§ 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; certified 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, 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.

(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 door, 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.

(b) 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.

(b) New Requirements of This AD

(1) 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.

(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.

(3) 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.
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 radiological and fluoroscopic safety 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 name their places 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 quantities “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 is inconsistent with the current status of x-ray equipment. 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 Technical 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 system will require definition of a “fluoroscopic system designed for interventional radiology.”
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 tabletop. 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 unnecessary 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 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/topics 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.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

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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.