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Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 01N–0275]

RIN 0910–AC34

Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the performance standard for diagnostic x-ray systems and their major components. The agency is taking this action to update the standard to account for changes in technology and use of radiographic and fluoroscopic systems as well as to fully utilize the currently accepted metric system of units in the standard. For clarity and ease of understanding, FDA is republishing the complete contents of the affected regulations. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA).

DATES: Submit written or electronic comments by April 9, 2003. See section III of this document for the proposed effective date of a final rule based on this document. Submit written comments on the information collection requirements by January 9, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments regarding the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St., NW. rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–3314, ext. 132.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Proposed Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components
A. Change in the Quantity Used to Describe X-Radiation From Exposure to Air Kerma
B. Clarification of Applicability of Requirements to Account for Technological Developments in Fluoroscopic X-Ray Systems Such as Digital Imaging, Digital Recording, and New Types of Solid-State X-Ray Imaging Devices
C. Changes and Additions to Definitions and Applicability Statements
D. Information to be Provided to Users (§ 1020.30(h))
E. Increase in Minimum Half-Value Layer (§ 1020.30(m)(1))
F. Change in the Requirement for Fluoroscopic X-Ray Field Limitation and Alignment (§ 1020.32(b))
G. Revisions and Change in the Limits to Maximum Air Kerma Rate (§ 1020.32(d) and (e))
H. New Modes of Image Recording
I. Entrance Air Kerma Rate at the Fluoroscopic Image Receptor
J. Requirement for Minimum Source-Skin Distance for Small C-Arm Fluoroscopic Systems (§ 1020.30(g))
K. Requirements for Display of Fluoroscopic Irradiation Time, Air Kerma Rate, and Cumulative Air Kerma (§ 1020.32(h) and proposed (k))
L. ''Last-Image Hold'' Feature on Fluoroscopic Systems (Proposed § 1020.32(j))
M. Modification of Previously Manufactured and Certified Equipment
N. Modification of Warning Label (§ 1020.30(j))
O. Corrections of § 1020.31(f)(3) and (m)
P. Corrections to Reflect Changes in Organizational Name, Address, and Law (§ 1020.30(c), (d), and (q))
Q. Removal of Reference to Special Attachments for Mammography
R. Change to the Applicability Statement for § 1020.32
S. Republication of §§ 1020.30, 1020.31, and 1020.32
III. Proposed Effective Date
IV. Environmental Impact
V. Paperwork Reduction Act of 1995
VI. Analysis of Impacts
A. Introduction
B. Objective of the Proposed Rule
C. Risk Assessment
D. Constraints on the Impact Analysis
E. Baseline Conditions
F. The Proposed Amendments
G. Benefits of the Proposed Amendments
H. Estimation of Benefits
I. Costs of Implementing the Proposed Regulations
J. Small Business Impacts
K. Reporting Requirements and Duplicate Rules
L. Conclusion of the Analysis of Impacts
VII. Federalism
VIII. Submission of Comments
IX. References

I. Background

The SMDA (Public Law 101–629) transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (RCHSA) (Public Law 90–602) from title III of the Public Health Service Act (PHS Act) (42 U.S.C. 201 *et seq.*) to chapter V of the act (21 U.S.C. 301 *et seq.*). Under the act, FDA administers an electronic product radiation control program to protect the public health and safety. FDA also develops and administers radiation safety performance standards for electronic products.

The purpose of the performance standard and these proposed amendments is to improve the public health by reducing exposure to and the detriment associated with unnecessary ionizing radiation from diagnostic x-ray systems while assuring the clinical utility of the images.

In order for mandatory performance standards to provide the intended public health protection, the standards must be modified when appropriate to reflect changes in technology or product usage. A number of technological developments have been or will soon be implemented for radiographic and fluoroscopic x-ray systems. Such developments, however, are not addressed in the current standard, but have presented problems in the application of the current performance standard.

FDA thus is proposing to amend the performance standard for diagnostic x-ray systems and their major components in §§ 1020.30, 1020.31, 1020.32, and 1020.33(h) (21 CFR 1020.30, 1020.31, 1020.32, and 1020.33(h)).

These proposed amendments will require additional features on newly manufactured x-ray systems that physicians may use to minimize x-ray exposures to patients. Advances in technology have made several of these newly required features possible or feasible at minimal cost.

In the **Federal Register** of August 15, 1972 (37 FR 16461), FDA issued a final rule for the performance standard, which became effective on August 1, 1974. Since then, FDA has made several

amendments to the performance standard to incorporate new technology, to clarify misinterpreted provisions, or to incorporate additional requirements necessary to provide for adequate radiation safety of diagnostic x-ray systems. (See, e.g., amendments published on October 7, 1974 (39 FR 36008); February 25, 1977 (42 FR 10983); September 2, 1977 (42 FR 44230); November 8, 1977 (42 FR 58167); May 22, 1979 (44 FR 29653); August 24, 1979 (44 FR 49667); November 30, 1979 (44 FR 68822); April 25, 1980 (45 FR 27927); August 31, 1984 (49 FR 34698); May 3, 1993 (58 FR 26386); May 19, 1994 (59 FR 26402); and July 2, 1999 (64 FR 35924)).

In the **Federal Register** of December 11, 1997 (62 FR 65235), FDA issued an advance notice of proposed rulemaking requesting comments on the proposed conceptual changes to the performance standard. The agency received 12 comments from State and local radiation control agencies, manufacturers, and a manufacturer organization. FDA considered these comments in developing this proposal. In addition, the concepts embodied in these proposed amendments were discussed on April 8, 1997, during a public meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). TEPRSSC is a statutory advisory committee (21 U.S.C. 360kk(f)(1)(A)) that FDA is required to consult before it may prescribe any electronic product performance standard under the act. The proposed amendments themselves were discussed in detail with the TEPRSSC during its meeting on September 23 and 24, 1998. TEPRSSC approved the content of the proposed amendments and concurred with their publication for public comment.

The proposed amendments described in section II of this document may be considered as nine significant amendments to the current standard and several other minor supporting changes, corrections, or clarifications. The nine principal amendments fall into the following three categories:

1. Amendments requiring changes to equipment design and performance;
2. Amendments designed to improve use of fluoroscopic systems by requiring enhanced information to users; and
3. Amendments applying the standard to new features and technologies associated with fluoroscopic systems.

II. Proposed Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components

A. Change in the Quantity Used to Describe X-Radiation From Exposure to Air Kerma

FDA proposes to change the quantity and the associated unit used to describe the radiation emitted by the x-ray tube or absorbed in air. The radiation quantity ''exposure'' would be replaced by the quantity ''air kerma.'' The units used to describe these quantities would be changed accordingly throughout the standard, wherever appropriate.

The International System of Units (SI) was named and adopted at the 11th General Conference on Weights and Measures (GCWM) in 1960 as an extension of the earlier metric systems. The SI, also referred to as the metric system, is the approved system of units for use in the United States. The U.S. Department of Commerce published an ''Interpretation and Modification of the International System of Units for the United States'' in the **Federal Register** on December 10, 1976, which set forth the interpretation of the SI system for the United States. The Omnibus Trade and Competitiveness Act of 1998 amended the Metric Conversion Act of 1975 to require each Federal agency to use the metric SI system in its activities. The FDA policy for use of metric measurements is described in a March 19, 1990, memorandum. This policy calls for use of the metric units followed by a parenthetic ''inch-pound'' declaration unless there is a cogent reason not to utilize dual metric and ''inch-pound'' measurements. The policy notes that there should be few such exceptions.

One of the objectives of the International Commission on Radiation Units and Measurements (ICRU) is to develop internationally accepted recommendations regarding quantities and units of radiation and radioactivity. The ICRU recommendations often form the basis of GCWM actions. In 1998, the ICRU published its Report 60, ''Fundamental Quantities and Units for Ionizing Radiation,'' superseding its previous Report 33. Report 60 uses the SI units and special names for some radiation units (Ref. 1). The ICRU had suggested phasing out by 1985 the use of certain special quantities and units that were not part of the SI system, including the special unit of exposure, the roentgen (R).

The current Federal performance standard for diagnostic x-ray equipment uses the special quantity exposure to describe the radiation emitted from an x-ray system. In the **Federal Register** of May 3, 1993 (59 FR 26386), FDA published a final rule which made a partial transition to the SI units by changing the unit for exposure from ''roentgen'' (R) to ''coulomb per kilogram'' (C/kg). This change required using an awkward conversion factor of 2.58×10^{-4} C/kg per R.

In view of current trends, scientific practice, the U.S. policy, and FDA directives, FDA proposes that a complete conversion be made to the SI quantities and units by amending the standard to require using the quantity air kerma in place of the quantity exposure. Additionally, the agency proposes that, in making this conversion, the absolute magnitude of the limits on radiation contained in the standard not be changed. This requires that the limits, when expressed in the new quantity air kerma and its unit, the gray, be expressed with numerical values different from the current limits that use the quantity exposure.

In its recent reports, the National Council on Radiation Protection and Measurement (NCRP) adopted the use of the SI quantity kerma, in particular air kerma, to describe the radiation emitted from an x-ray system. This change in the NCRP recommendations was made without significant concern that previous limits in the voluntary recommendations were slightly increased by this change when numerical values for the limits were not changed but were expressed in the new units. This change in the NCRP recommendations resulted in an increase in the limits, compared to previous recommendations, of about 15 percent.

FDA is not proposing such an increase in this proposal. Instead, FDA is proposing that the numerical values for limits in the standard relating to radiation, when expressed in the new quantity, be changed as well so the new limits will be equivalent to the current limits, thereby making no change to the level of radiation protection provided by the standard. FDA has dropped earlier draft proposals to change the numerical values in a manner similar to the changes made to the voluntary recommendations by the NCRP because of several comments that were received. The comments objected to any changes to the level of radiation protection provided by the limits in the current mandatory standard.

