 (21 U.S.C. 360hh–360ss)), administers an electronic product radiation control program to protect the public health and safety. This authority provides for the development and administration of radiation safety performance standards for electronic products.

In order for mandatory performance standards to achieve intended public health protection, attention must be given to keeping the requirements of standards updated and appropriate. A number of technological developments have been or will be implemented for radiographic and fluoroscopic x-ray systems that are not addressed by the performance standard or that present problems in the application of the requirements of the current standard. FDA is developing proposed amendments to the performance standard for radiographic and fluoroscopic systems that take into account new technology, clarify certain provisions, and address additional requirements that may be determined to be necessary to provide for adequate radiation safety of these systems.

On October 16 and 17, 1992, the American College of Radiology and FDA sponsored a workshop on fluoroscopy to develop strategies for improvement in performance, safety and control of fluoroscopic equipment. Physicians, physicists, State and Federal government regulators, and fluoroscopic equipment manufacturers attended the workshop. They discussed and made recommendations for different ways to approach fluoroscopic radiation safety issues and concerns, including regulatory solutions.

In the **Federal Register** of May 19, 1994 (59 FR 26402), FDA published a final rule effective May 19, 1995, amending performance requirements for fluoroscopic systems to address the immediate concern of preventing unlimited exposure rates during the high-level control mode of fluoroscopic system operation. The TEPRSSC discussed the status of standards for fluoroscopic systems and new clinical uses during a meeting held on April 9 through 10, 1996. TEPRSSC is a permanent statutory advisory committee established by statute that FDA must consult prior to issuing standards under the RCHSA.

At a meeting of the TEPRSSC held on April 8 through 9, 1997, FDA presented general concepts for amendments to the performance standard for radiographic and fluoroscopic systems.

The committee recommended that FDA pursue development of the amendments in the areas discussed in section II of this notice.

A transcript of the TEPRSSC April 8 through 9, 1997, meeting may be ordered from Miller Reporting Co., Inc., 507 C St. NE., Washington, DC 20002, 202–546–6666 or FAX 202–546–1502.

Individuals or organizations wishing to receive copies of draft amendments or related documents distributed for review during the development of these amendments may have their names placed on the mailing list by writing to: Office of Science and Technology (HFZ–140), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301–443–9101, e-mail: TBS@CDRH.FDA.GOV.

II. Concepts for Amendments to the Standard

FDA has identified the following nine areas as candidates for amendments to accommodate changes in technology and clinical use of radiographic and fluoroscopic systems. The discussion below each concept is not intended to indicate the specific content of the proposed amendment to be developed, but is meant only to describe the need and FDA's proposed approach. The specific regulatory changes or proposed standards will be included in a future proposed rule. Comments received in response to this notice will be used to develop the proposed amendments. FDA requests comments on the following conceptual changes:

1. Conversion to the International System of Units (SI) quantities and units for the entire standard. This proposal is to amend all sections of the performance standard for diagnostic x-ray systems to use the radiation quantity ''air kerma'' in place of the quantity ''exposure'' and to change the units to the SI.

2. Clarification of applicability of requirements to technological developments, such as digital imaging, digital recording and solid-state x-ray imagers. The current organization and structure of the standard assumes the presence of an x-ray image intensifier as the basis for many of the requirements for fluoroscopic systems. This assumption may be inappropriate for digital fluoroscopy systems that may use new types of digital image receptors. Such systems may not have an image intensifier tube. The structure of the radiographic section of the standard is based on radiographic film as the image receptor and revisions are needed to incorporate technological developments in that area. It would be desirable to the extent possible to use terminology consistent with usage adopted by the International Electrotechnical Commission (IEC).

3. Amendment to incorporate draft Compliance Policy Guide on Information to be Provided to Users (21 CFR 1020.30(h)). This proposal would amend the requirements on the content of information that must be provided to users to include specific information on the air kerma rate for certain fluoroscopic modes of operation. This amendment would incorporate into the standard a draft Compliance Policy Guide that has been developed, but not yet issued, and is intended to interpret § 1020.30(h) for certain ''unique'' modes of fluoroscopic system operation.