This proposed approach to the numerical limits results in numerical values that are not integer numbers or multiples of 5 or 10, as is the case in the current standard, when limits are expressed in the non-SI unit for

exposure, roentgen. For example, the current limit for an exposure rate of 10 R/minute (R/min), 2.58 x 10^{-3} C/kg per min, becomes an air kerma rate (AKR) limit of 88 milligray per minute (mGy/min) under the proposed approach.

FDA is proposing new definitions of the quantities kerma, as used by the ICRU, and air kerma in § 1020.30(b). Because the quantity air kerma is a different quantity from exposure and not numerically equivalent, FDA is proposing in the amended standard to express the limits in terms of air kerma and indicate the equivalent limit in terms of exposure using the word ''vice'' to indicate this equivalence. Thus, the change described above would be given in the proposed amendments as a limit expressed as ''88 mGy/min (vice 10 R/min)'' indicating that the new limit of 88 mGy/min air kerma is equivalent to the previous limit 10 R/min exposure.

Current International Electrotechnical Commission (IEC) standards for diagnostic x-ray systems use the quantity air kerma to describe the radiation emitted by the x-ray system. The current limits on maximum fluoroscopic exposure rates in the performance standard were established to be consistent with the recommendation of the NCRP. The proposed amendment maintains agreement between the performance standard and the voluntary standards in terms of the quantities and units used. But in order to maintain the current level of radiation protection and in response to the comments received, the change results in numerical limits for some of the requirements different from those used in the current recommendations of the NCRP.

The term ''exposure'' is also used with a second meaning in the performance standard that does not refer to a quantity of radiation as defined here. The second meaning of ''exposure'' refers to the process or condition during which the x-ray tube is activated by a flow of current to the anode and radiation is produced. The second meaning of exposure will continue to be used where appropriate. FDA is proposing to revise the definition of the quantity exposure in § 1020.30(b) to match the current ICRU definition.

FDA also proposes in § 1020.30(b) to amend the definitions of ''half-value layer'' (HVL) and ''x-ray field'' to reflect the change from the quantity exposure to air kerma.

B. Clarification of Applicability of Requirements to Account for Technological Developments in Fluoroscopic X-Ray Systems Such as Digital Imaging, Digital Recording, and New Types of Solid-State X-Ray Imaging Devices

When the performance standard was originally developed, the only means for producing a fluoroscopic image was either a screen of fluorescent material or an x-ray image intensifier tube. Thus, the standard was originally written with these two types of image receptors in mind. The advent of new types of image receptors, such as solid-state x-ray imaging (SSXI) devices, and new modes of image recording, such as digital recording to computer memory or other media, has made the application of the current standard to systems incorporating these new technologies cumbersome and awkward. These new aspects of fluoroscopic system design have required a series of interpretations to apply the standard appropriately. With this in mind, FDA proposes to amend the performance standard to recognize these new types of image receptors and modes of image recording and to clarify how the requirements of the standard apply in each case. This amendment would result in replacing the terms ''x-ray image intensifier'' or ''image intensifier'' with the more general term ''fluoroscopic image receptor'' in numerous sections.

Although the basic radiation protection and safety requirements for fluoroscopic equipment in the performance standard are based on the presence of an x-ray image intensifier, these requirements are also appropriate for newer imaging systems that do not use an x-ray image intensifier. The newer imaging systems may incorporate an image receptor consisting of an absorbing material and an array of solid state transducers that intercepts x-ray photons and directly converts the photon energy into a modulated electrical signal. The signal often goes through analog-to-digital conversion as part of the image formation process to perform both fluoroscopy and radiography. FDA proposes to modify the structure and organization of the standard to address this new type of x-ray imaging equipment. The specific changes proposed are described below in section II.C of this document.

For SSXI, new performance considerations are relevant because of the different construction and the use of solid-state materials such as silicon and selenium. These new considerations include: Changes in spatial resolution, as quantified in the modulation transfer function (MTF), dynamic range, and detective quantum efficiency; the introduction of aliasing artifacts; reduced geometrical efficiency (fill factor); and differences in the range of quantum-limited operation when compared to the older vacuum-tube-based fluoroscopic equipment. Because consensus is not available on some aspects of the performance for these new devices, the agency has relied on premarket review and associated guidance documents to provide the necessary radiation safety control for these devices. (See, e.g., the ''Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices '' (Ref. 2).)

An example of a new performance consideration for the SSXI is the active detector area. Because of the need for electrical separation/insulation between individual detector elements, the detector area has both active and inactive regions, in terms of detecting image information. The relative areas of the active and inactive detector areas are usually described in terms of the fill factor. The fill factor, to a first approximation, is the pixel area (active area in terms of image formation) times the number of pixels divided by the total detector area exposed to the input image flux.

The fill factor and other characteristics can have significant effects on imaging performance. The imaging performance must also be considered when obtaining a complete picture of the effectiveness of these devices. Although FDA is not offering specific proposals for imaging performance at this time, FDA is inviting comment on possible approaches to ensuring radiation protection and safety in the application of these SSXI devices.

C. Changes and Additions to Definitions and Applicability Statements

To address the changes in technology and the new types of image receptors and to allow these items to be appropriately integrated into the standard, FDA proposes the following changes in definitions and applicability sections of the standard. The changes in definitions described here are in addition to those described above in section II.A of this document.

First, in § 1020.30(b), FDA proposes to amend the definition of ''fluoroscopic imaging assembly,'' ''image receptor,'' ''spot-film device,'' and ''x-ray table'' by removing the reference to an x-ray image intensifier as the descriptor of the image receptor or by replacing image intensifier with the more general term fluoroscopic image receptor.

Second, FDA also proposes in § 1020.30(b) to amend the definition of the term ''recording'' by removing the word ''permanent'' and replacing it with the word ''retrievable,'' and to remove the examples of ''recording,'' to clarify the definition of the term ''recording'' in the context of images stored on recording media other than film.

Third, in § 1020.30(b), FDA proposes to clarify the applicability of the standard or to bring precision to the meaning of specific requirements by adding definitions for the terms solid state x-ray imaging device, fluoroscopy, radiography, non-image intensified fluoroscopy, automatic exposure rate control, isocenter, last image hold (LIH) radiograph, mode of operation, and source-skin distance (SSD).

Last, under § 1020.30(b), FDA proposes to add a definition of ''lateral fluoroscope'' to clarify the distinction between a lateral fluoroscope and what is commonly referred to as a C-arm fluoroscope. In an August 29, 1977, Compliance Policy Guide, FDA described the geometry for measuring, during a compliance test, the entrance exposure rate for lateral fluoroscopes. The standard does not define a system by the way it is used but allows the manufacturer to specify the use for which the equipment is designed. The design of the system determines whether the system is a C-arm or a lateral fluoroscope. If the system is a C-arm, it is tested using the test geometry for a C-arm system, even if it is used with a lateral beam direction. If the system is a dedicated lateral fluoroscope used with a biplane system, the more restrictive measurement geometry, as described for a lateral fluoroscope in the current § 1020.32(d)(4)(iv) and (e)(3)(iv), will be used. This test geometry is described in proposed § 1020.32(d)(3)(v).

The lateral fluoroscope consists of a support structure holding a tube housing assembly and a fluoroscopic imaging assembly with the x-ray beam in a lateral projection parallel to the plane of the tabletop. Thus, the geometry of the source and image receptor is fixed relative to the patient or x-ray table. The entrance air kerma would be measured with the radiation measurement instrument detector placed 15 centimeters (cm) from the center of the table in the direction toward the x-ray source. (This position is considered to be typical of the entrance skin surface of the patient.) During the measurement, the tube housing assembly is positioned as close to this location as allowed by the system. For C-arm system measurement geometry, the patient is assumed to be as close to the image receptor as possible and, therefore, the detector is placed 30 cm from the entrance surface of the image receptor. In a lateral fluoroscope, the patient cannot be placed against the image receptor, and the measurement point is referenced to the center of the table. The standard does not require that the table have the centerline indicated. Testing is performed relative to the centerline and the center is located by measurement if necessary.

Additionally, FDA proposes to correct two minor typographical errors that were introduced into the definitions of ''leakage technique factors'' and ''spot-film device'' in the May 3, 1993, **Federal Register**.

FDA proposes in §§ 1020.31 and 1020.32 to amend the applicability statements by removing the reference to an x-ray image intensifier as the descriptor of the image receptor used to distinguish between radiography and fluoroscopy. FDA proposes to further modify the applicability statements to clearly identify the type of x-ray imaging equipment to which each section applies and to distinguish between radiographic and fluoroscopic imaging.

Additionally, to complete the transition to the use of the terminology ''fluoroscopic image receptor,'' FDA proposes in § 1020.32(a)(1) and (a)(2), to replace the term ''image intensifier'' with the more inclusive term ''fluoroscopic image receptor'' to reflect the changes in fluoroscopic image receptor technology and design. This change will, therefore, include SSXI devices, x-ray image intensifiers, and other fluoroscopic image receptors within the transmission limit and measurement criteria of paragraphs (a)(1) and (a)(2).

Similarly, FDA proposes in § 1020.32(g) to remove ''image-intensified fluoroscope'' and add in its place the generic term ''fluoroscope'' in the description of the requirement for minimum SSD for systems intended for specific surgical applications.

Finally, in § 1020.32(i), FDA proposes to remove the term ''intensified imaging'' and add in its place ''image receptor incorporating more than a simple fluorescent screen.'' This removes the reference to a specific type of fluoroscopic image receptor, the image intensifier, and includes all types of receptors other than a simple fluorescent screen as meeting the requirement of § 1020.32(i).

D. Information to be Provided to Users (§ 1020.30(h))

FDA proposes to add two paragraphs to § 1020.30(h). Proposed § 1020.30(h)(5) and (h)(6) would require manufacturers to provide in the instructions for users additional information regarding fluoroscopic x-ray systems.

Recent developments in the technology of fluoroscopic systems have resulted in equipment being increasingly provided with a variety of special modes of operation and methods of recording fluoroscopic images. Some of these modes of operation may significantly increase the entrance AKR to the patient compared to conventional fluoroscopy. There is concern that the operating instructions provided with the fluoroscopic system lack sufficient information concerning the characteristics of these special modes of operation to permit the operator to adequately evaluate the increased radiation output and consequent increased exposure to the patient and operator from these modes of operation. There is typically little information provided to users on the clinical procedure(s) for which each mode was designed, resulting in potential inappropriate application of the mode by a user who is not fully aware of the intended application of the particular mode of operation.

Proposed § 1020.30(h)(5) would require that the information provided to users contain a detailed description of each mode of operation and specific instructions on the manner in which the mode is engaged or disengaged. The manufacturer would also be required to provide information on the specific types of clinical procedures or imaging tasks for which the mode is intended and instructions on how each mode should be used. This information is to be provided in a special section of the user's instruction manual or in a separate manual devoted to this purpose.

Section 1020.30(h)(1)(i) of the performance standard states that the information to users shall contain ''Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment * * *.'' FDA considers any mode of operation that yields an entrance AKR above 88 mGy/min to be a unique feature of the specific fluoroscopic equipment and thus must have a full and complete description in the instructions for its use.

FDA is also of the opinion that, for modes of operation where the entrance

AKR exceeds 88 mGy/min, the manufacturer should provide detailed information to permit the user to assess the exposure to the patient relative to that delivered in the normal mode of operation. Such information would give operators important radiation safety data with which to make better judgments on the possible hazards involved with a particular procedure. FDA has learned that, because of the multiple number of modes and options available with many of the systems, many users are not aware of when or how such modes are engaged and disengaged or the radiation output consequences of such modes. FDA had originally considered requiring the manufacturer to provide data on the entrance AKRs for each mode of operation of the fluoroscopic system. However, the large number of possible combinations of modes and options for operation available with many of the systems makes this impractical. The proposed amendment described in section II.J of this document would require the manufacturer to provide a display of the AKR and cumulative air kerma. With this information, the user is made aware of the relative changes in the AKR when changing from one mode of operation to another. Awareness of such changes will inform the user of the relative output changes of the system as a function of mode of operation, patient size, and system geometry.

FDA believes that manufacturers are already providing much of the information proposed in this requirement. However, the information may not be displayed in a separate section of the manual where users can readily find it, and the information may not contain enough detailed information on the intended use of the various modes of operation to assure proper use of the system.

Proposed § 1020.30(h)(6) would require manufacturers to provide users with information regarding the new features of fluoroscopic systems described in proposed § 1020.32(k). Proposed § 1020.30(h)(6) would also require manufacturers to provide information regarding the display of values of AKR and cumulative air kerma. This information will include a statement of the maximum deviation of the actual values of AKR and cumulative air kerma from their displayed values, maintenance and instrumentation calibration information, and a description of the spatial coordinates of the reference location for which the displayed values are given.

E. Increase in Minimum Half-Value Layer (§ 1020.30(m)(1))

FDA proposes to modify the requirement for minimum HVL to recognize changes in x-ray tube and x-ray generator technology over the last few decades.

The use of x-ray filtration to increase the quality or homogeneity of an x-ray beam through selective absorption of the low energy photons has been a recommended practice for a long time. A 1968 report published by NCRP (appendix B, table 3, in Ref. 3) provides the beam quality in terms of HVL, as a function of tube potential, that would result from specified values of total x-ray filtration in the x-ray beam. However, the values of HVL in the table would only result if one used the NCRP suggested values of total filtration in diagnostic x-ray equipment of that era (i.e., the 1960s to early 1970s). It should be noted that diagnostic x-ray equipment of that era was characterized by x-ray tubes with a large x-ray target angle and x-ray generators with significant ripple in the high voltage waveform (e.g., an x-ray target angle of 22° and a high voltage ripple of 25 percent).

The requirements on beam quality in the current IEC international standard (Ref. 4) are also expressed in a similar manner as the NCRP Report No. 33 (i.e., a total filtration requirement plus a set of minimum HVL values). The Institute of Physical Sciences in Medicine has recently published a report which can be used to estimate the total filtration from HVL data as a function of x-ray target angle and high voltage ripple (Ref. 5). These data point out the lack of correspondence between a total filtration of 2.5 millimeters (mm) of aluminum and the minimum HVL requirements in the performance standard for state-of-the-art x-ray equipment (e.g., an x-ray target angle of 12° and a high voltage ripple of 10 percent). For these types of equipment, the minimum HVL requirements in the performance standard can be met with about 1.8 mm of total filtration versus the required 2.5 mm of total filtration as specified in the IEC standard (Ref. 4). Only equipment with large x-ray target angles (22°) and a great deal of high voltage ripple (25 percent) need a total filtration of 2.5 mm of aluminum to meet the minimum HVL requirements in the performance standard. In terms of skin-sparing effect, the performance-oriented set of minimum HVL values in the performance standard have not kept up with changes in x-ray equipment when compared to the design-oriented requirement of a total filtration of 2.5 mm of aluminum.

For these reasons, FDA proposes to increase the minimum HVL values for radiographic and fluoroscopic equipment excluding mammography equipment and dental equipment designed for use with intraoral image receptors. The proposed minimum HVL values represent the values obtained with a total filtration of 2.5 mm of aluminum on state-of-the-art diagnostic x-ray equipment (i.e., an x-ray target angle of 12° and a high voltage ripple of 10 percent). FDA used the data in the Institute of Physical Sciences in Medicine report to arrive at the proposed minimum HVL values.

As a separate x-ray filtration issue, there has been a substantial increase over the past 20 years in the use of x-ray fluoroscopy as a visualization tool for a wide range of diagnostic and therapeutic procedures. Because of the long catheter manipulation times and the need, in some cases, for a stationary x-ray field, these procedures have the potential, sometimes realized, for high radiation dose to patients and clinical personnel (Ref. 6). In fact, the agency has been actively involved in promoting recommendations for the avoidance of serious, x-ray-induced, skin injuries to patients during fluoroscopically-guided interventional procedures. As a result, there continues to be an interest in dose reduction techniques for these procedures.

In general, the addition of either beam-hardening or K-edge x-ray filters can provide a significant reduction in the exposure, particularly skin exposure, to the patient. However, this reduction in exposure is accompanied by an attendant increase in tube load (Ref. 7). It should be noted that one of the recommendations of the work group on the technical aspects of fluoroscopy at the 1992 American College of Radiology (ACR)/FDA workshop on fluoroscopy (Ref. 8) was to increase the minimum HVL. Therefore, FDA is also proposing an additional requirement for fluoroscopic x-ray systems incorporating x-ray tubes of high heat-load capacity. Manufacturers of these systems would be required to provide a means, at the user's option, for adding additional x-ray filtration over and above the amount needed to meet the proposed new minimum HVL values. This requirement is based on the assumption that x-ray tubes with high heat-load capacity are typically required or provided on equipment designed for use in interventional procedures due to the imaging task requirements and the extended exposure times associated with interventional procedures. The

method of implementation and the actual values of additional filtration to realize the reduction in skin exposure will be left to the discretion of the manufacturer.

F. Change in the Requirement for Fluoroscopic X-Ray Field Limitation and Alignment (§ 1020.32(b))

FDA proposes to reorganize and add new paragraphs to § 1020.32(b) to require improved x-ray field limitation for fluoroscopic x-ray systems. Section 1020.32(b) would be reorganized to retain the current requirements applicable to systems manufactured before the effective date of these amendments. For systems manufactured after the effective date, new requirements are proposed in § 1020.32(b)(4) and (b)(5) respectively, for systems with inherently circular or rectangular image receptors. These proposed new requirements will result in increased geometric efficiency or more efficient use of radiation as described below.

The proposed reorganization and retention of the existing requirements in § 1020.32(b) will be accomplished in the following manner: Section 1020.32(b)(1)(i) will be redesignated as § 1020.32(b)(3); § 1020.32(b)(1)(ii) and (b)(2)(iii) will be combined and redesignated as § 1020.32(b)(1) with appropriate revisions to paragraph references to reflect the reorganization of § 1020.32(b); § 1020.32(b)(2)(iv) will be redesignated as § 1020.32(b)(2) with a minor clarification; and § 1020.32(b)(3) will be moved and redesignated as new § 1020.32(b)(6). Additionally, § 1020.32(b)(2)(i) and (b)(2)(ii) will be moved to §1020.32(b)(4)(i) as § 1020.32(b)(4)(i)(A) and (b)(4)(i)(B).

New requirements of improved efficiency for systems manufactured after the effective date of the amendments are proposed in § 1020.32(b)(4)(ii) for systems with inherently circular image receptors. Section 1020.32(b)(5) would contain the field limitation requirements for systems with inherently rectangular image receptors. The requirements proposed for systems with rectangular image receptors are the same as those currently applicable to radiographic systems provided with positive beam limitation or to spot-film devices that utilize rectangular image receptors. As such, the proposed tolerances for x-ray field limitation are considered technically feasible.

A reduction in unnecessary patient exposure is the basis for all of the x-ray field limitation and alignment requirements in the performance standard. For example, any radiation falling outside the visible area of the image receptor provides no useful diagnostic or visualization information and, therefore, represents unnecessary patient exposure. Once it is recognized that restricting the size of the x-ray field provides an effective control of unnecessary radiation exposure, the question shifts to what is the tolerance technically achievable by the manufacturer for the matching of the x-ray field and the visible area of the image receptor.

The current performance standard (§ 1020.32(b)(2)(i)), states ''neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.'' These requirements result in worst-case values of geometrical efficiency enumerated in table 1 of this document for what are typical geometrical and operating conditions on fluoroscopic systems. Geometrical efficiency is defined as the ratio of the visible area divided by the area of the x-ray field. It should be noted that the requirements in the existing IEC international standard with respect to x-ray field limitation are more stringent than in the performance standard (Ref. 4). When the x-ray field is rectangular and the visible area is circular, the IEC standard requires that the length and width of the x-ray field be less than the diameter of the maximum visible area of the image intensifier. Thus, if the x-ray field is centered on the visible area of the image intensifier, the x-ray field would exceed the visible area of the image intensifier only in the corners of a rectangular x-ray field, unlike what could result from following the current performance standard.