4. Amendment to add requirements for minimum half-value layer (HVL) for systems designed for interventional radiology (§ 1020.30(m)). This proposal would increase the minimum half-value layer requirements for fluoroscopic systems designed for interventional radiology. Such a requirement will require definition of a ''fluoroscopic system designed for interventional

fluoroscopy.'' As a concept for discussion, fluoroscopic systems designed for interventional radiology might be defined as systems that permit the beam axis to be positioned at an angle relative to the normal to the table top. Systems in which the x-ray beam direction is fixed with respect to the plane of the tabletop, such as conventional radiographic/ fluoroscopic systems, would not be included in this definition.

5. Amendment to require improved x-ray field limitation (21 CFR 1020.32(b)(2)(v)). This proposal would require improved limitation of the x-ray field for fluoroscopic equipment to match the actual area of the image receptor being used for image capture, thereby reducing the amount of non-useful beam striking the patient.

6. Amendment to clarify the requirements for the minimum source-skin distance for small, mobile, or portable mini C-arm systems (§ 1020.32(g)). This amendment would address numerous requested and granted variances for fluoroscopic systems that have limited source-image receptor distances. The amendment would specify the conditions under which a shorter-than-standard source-skin distance is permitted and would obviate the need for continued variances from the standard.

7. Amendment to require indication of cumulative exposure time on fluoroscopic systems (§ 1020.32(h)). The proposed amendment would require the means to indicate the cumulative time of fluoroscopic irradiation of a patient during an examination or procedure.

8. Amendment to require provision of ''last-image-hold'' feature on fluoroscopic systems (§ 1020.32(j)). This amendment would require that all fluoroscopic x-ray systems be provided with a means to continuously display the last image acquired following termination of any exposure period.

9. Amendment to require indication of air kerma rate and cumulative air kerma on fluoroscopic systems (§ 1020.32(k)). The proposed amendment would require the means to display to the fluoroscopist at the fluoroscopist's working position the cumulative air kerma and the air kerma rate (air kerma per unit time) at which air kerma accrues during irradiation of a patient in an examination or procedure.

III. Electronic Access

The summary of concepts for amendments entitled ''Concepts for Proposed Amendments to the Performance Standard for Diagnostic X-ray Systems, August 1, 1997,'' may be accessed at the CDRH Home Page on the World Wide Web. It is available on the Topic Index page at: http://www.fda.gov/cdrh/topindx under ''Fluoroscopy''. A text-only version of the CDRH site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there, follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA Home Page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there, select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

The document may also be obtained by fax by calling the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 591 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

A summary of the TEPRSSC April 8 through 9, 1997, meeting is available on the CDRH Home Page at the same address given above for the concepts for amendments document.

IV. Comments

Interested persons may, on or before March 11, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed amendment. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons also are invited to participate in the development of proposed amendments by submitting written data, views, or arguments concerning the subject matter of the amendments, or related topics suggested for inclusion in the amendments. In addition to general comments and recommendations, respondents are encouraged to include suggested text for provisions of the proposed amendments that reflect their recommended performance requirements. A statement of rationale should accompany any such proposed text. When a determination is made on the content of the proposed amendments, they will be published as notices of proposed rulemaking with opportunity given for public comment. Information and comments are specifically invited on the following topics:

1. For concepts 4 through 9 in section II of this document, recommendation for whether the amendments should be limited only to equipment designed for interventional procedures or for all fluoroscopic systems. If only for interventional systems, how should ''interventional fluoroscopic systems'' be defined?

2. The desirability and technical feasibility of amendments of the type described in section II of this document.

3. Recommended performance requirements to be included in the proposed amendments, including attendant methods and conditions of measurement.

4. Suggestions and supporting data for other amendments to the performance standard for radiographic or fluoroscopic equipment, including moving towards more outcome-based performance standards, which may be needed to provide for adequate radiation safety.

5. The possible environmental impact of this action, including factors such as radiation exposure reduction or prevention and economic consequences in relation to expected benefits (cost-benefit relationship), and the anticipated costs of providing such features or meeting the requirements.

6. Any additional terms or definitions that are needed to better specify the intent or meaning of the regulations as they apply to the equipment.

This ANPRM is issued under 21 U.S.C. 321 and under the authority of the Commissioner of Food and Drugs.

Dated: October 29, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32462 Filed 12–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE45

Endangered and Threatened Wildlife and Plants; Proposed Revision of Special Regulations for the Gray Wolf

AGENCY: Fish and Wildlife Service, Interior.