TABLE 1.—WORST-CASE GEOMETRICAL EFFICIENCY IN PERCENTAGE FOR A FLUOROSCOPIC SYSTEM[1]

Visible Area (circular, cm^2)	X-Ray Field (worst case, square, cm^2)	Efficiency (%)
113	196	57
177	289	61
415	625	66
707	1,024	69

[1] Worst-Case Geometrical Efficiency in Percentage for a Fluoroscopic System With a Source-Image Receptor Distance (SID) of 100 cm, a Square X-Ray Field Size at the Limits Allowed by § 1020.32(b)(2)(i), and Image Intensifiers With 12-, 15-, 23-, and 30-cm Diameter Visible Areas.

As can be seen from table 1 above, the current performance standard allows the possibility of relatively low geometrical efficiency, particularly in modes of operation corresponding to small visible areas on the image intensifier. It should be noted that many fluoroscopically-guided interventional procedures involve the use of small visible areas on the image intensifier (Ref. 9). These low values of geometrical efficiency are a direct result of using a square collimator for the x-ray field when faced with an inherently circular visible area for the image receptor. The use of a continuously adjustable, circular collimator and/or circular apertures along with adjustable rectangular collimation would increase the geometrical efficiency.

Many currently marketed x-ray systems suitable for fluoroscopically-guided interventional procedures provide continuously adjustable, circular collimators as a basic and/or optional capability (Ref. 10). Thus, a continuously adjustable, circular collimator is technically feasible, albeit at some additional cost to the user community. Fluoroscopic x-ray systems with this feature can provide a substantial increase in geometrical efficiency that is important for all types of radiological procedures but particularly important for interventional procedures resulting in high skin exposure.

It is for these reasons that FDA proposes to require geometrical efficiencies of 80 percent or more for all fluoroscopic x-ray systems. When the visible area of the image receptor is

greater than 34 cm in any direction, a geometrical efficiency of 80 percent is no longer sufficiently stringent. FDA proposes to change the requirement to a sizing tolerance at that point (i.e., the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the visible area of the image receptor by more than 2 cm). This oversizing tolerance will ensure geometrical efficiencies of better than 80 percent for large image receptors. In those unusual cases where the x-ray field is not uniformly intense over its cross-section, the proposed field limitation and alignment requirement provides for measurement of efficiency in terms of air kerma integrated over the x-ray field incident on the visible area of the image receptor (Ref. 11).

The intent is to promote the incorporation of continuously adjustable, circular collimators into all types of fluoroscopic x-ray systems with circular image receptors. FDA acknowledges that the new requirements could be met through the use of less complex, currently available, rectangular collimation and underframing. For example, the amount of underframing (defined as the difference in the width of the x-ray field versus the diameter of the visible area) of a rectangular x-ray field needed to meet the new requirements is enumerated in table 2 of this document for the same geometrical and operating conditions of fluoroscopic systems described in table 1 of this document. The agency is soliciting comments on the ramifications of this amount of underframing. These proposed requirements for increased x-ray utilization efficiency would appear in proposed § 1020.32(b)(4)(ii) for systems manufactured after the effective date of the amendments.

TABLE 2.—UNDERFRAMING OF A RECTANGULAR X-RAY FIELD[1]

Visible Area Diameter (cm)	X-Ray Field Width (cm)	Underframing (cm)
12	11.9	-0.1
15	14.9	-0.1
23	22.8	-0.2
30	29.7	-0.3

[1] Amount of Underframing of a Rectangular X-Ray Field Needed to Meet the New Field Limitation Requirements for a Fluoroscopic System With an SID of 100 cm and Image Intensifiers With 12-, 15-, 23-, and 30-cm Diameter Visible Areas.

Although the field limitation requirements for fluoroscopic equipment in the performance standard are predicated on the presence of an x-ray image intensifier, the requirements are also appropriate for newer imaging systems that do not use an x-ray image intensifier. As mentioned previously, the newer imaging systems may incorporate an image receptor consisting of an absorbing material backed by an array of solid state transducers that intercepts x-ray photons and converts the photon energy into a modulated electrical signal with eventual analog-to-digital conversion. These image receptors are inherently rectangular. As is the case for image intensifier based systems, magnification modes are available through the use of a ''digital zoom'' where only a selected portion of the digital array is visible to the operator. FDA is proposing to apply the current requirements of the standard for x-ray field limitation that are used for spot-film devices or radiographic systems equipped with positive beam limitation, and which also use rectangular fields, to this new type of image receptor. These requirements result in worst-case values of geometrical efficiency (defined as the square visible area divided by the area of a square x-ray field) enumerated in table 3 of this document for what are typical geometrical and operating conditions of fluoroscopic systems.

TABLE 3.—WORST-CASE GEOMETRICAL EFFICIENCY IN PERCENTAGE FOR A FLUOROSCOPIC SYSTEM[1]

Visible Area Diameter (square, cm^2)	X-Ray Field (square, cm^2)	Efficiency (%)
144	196	73
225	289	78
529	625	85
900	1,024	88

[1] Worst-Case Geometrical Efficiency in Percentage for a Fluoroscopic System With an SID of 100 cm, a Square X-Ray Field Size at the Limits Allowed by § 1020.32(b)(2)(i), and Solid-State X-Ray Images with 12 cm x 12 cm, 15 cm x 15 cm, 23 cm x 23 cm, and 30 cm x 30 cm Visible Areas.

As can be seen from table 3 above, the current standard provides relatively high geometrical efficiency. In this case, the high values of geometrical efficiency are a direct result of using a rectangular collimator for the x-ray field when faced with an inherently rectangular visible area for the image receptor. Proposed § 1020.32(b)(5) would explicitly state the field limitation requirements for systems with inherently rectangular image receptors.

G. Revisions and Change in the Limits to Maximum Air Kerma Rate (§ 1020.32(d) and (e))

In § 1020.32, FDA proposes to revise and reorganize § 1020.32(d) and (e) to clarify and simplify the requirements on maximum AKR for fluoroscopic x-ray systems. In § 1020.32(d), FDA proposes to incorporate all of the requirements for AKR limits regardless of the date of manufacture of the x-ray system. The revised paragraph would also incorporate the new quantity kerma and the corresponding limits on entrance

AKRs. FDA proposes to move the current requirements of § 1020.32(e) that are applicable to equipment manufactured on or after May 19, 1995, to the revised § 1020.32(d). This would consolidate all of the requirements for limits on the maximum AKR in a single section (i.e., revised § 1020.32(d)). Section 1020.32(e) would be reserved.

The requirements applicable to fluoroscopic systems manufactured before May 19, 1995, currently contained in § 1020.32(d)(1) through (d)(3), would be contained in revised § 1020.32(d)(1). No change in the limit on maximum AKR for previously manufactured fluoroscopic systems is introduced by the reorganization and simplification of current § 1020.32(d). This simplification is obtained by describing the exceptions to the maximum AKR only one time in proposed § 1020.32(d)(1)(v) rather than three times as in current § 1020.32(d)(1) through (d)(3).

Proposed § 1020.32(d)(1) also includes § 1020.32(d)(1)(iv) that makes explicit the fact that systems manufactured before May 19, 1995, may be modified to comply with new requirements contained in proposed § 1020.32(d)(2). The rationale for this addition is described in section II.M of this document.

Proposed § 1020.32(d)(2) would include the requirements applicable to fluoroscopic systems manufactured on or after May 19, 1995. Section 1020.32(d)(2)(i) would contain the language currently in § 1020.32(e)(1) that requires systems with the capability for AKR greater than 44 mGy/min to be provided with automatic exposure rate control.

Section 1020.32(d)(2)(ii) would contain the requirements of current § 1020.32(e)(2) that became effective on May 19, 1995, and establish an upper limit on the AKR during high-level control mode of operation. Section 1020.32(d)(2)(iii) would incorporate the exceptions to the maximum AKR limit given in § 1020.32(d)(2)(ii). Section 1020.32(d)(2)(ii)(A) would contain the exception currently found in § 1020.32(e)(2)(i) that addresses the recording of images using a pulsed mode applicable to equipment manufactured prior to the effective date of these amendments. For equipment manufactured after the effective date of these amendments, § 1020.32(d)(2)(ii)(B) would add an additional new exception described below in section II.H of this document. Finally, the exception currently found in § 1020.32(e)(2)(ii) addressing high-level control mode of operation would be moved to § 1020.32(d)(2)(ii)(C).

The conditions under which compliance is determined are currently found in § 1020.32(d)(4) and (e)(3). These conditions would be moved to § 1020.32(d)(3). Section 1020.32(d)(3)(vi) would be added to specifically address the measurement conditions for systems with SIDs less than 45 cm. For these systems, FDA is proposing that compliance be determined by measurement at the minimum SSD.

The exemption for radiation therapy simulation systems currently found in § 1020.32(d)(5) and (e)(4) would be incorporated into a proposed revision of § 1020.32(d)(4).

H. New Modes of Image Recording

New requirements would be established in a § 1020.32(d)(2)(iii)(B) to further limit the conditions under which the limit on the maximum AKR rate would not apply. In May 1994, the agency amended the requirements in the standard pertaining to the limit on entrance exposure rate (EER) during fluoroscopy. (For convenience in discussing the current standard and proposed changes, reference will be made to the limits on EER rather than to entrance AKR which will be the quantity used in the amended standard.)

These 1994 amendments prescribed an exception to the limit on EER during the recording of images ''from an x-ray image intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.'' (Pulsed mode is defined as operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.) These amendments also prescribed a limit on EER of 20 R/min when an optional high-level control was activated during fluoroscopy.

The basic premise of these amendments was to provide for a set of limits on the maximum EER during fluoroscopy, and for an exception during radiographic modes of operation such as cine-radiography. The defining terms for determining whether the equipment was in fluoroscopy versus radiography mode of operation were ''recording of images'' and ''pulsed mode.'' In retrospect, these terms were not explicit enough for making a determination of the mode of operation. For example, the current wording would allow adding a recording device such as a video tape recorder to the imaging chain in a pulsed mode of operation. This would, thereby, circumvent the intent of the regulation and allow the limit on maximum EER during fluoroscopy to be exceeded, even though the recorded images are never used in the radiological examination and are used only for archiving purposes, if used at all.

As mentioned in the earlier discussion on new types of image receptors, FDA is proposing new definitions for fluoroscopy and radiography. These definitions are needed to make a clearer distinction between fluoroscopy and radiography, regardless of the type of image receptor being used. A key element in the new definitions is that radiographic images recorded from the fluoroscopic image receptor must be available for viewing after the acquisition of the images and during or after the procedure, whereas fluoroscopic images are viewed in real time, or near-real time during the procedure. Thus, the definitions of the two modes of operation, i.e., radiography and fluoroscopy, are tied to the intended use, and not to an arbitrary interval of time, as under the current ''pulsed mode'' definition.

In addition to the proposed new definitions, FDA proposes to change the description of the conditions under which exceptions to the limit on maximum AKR are allowed. Section 1020.32(d)(2(iii) would contain two exemptions. The exemption currently in § 1020.32(e)(2)(i) would be moved to § 1020.32(d)(2)(iii)(A) and would apply to fluoroscopic systems manufactured on or after May 19, 1995, but before the effective date of the proposed amendment. A new exception would be added in § 1020.32(d)(2)(iii)(B). This exception would recognize that image receptors other than x-ray image intensifiers tubes are now used in fluoroscopy and would remove the reference to operation in a pulsed mode. Instead, the exception to the limit on maximum AKR would apply to any recording of images from the fluoroscopic image receptor except when the recording of images is accomplished using a video tape recorder or a video disk recorder. This would prevent the simple addition of an analog image-recording device to the fluoroscopic system as a means to overcome the limit on maximum AKR during normal fluoroscopy.

As discussed in the preamble of the proposed 1993 amendments (58 FR 26407, May 3, 1993), the agency is still interested in receiving information on any clinical situations that could require higher AKR than currently permitted. Such situations have been suggested to arise due to the necessity of momentarily viewing the patient or the state of a device in a patient as best as can be done or with the highest image quality obtainable during fluoroscopy

mode of operation. Some anecdotal evidence seems to argue for an increase in the EER above the current 20 R/min limit under high-level control. The 1994 change in the regulations underwent an extensive review and comment period. The consensus of that review, although not unanimous at the time of issuance of the regulations, was that 20 R/min would be sufficiently high for most clinical fluoroscopy situations. The agency was and is still sensitive to the concern that the limits on EER may in some cases compromise the clinical utility of the fluoroscopic equipment.

Because of these concerns regarding the appropriate upper limit AKR, FDA is encouraging further comment on the topic of limits on AKR under normal and high-level fluoroscopy modes. For example, some members of the radiological community have proposed that fluoroscopic equipment allow a momentary viewing of the state of an intervention at an increased but unspecified AKR. This momentary view would have a maximum duration of 10 to 15 seconds. This proposal was accompanied with the comment that if physicians are not allowed to use such a mode, they will continue the practice of using cineradiography bursts at high AKRs to accomplish the clinical task.

I. Entrance Air Kerma Rate at the Fluoroscopic Image Receptor

Comments received by the agency suggest that an alternative approach in place of or in addition to limits on AKR during fluoroscopy would be more useful and effective in limiting unnecessary radiation and assuring optimum system performance. The suggestion is that the limits on AKR to the patient (represented by a measurement made according to the compliance geometry described in current § 1020.32(e)(3)) be replaced by limits on the entrance AKR at the input surface of the image receptor (EAKIR). Different EAKIR limits could be established for different modes of fluoroscopic imaging, depending on the image performance required for the clinical task.

There is a precedent for this approach in other consensus documents such as the NCRP Report No. 99 and NCRP Report No. 102 (Refs. 12 and 13). For example, the NCRP Report No. 99 states that during fluoroscopy ''typical image intensifier entrance exposure should be in the range of 13 to 52 nC/kg/image (50 to 200 μR/image) depending on image intensifier size * * *.'' (Note that, in the opinion of FDA, there is an error in the NCRP Report No. 99: these numbers reflect exposure per second, not exposure per image.) In the same manner, the NCRP Report No. 102 provides a table with ''air kerma rate values to produce acceptable fluoroscopy images'' and ''air kerma to produce static images equivalent to that produced by a par speed screen-film system.'' FDA invites comments on the feasibility and desirability of this approach to limit unnecessary radiation from fluoroscopic systems.

J. Requirement for Minimum Source-Skin Distance for Small C-Arm Fluoroscopic Systems (§ 1020.32(g))

FDA proposes in § 1020.32(g) to add § 1020.32(g)(2) to establish a minimum source-skin distance (MSSD) for ''C-arm'' type x-ray systems having source-to-image-receptor distances of 45 cm or less and intended for imaging extremities. This amendment would incorporate into the performance standard the content of variances from the performance standard granted according to § 1010.4.

FDA has granted variances from the requirement set out in §1020.32(g) for a limit on the MSSD for fluoroscopic x-ray systems that were designed as small portable C-arm systems. These are fluoroscopic systems that were originally designed to be hand-held and were used at sporting events for a quick examination/diagnosis of orthopedic injuries. In fact, some of the early systems used a radioisotope instead of an x-ray tube as the source of the radiation and were, therefore, outside the purview of FDA under the RCHSA (although they are regulated as medical devices). Over time, manufacturers of these devices enlarged the distance or opening between the x-ray source and the image receptor to allow examination of larger extremities. The argument was that some athletes had larger extremities and a larger opening was needed to permit the use of the systems on them. The systems were marketed under a variance from § 1020.32(g) and were labeled for extremity use only. As the size of the opening on systems for which variances have been requested has increased from about 20 cm to 35 cm, and manufacturers have increased the radiation output of these systems, the agency has become concerned about the loss of the skin-dose sparing properties of the MSSD requirement. In addition, because a variance is granted for a finite time period, renewal of the variances and the reviewing of new conditions for use present resource implications for FDA and the manufacturers.

The justification for a variance from § 1020.32(g) used by many manufacturers of these small C-arm systems is geometrical scaling. Manufacturers have stated in their variance applications that the MSSD is proportional to the source-image receptor distance in comparison to full-sized C-arm systems. Although extremities can be considered to scale geometrically in a similar manner compared to the trunk or large body parts, other body parts do not scale in such a manner as to maintain a similar skin dose. For the source-image receptor distances used in these systems, evaluation of this geometrical relationship shows that the factor, by which the entrance AKR to the body part increases over that for thinner parts, increases significantly as the thickness of the body part being imaged reaches over 15 or 16 cm. This increase reaches a factor of two for a thickness of 26 cm and increases rapidly for thicker parts. In their original configuration, these devices had a very small opening and could not accommodate anything other than a limb. The latest configurations can easily accommodate the whole body of a neonate or a pediatric patient.

At some point, these systems no longer represent small C-arms for extremity use alone but are simply slightly smaller versions of conventional C-arms for whole-body, general-purpose examinations. If the system can be used for whole-body examination purposes, it should meet the minimum radiation safety standards applicable to conventional C-arm systems. Through the variance petition process, FDA has limited the small C-arm systems to extremity use only.

To incorporate the protection provided by the conditions imposed by the variances and to incorporate this requirement in the performance standard, FDA proposes to limit the source-skin distance to not less than 19 cm for fluoroscopic systems having source-image receptor distances of 45 cm or less. Provision would be allowed for systems designed for specific surgical applications to be operated with a source-skin distance of not less than 10 cm. Systems subject to this requirement would be required to be labeled for use for imaging extremities only. Manufacturers would be required to include appropriate precautions in the information provided to users under § 1020.30(h).

K. Requirements for Display of Fluoroscopic Irradiation Time, Air Kerma Rate, and Cumulative Air Kerma (§ 1020.32(h) and Proposed (k))

FDA is proposing that newly manufactured fluoroscopic systems display directly to the fluoroscopist information related to three

fundamental aspects of patient irradiation—the duration, rate, and amount of x-ray emissions. Generally, fluoroscopic systems do not currently provide such information at all. Irradiation time, AKR, and cumulative air kerma are basic radiological variables important for medical radiation protection. Their values may be applied to the process of optimization (i.e., obtaining radiological images with the least amount of radiation required), to the assessment of radiation detriment as a factor affecting patient-outcome efficacy, and to the development of reference levels representative of normal clinical practice. Optimization, efficacy, and reference levels currently comprise a conceptual vanguard of radiation protection in medicine at the international level (Refs. 14 to 17). When monitored in the clinic, irradiation time, AKR, and cumulative air kerma may be used to indicate risk of acute skin injury arising from potentially prolonged irradiation associated with some interventional procedures (Refs. 18 to 20). Values displayed directly to practitioners as an examination or procedure progresses can feed back to them indices of radiation burden, and practitioners can respond promptly by adjusting protocols and techniques to minimize dose to patients and practitioners as practitioners optimize radiation levels necessary for medical imaging. Moreover, for fluoroscopy and radiography in general, knowledge of irradiation levels at patient skin entrance is an essential starting place for evaluation of absorbed dose to internal tissues (Refs. 9 and 21). Such doses are stochastically linked to cancer morbidity, mortality, and to genetically transmissible defects (Refs. 14 and 22). Estimates of cumulative doses absorbed in tissues foster risk communication between medical staff and patients and, when tracked over time, are effective indicators of practice consistency, variability, or anomaly in the quality assurance activities associated with assuring the safety of clinical procedures.

The need for displays of irradiation variables was recognized at the 1992 national workshop on safety issues in fluoroscopy organized by the ACR and FDA (Ref. 8). In October 1995, the need was also recognized internationally by the workshop on efficacy and radiation safety in interventional radiology, sponsored jointly by the World Health Organization and the Institute of Radiation Hygiene, Radiation Protection Ministry, Federal Republic of Germany (Ref. 23). Recently, requirements for displays of irradiation parameters have been incorporated into an international standard for x-ray systems for interventional radiology (Ref. 24). With the advent of commercially available and relatively inexpensive means to measure and display real-time AKR and cumulative air kerma produced by fluoroscopic systems (Ref. 25), it is feasible as well as desirable to require that this information be directly observable by fluoroscopists at their working positions.

The proposed display requirements would apply to all types of newly manufactured fluoroscopic equipment (i.e., from systems found in cardiac catheterization suites, to equipment used for upper gastrointestinal fluoroscopy, to ''mini'' C-arms, and also to each fluoroscopic x-ray tube as part of any system). FDA invites comments about whether these requirements would be suitable to all types, or to a limited set of fluoroscopic equipment, namely, to stationary C-arm fluoroscopes that are typically used in interventional procedures.

1. Fluoroscopic Irradiation Time, Display, and Signal

Fluoroscopic irradiation time is profoundly tied to patient dose in a complex way that involves many other factors (e.g., see Ref. 26). FDA believes it advantageous to require that cumulative irradiation-time values be treated in their own right, in addition to the other variables cited in the proposed § 1020.32(k), as radiological parameters whose control would facilitate radiation-protection optimization. Physician members of TEPRSSC pointed out at its September 1998 meeting that irradiation time is the single fundamental variable over which a physician using fluoroscopy has the most direct and easiest control through activating or deactivating x-ray production, typically by means of a pedal switch (Ref. 27).

FDA proposes to add § 1020.32(h)(2) to the regulations to change the current fluoroscopic timer requirement in two ways. First, § 1020.32(h)(2)(i) would require that the values of the cumulative irradiation times associated with each of the fluoroscopic tubes of a system used in an examination or procedure be displayed to the fluoroscopist at his or her working position. The displayed values would be indicated from the beginning, throughout, and after an examination ends, available until the cumulative irradiation timer is reset to zero prior to a new examination. Second, § 1020.32(h)(2)(ii) would require an audible signal cycle different from that of current equipment for each x-ray tube used during an examination or procedure. Contrary to the current provision that allows the timing device to be preset to any interval up until a maximum cumulative irradiation time of 5 minutes, FDA proposes that a signal audible to the fluoroscopist sound at each fixed interval of 5 minutes of irradiation time. Also contrary to the current requirement, instead of sounding until reset, the audible signal would sound (while x-rays are produced) for a minimum of only 1 second, after which the signal could stop until a subsequent 5 minutes of irradiation elapses. The audible signal would not affect the production of x-rays, the display of cumulative irradiation-time values required by § 1020.32(h)(2)(i), or any of the other displays proposed in § 1020.32(k).

Considering advice offered at the 1998 TEPRSSC meeting (Ref. 27), FDA now believes that a fixed, standard (5 minute) period for an alert signal would avoid potential confusion that could ensue with a fluoroscopic timer that is variably preset. For example, such confusion could arise in a busy clinical facility with many different users, where fluoroscopists might not be aware of the need to readjust alert intervals that had been changed previously by other fluoroscopists to accommodate the individual protocol requirements associated with particular patient examinations. Furthermore, FDA believes that an audible signal of short duration would be a more effective and useful alert than a signal that sounds continuously, requires a reset, and therefore, could pose a distraction to users. FDA seeks comments about the audible signal cycle in proposed § 1020.32(h)(2)(ii), particularly in comparison to the suggested alternative below that is not currently in the proposal.

As an alternative approach, the selection of the time period until the alarm sounds could be at the discretion of the fluoroscopist. The timer could be preset to any period (less than, equal to, or greater than 5 minutes), or preset even to not sound at all. Under this approach, before an examination or procedure, the fluoroscopist could select a period beyond which an audible signal would sound until the timer could be reset (or else sound briefly then remain silent until the preset fluoroscopic period elapses again). Presuming clinicians maintain personal cognizance of fluoroscopic timer options and adaptability, such alternatives would offer them flexibility and opportunity to apply standard features of equipment operation to their

own individual clinical protocols and practices.

FDA also seeks comment on whether the display of the cumulative irradiation time should be visible to the fluoroscopist at his or her working position or whether it is sufficient to display the cumulative time at the control console. It has been suggested that this display should be available to the fluoroscopist to permit constant monitoring by the fluoroscopist. Other opinions are that such a display at the working position would only add confusion to an already complex visual environment, and display of the cumulative irradiation time at the x-ray control would make the information available in any case. Display at the fluoroscopist's working position may be slightly more complex or costly than display at the x-ray control.

2. Displays of Air Kerma Rate and Cumulative Air Kerma

FDA believes that a requirement for displays of AKR and cumulative air kerma values would significantly advance the optimization of radiation safety, in consideration of recent developments in clinical practice and technology (Refs. 23, 25, and 26), an evolving consensus for a radiation-protection framework (Refs. 14 to 17), and specific guidance (Refs. 18 to 20). Air kerma and AKR are fundamental radiological quantities of the amount and rate of charged-particle kinetic energy liberated per mass of air traversed by incident x-rays (Ref. 1). For this reason, FDA proposes to add § 1020.32(k) to require that all new fluoroscopic systems be capable of displaying real-time values of the AKR and cumulative air kerma delivered by each x-ray tube at reference locations representative of x-ray beam entry to the patient skin surface. These displays would be directly discernible at the fluoroscopist's working position, and the displayed values would deviate by no more than ±25 percent from actual values. To elucidate these requirements and those of the other proposed amendments, the definitions of the terms ''fluoroscopy,'' ''mode of operation,'' ''and radiography'' are proposed in § 1020.30(b). The utility of the display requirements could be broadly leveraged among practitioners in a variety of clinical settings through familiarization with relatively standardized display formats. Such standardization is proposed in § 1020.32(k)(1) through (k)(7), where the particular requirements proposed conform generally to those of the recently published IEC standard (Ref. 24).

During fluoroscopy or while recording images during a fluoroscopic procedure, the displayed value of the AKR would represent in real time the magnitude of air kerma per unit time being delivered at any geometrical point within a specified reference locus. The displayed value of the cumulative air kerma would represent a sum of two parts: (1) The fluoroscopic AKR integrated over an interval until update, and (2) all contributions to the air kerma (at any point in the same reference locus) from radiography occurring in that interval. The cumulative air kerma would be updated throughout the examination or procedure, and the integration interval would be the time between the start of an examination or procedure and the end of the most recent episode of either fluoroscopy or radiography during that same examination or procedure.

For each x-ray tube used during fluoroscopy or during recording of fluoroscopy, the value of the AKR will be displayed. After the cessation of fluoroscopy, the cumulative air kerma will be displayed and will remain displayed until the resumption of fluoroscopy or a radiographic mode is activated or the display is reset for a new patient or procedure. Thus, the cumulative air kerma will be displayed after x-ray production ceases from either fluoroscopy or radiography.

Values of the AKR are displayed at times other than those for the cumulative air kerma in order to underscore the distinction between these two variables and also to reduce the potential for overwhelming the fluoroscopist with too much information presented at once. At any particular moment during an examination or procedure, only values of the irradiation time and AKR (or cumulative air kerma) would be on display for each tube used. If, for example, a biplane fluoroscopic system were used in some cardiac catheterization procedure, two separate sets of values—one set for each of the x-ray tubes of the biplane—would be displayed. Under such circumstances of multiple presentations of related information, it is important that the values displayed be distinguishable enough from each other to be easily recognized and associated with the different radiological variables they represent. For this reason, FDA proposes in § 1020.32(h)(2)(i) and (k)(3) to require that the units of measurement be displayed as well as the values per se. FDA also proposes in § 1020.32(k)(1) and (k)(2) to require that the measurement units mGy/min and mGy be displayed respectively alongside the values for AKR and cumulative air kerma. These values would serve as a labeling distinction to preclude potential confusion of the quantities.

As measures of fundamental radiological quantities, the displayed values of AKR and cumulative air kerma would refer to free-in-air irradiation conditions (i.e., their evaluations would be made minus any contributions of scatter radiation, particularly contributions backscattered from a patient (or from a measurement phantom)). Also, the displayed values would refer to irradiation conditions at a reference location (i.e., at any geometrical point contained within a specific reference locus defined according to the type of fluoroscopic system). Each reference location is intended to represent, at least nominally, a place of x-ray beam entry to the patient skin. For fluoroscopes with the x-ray source below or above the table, or of the lateral type, § 1020.32(k)(5)(i) would have skin-entrance reference locations correspond identically and respectively to those specified in § 1020.32(d)(3)(i), (d)(3)(ii), or (d)(3)(v). These locations define the geometry for measuring compliance with the regulatory maxima of the AKR.

For C-arm type fluoroscopes, however, in many cases the locations proposed for measuring compliance with the regulatory maxima of the AKR, given in § 1020.32(d)(3)(iii) and (d)(3)(iv), would not suitably represent where the x-ray field enters the patient skin. This is especially true for oblique angulations and extended distances between the x-ray source and image receptor. Therefore, in § 1020.32(k)(5)(ii), for C-arm systems, FDA is proposing a skin-entrance reference location for display quantities that is different from the location for measuring compliance with regulatory AKR limits. For evaluation of displayed values, the skin-entrance reference location would be either 15 cm from the isocenter toward the x-ray source along the beam axis (irrespective of angulation) or, alternatively, along the beam axis at a point deemed by the manufacturer to represent the intersection of the x-ray beam and the entrance surface of the patient skin. A definition of ''isocenter'' is proposed in § 1020.30(b). Proposed § 1020.32(k)(5)(ii) would allow manufacturers to choose either the 15-cm locus or specify the alternative. The alternative locus would offer manufacturers flexibility to provide systems that could evaluate AKR and cumulative air kerma in closer proximity to actual places of x-ray beam entry to patients than could systems with reference skin entrance defined

generically at a 15-cm locus from the isocenter. An alternative skin-entrance reference location may be particularly appropriate for mini C-arm fluoroscopes (i.e., those with SID less than 45 cm, for which the 15-cm locus from the isocenter may be physically unrealizable). In any case, new paragraphs § 1020.30(h)(6)(iii) and (h)(6)(iv) would require that manufacturers identify to the user the spatial coordinates of the irradiation location to which displayed values refer and also provide a rationale justifying any reference location identified as an alternative to the 15-cm locus.

In patient examinations or procedures with C-arm systems, one possible result of having reference locations of x-ray beam skin-entry different from the measurement sites for AKR compliance is that displayed values could actually exceed the regulatory maxima even though the system is fully compliant. Such a situation could arise for some irradiation geometry when the reference skin-entrance location is closer to the x-ray source than is the site for measuring compliance. Displayed values of the AKR and cumulative air kerma are intended to inform the fluoroscopist of radiation burden to the patient. Conversely, the AKR regulatory maxima, practicably measured 30 cm from the imaging-assembly input, according to § 1020.32(d)(3)(iii) or at the minimum SSD according to § 1020.32(d)(3)(iv), are intended to impose upper limits on radiation output that are compatible with the levels needed by the imaging chain for adequate fluoroscopic visualization.

Reset of the displays to zero would occur between sessions with successive patients. Before reset, a final value of the cumulative air kerma may serve to reinforce an association between the culmination of a radiological examination or procedure and the radiation burden incurred by the patient. FDA believes that the availability of this value would greatly facilitate the implementation of previously published recommendations (Refs. 18 to 20) on recording information in the patient's medical record to identify the potential for serious x-ray-induced skin injuries in order to avoid them.

L. ''Last-Image Hold'' Feature on Fluoroscopic Systems (Proposed § 1020.32(j))

FDA proposes to add a paragraph to require that all fluoroscopic x-ray systems be provided with a means to continuously display the last image acquired prior to termination of exposure.

The wide availability of electronic methods for the recording and displaying of video images makes possible the provision of a ''last-image hold'' or ''freeze-frame'' capability on fluoroscopic x-ray systems. This feature allows the fluoroscopic x-ray system to continuously present a static image of the last fluoroscopic scene captured or presented at termination of the fluoroscopic exposure. This feature also provides the user with the ability to conveniently view fluoroscopic images without continuously irradiating the patient.

This feature is especially useful in procedures such as fluoroscopically-guided needle placement for biopsy or drainage, catheter or tube placement, and other diagnostic or therapeutic interventional procedures. Systems provided with this feature reduce fluoroscopic exposure times while enabling extended examination and planning during fluoroscopically-guided procedures.

This capability is provided as a basic or optional feature on many currently marketed fluoroscopic systems. Many individuals have expressed the opinion that because of the radiation dose reduction afforded by such a feature, it should be provided on all new fluoroscopic systems. Such a recommendation was strongly endorsed at the workshop on fluoroscopy in 1992 (Ref. 8). In addition, a requirement for this capability is included in the recently published IEC standard for the safety of x-ray equipment for interventional radiology (Ref. 24). Establishing this requirement would assure that all new fluoroscopic systems have this patient radiation dose reduction feature and that it is available when its use is appropriate. Without such a requirement, some systems may for economic reasons continue to be purchased without this feature, thereby denying dose reduction benefits to patients.

Proposed § 1020.32(j) would permit the displayed image to be obtained from the last or a combination of the last few fluoroscopic video frames obtained just prior to termination of fluoroscopic exposure or by an alternative implementation via a radiographic exposure automatically produced at termination of the fluoroscopic exposure. Comments are solicited as to whether these approaches to implementation of last image-hold are appropriate and needed.

M. Modification of Previously Manufactured and Certified Equipment

FDA proposes to add language to § 1020.32(d)(1)(iv) and (h) to make explicit the opportunity under § 1020.30(q) for modifications to be made to existing certified x-ray systems. Modifications are currently permitted as long as the modification does not result in a failure to comply with the requirements of the performance standard. Changes in performance resulting from amendments to the performance standard often result in enhanced radiation safety or features not available on previously manufactured and certified systems.

The existing performance standard requires manufacturers to certify that their products meet the applicable performance requirements in effect at the time of manufacture. Therefore, amendments to the performance standard are generally not retroactive and effective dates implementing the standard are specified in the regulations. Usually, a 1-year effective date is provided in order to allow manufacturers time to adjust manufacturing and assembly of their products under the new or amended regulations. Indeed, it would be unreasonable to require the manufacturer to retrofit or to remanufacture previously produced products because of a change in the standard for equipment that could have a useful life of 20 or more years.

In particular, the performance requirements regarding maximum exposure rate limits (proposed to become maximum AKR limits), established in 1994 (59 FR 26402), and the proposed requirements in § 1020.32(h) for fluoroscopic timers are requirements or performance features that users of older fluoroscopic equipment may wish to implement on their systems. The earlier amendment in 1994 and the current proposal apply to new equipment manufactured after the effective date of the amendment. The language proposed for inclusion in § 1020.32(d) and (h) would provide a mechanism for users of older equipment to obtain the performance required under the proposed amendments. These changes would allow older systems to be modified to meet the maximum AKR limit and fluoroscopic timer performance that will be required under the proposed requirements.

The owner of the fluoroscopic system modified under § 1020.30(q) is responsible for assuring that the modified x-ray system complies with the applicable requirements of the performance standard following the modification. The modification to the system may be accomplished by a third party or by the original equipment manufacturer. The system owner, however, is responsible for assuring,

through contract requirements with the party performing the modification or through testing, that the modified system complies with the standard following the modification.

N. Modification of Warning Label (§ 1020.30(j))

FDA proposes to modify the language of the warning label required by § 1020.30(j). The current statement warns that safe exposure factors and operating instructions must be followed. FDA proposes to modify the warning label statement by adding the phrase ''maintenance schedules.'' This addition incorporates the suggestion of the TEPRSSC and further emphasizes the need for diagnostic x-ray systems to be properly maintained and calibrated. Manufacturers of diagnostic x-ray systems are required under § 1020.30(h)(1)(ii) to provide a schedule of the maintenance necessary to keep the equipment in compliance with the performance standard. The standard places no requirement on owners or users of diagnostic systems to properly maintain these systems. However, the revised wording of the warning label is intended to alert users and facility administrators of the need to properly maintain the systems.

O. Corrections of § 1020.31(f)(3) and (m)

FDA proposes to correct oversights in § 1020.31(f)(3) and (m) that occurred when the July 2, 1999, amendment was published. Section 1020.31(f)(3) addresses the x-ray field limitation requirement for mammographic x-ray systems and § 1020.31(m) addresses the primary barrier required for mammographic x-ray systems. Prior to September 30, 1999 (the effective date of the final rule), the heading to § 1020.31(m) was ''Transmission limit for image receptor supporting devices used for mammography.''

When an existing radiation safety performance standard is amended, the new or modified requirement applies only to products that are manufactured after the effective date of the amendment. Normally, the requirement that existed prior to the amendment is retained in the Code of Federal Regulations (CFR) to provide a record of the requirements of the standard applicable to products on their date of manufacture. When the final rule amending § 1020.31(f)(3) and (m) was published on July 2, 1999, the provisions describing the requirements for equipment manufactured prior to September were inadvertently omitted. Thus, the CFR (21 CFR part 1020) has no record of the requirements imposed by § 1020.31(f)(3) and (m) for equipment manufactured between the initial effective dates for § 1020.31(f)(3) and (m) and September 30, 1999. To correct this oversight, FDA proposes to reinstate the provisions describing the requirements that apply to equipment manufactured prior to September 30, 1999, under the earlier versions of § 1020.31(f)(3) and (m). This correction will provide a record of the requirements applicable before September 30, 1999, and close the gap that exists as a result of the oversight in the publication of the final rule.

Additionally, further review of this issue revealed that the original publication of § 1020.31(f)(3) in 1977 (42 FR 44230) did not indicate an effective date for this paragraph, which was November 1, 1977. FDA proposes to insert the omitted effective date. The omission was of little consequence because the original requirement reflected the then current designs of mammographic systems. FDA proposes to insert the date to provide an accurate record of the applicable x-ray field limitation requirements as a function of the date of manufacture of mammographic x-ray systems.

No changes in the previously applicable or current requirements are proposed or intended by these corrections to § 1020.31(f)(3) and (m). The corrections are only intended to make explicit the current or previously applicable requirements that existed on the date of manufacture.

FDA proposes to revise § 1020.31(f) by adding § 1020.31(f)(3)(i), the requirement applicable to equipment manufactured on or after November 1, 1977, and before September 30, 1999. The current requirement, applicable to equipment manufactured after September 30, 1999, would be § 1020.31(f)(3)(ii). Section 1020.31(f)(3)(iii) would contain the requirement for permanent markings that are applicable to all equipment manufactured after November 1, 1977.

FDA proposes to amend § 1020.31(m). Section 1020.31(m)(1) would be revised to contain the requirement applicable to systems manufactured on or after September 5, 1978, and before September 30, 1999; such requirement was previously omitted. Section 1020.31(m)(2) would be revised to contain the current requirements applicable to equipment manufactured after September 30, 1999, in § 1020.31(m)(2)(i), (m)(2)(ii), (m)(2)(iii), and (m)(2)(iv). Section 1020.31(m)(3) would be revised to contain the description of the method for measuring compliance; such description is common to both § 1020.31(m)(1) and (m)(2). A minor technical clarification is also proposed in § 1020.31(m)(2)(ii) where the term ''x-ray tube'' found in current § 1020.31(m)(2) is replaced by the term ''x-ray system'' to reflect the fact that it is the x-ray system, not the x-ray tube, that controls initiation of x-ray exposure. This change does not change the intent or effect of the requirement.

P. Corrections to Reflect Changes in Organizational Name, Address, and Law (§ 1020.30(c), (d), and (q))

FDA proposes to amend §1020.30(c) to reflect the current organizational title of the Office of Compliance of the Center for Devices and Radiological Health. FDA also proposes in § 1020.30(d) to remove the specific address that is subject to change from time to time. Additionally, FDA proposes to amend paragraph § 1020.30(q) to reflect the transfer of sections 358(a)(5) and 360B(b) of the PHS Act to the act by the SMDA.

Q. Removal of Reference to Special Attachments for Mammography

FDA proposes to remove reference to ''special attachments for mammography'' in § 1020.31(d) and (e). The Mammography Quality Standards established in part 900 (21 CFR part 900), particularly § 900.12(b)(1), require that only diagnostic x-ray systems designed specifically for mammography be used to perform mammography in the United States. Therefore, the use of special attachments intended for use with general-purpose diagnostic x-ray systems to perform mammography is inappropriate. No such devices may continue to be used, and retaining this reference in the standard would imply that such devices or components were acceptable.

R. Change to the Applicability Statement for § 1020.32

FDA proposes in the applicability statement of § 1020.32 to remove the reference to ''fluoroscopy'' and replace it with ''fluoroscopic imaging'' and to remove ''recording of images through an image intensifier tube'' and replace this reference with ''radiographic imaging when the radiographic images are recorded from the fluoroscopic image receptor.'' This change is necessary to clarify the applicability of this section and to incorporate the proposed requirements addressing the production of radiographic images for the last image hold feature.

S. Republication of §§ 1020.30, 1020.31, and 1020.32

Because of the large number of proposed changes in §§ 1020.30,

1020.31, and 1020.32, FDA is republishing these entire sections, including the proposed amendments, rather than publishing only the proposed individual changes to these sections. Although some of the paragraphs in these sections are not changed by this proposal, republication of the entire sections will result in a more reader-friendly version when the final regulation is published.

III. Proposed Effective Date

FDA proposes that any final rule based on this proposal become effective 1 year after the date of publication of the final rule in the **Federal Register**.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(i) and 25.34(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

A. Summary

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3502). A description of these provisions is given in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

The information collection burden of the current performance standard is covered by an existing information collection clearance, OMB control number 0190–0025. FDA is seeking new information collection clearance for proposed §§ 1020.30(h)(5) and (6), and 1020.32(j)(4).

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Performance Standard for Diagnostic X-Ray Systems and their Major Components (21 CFR 1020.30 and 1020.32 amended)

Description: FDA is proposing to amend the performance standard for diagnostic x-ray systems by establishing, among other things, requirements for several new equipment features on all new fluoroscopic x-ray systems. In the current performance standard, § 1020.30(h) requires that manufacturers provide to purchasers of x-ray equipment, and to others upon request, manuals or instruction sheets that contain technical and safety information. This required information is necessary for all purchasers (users of the equipment) to have in order to safely operate the equipment. Section 1020.30(h) currently describes the information that must be provided.

The proposed rule would add to § 1020.30(h) paragraphs (5) and (6) describing additional information that would need to be included in these manuals or instructions. In addition, proposed § 1020.32(j)(4) would specify additional descriptive information to be included in the user manuals for fluoroscopic x-ray systems required by § 1020.30(h). This additional information would be descriptions of features of the x-ray equipment required by the proposed amendments and information determined to be appropriate and necessary for safe operation of the equipment.

Description of Respondents: Manufacturers of fluoroscopic x-ray systems that introduce fluoroscopic x-ray systems into commerce following the effective date of the proposed amendments. FDA estimates the burden of this collection of information as follows:

TABLE 4.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN FOR THE FIRST YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1020.30(h)(5) and (h)(6) and 1020.32(j)(4)	20	10	200	180	36,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 5.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN FOR SECOND AND FOLLOWING YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1020.30(h)(5) and (h)(6) and 1020.32(j)(4)	20	5	100	180	18,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Estimate of Burden

As described in the assessment of the cost impact of the proposed amendment (Ref. 33), it is estimated that there are about 20 manufacturers of fluoroscopic x-ray systems who market in the United States. Each of these manufacturers is estimated to market about 10 distinct models of fluoroscopic x-ray systems. Immediately following the effective date of the proposed amendments, for each model of fluoroscopic x-ray system that manufacturers continue to market, each manufacturer would have to supplement the user instructions to include the additional information required by the proposed amendments.

Manufacturers already develop, produce, and provide x-ray system user manuals or instructions containing the information necessary to operate the systems, as well as the specific information required to be provided by the existing standard in current § 1020.30(h). Therefore, it is assumed that no significant additional capital,

operating, or maintenance costs will occur to the manufacturers in connection with the provision of the newly required information. The manufacturers already have procedures and methods for developing and producing the user's manuals, and the additional information required by the proposed requirements is expected to only add a few printed pages to these already extensive manuals or documents.

The burden that will occur to manufacturers from the new requirements for information in the user's manuals will be the effort required to develop, draft, review, and approve the new information. The information or data to be contained within the new user instructions will already be available to the manufacturers from their design, testing, validation, or other product-development documents. The burden will consist of gathering the relevant information from these documents and preparing the additional instructions from this information.

It is estimated that about 3 weeks of professional staff time (120 hours) would be required to gather the required information for a single model of an x-ray system. It is estimated that an additional 6 weeks (240 hours) of professional staff time would be required to draft, edit, design, layout, review, and approve the new portions of the user's manual or information required by the proposed amendments. Hence FDA estimates a total of 360 hours to prepare the new user information that would be required for each model.

For a given manufacturer, FDA anticipates that every distinct model of fluoroscopic system will not require a separate development of this additional information. Because it is thought highly likely that several models of fluoroscopic x-ray systems from a given manufacturer will share common design aspects, it is anticipated that similar means for meeting the proposed requirement for display of exposure time, air kerma rate, and cumulative air kerma and the requirement for the last-image-hold feature will exist on multiple models of a single manufacturer's products. Such common design aspects for multiple models will reduce the burden on manufacturers to develop new user information. Hence the average time required to prepare new user information for all of a manufacturer's models will be correspondingly reduced. It is assumed that the applicability of the new user information developed to multiple models will reduce the average burden from the 360 hours to about 180 hours per model under the assumption that each set of user information for a given equipment feature design will be a applicable to at least two different models of a manufacturer's fluoroscopic systems. Under this assumption, the total estimated time for preparing the new user information that would be required is 36,000 hours, as shown in table 4 of this document.

In each succeeding year the burden will be less, as the reporting requirement will apply only to the new models developed and introduced by the manufacturers in that specific year. FDA assumes that every two years each manufacturer will replace each of its models with a newer model requiring new user information. The multiple system applicability of this information is accounted for by also assuming that each new model only requires 180 hours of effort to develop the required information. These assumptions result in an estimated burden of 18,000 hours for each of the years following the initial year of applicability of the proposed amendments, as shown in table 5 of this document.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**).

VI. Analysis of Impacts

A. Introduction

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) (UMRA). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition the proposed rule is economically significant under Executive Order 12866 and is major under the Congressional Review Act. Therefore the proposal is subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. An analysis of available information suggests that costs to small entities are likely to be significant, as described in the following analysis. FDA believes that this proposed regulation will likely have a significant impact on a substantial number of small entities, and it conducted an initial regulatory flexibility analysis (IRFA) to ensure that any such impacts were assessed and to alert any potentially impacted entities of the opportunity to submit comments.

Section 202(a) of the UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The UMRA does not require FDA to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is about $110 million.

The agency has conducted preliminary analyses of the proposed rule, including a consideration of alternatives, and has determined that the proposed rule is consistent with the principles set forth in the Executive order and in these statutes. The costs and benefits of the proposed rule have been assessed in two separate preliminary analyses that are described in section VI of this document and that are available at the Dockets Management Branch (see **ADDRESSES**) for review. As reviewed below, these preliminary analyses have an estimated upper limit to the annual cost of $30.8 million during the first 10 years after the effective date of the proposed amendments. The analysis of benefits projects an average annual amortized pecuniary savings in the first 10 years after the effective date of at least $320 million, with an estimated 90 percent confidence interval spanning a range between $88.35 million and $1.160 billion. FDA believes this analysis of impacts complies with Executive Order 12866, and that the proposed rule is a significant regulatory action as defined by the Executive order. Because of the preliminary nature of these cost and benefit analyses and estimates, FDA requests comments on any aspect of their methodologies, assumptions, and projections. Comments may be

submitted to the Dockets Management Branch (see **ADDRESSES**).

B. Objective of the Proposed Rule

The primary objective of the proposed rule is to improve the public health by reducing exposure to and detriment associated with unnecessary ionizing radiation from diagnostic x-ray systems, while maintaining the diagnostic quality of the images. The proposed rule would meet this objective by requiring features on newly manufactured x-ray systems that physicians may use to minimize unnecessary or unnecessarily large doses of radiation that could result in adverse health effects to patients and health care personnel. Such adverse effects from x-ray exposure can include acute skin injury and an increased potential for cancer or genetic damage. The secondary objectives of this proposed rule are to bring the performance standard up to date with recent and emerging technological advances in the design of fluoroscopic x-ray systems and to assure appropriate radiation safety for these designs. The proposed amendments would also align the performance standard with performance requirements in current international standards that were developed since the original publication of the performance standard in 1972. In several instances, the international standards contain more stringent requirements on aspects of system performance than the current U.S. performance standard. The proposed changes would ensure that the different safety standards are harmonized to the extent that systems meeting one standard will not be in conflict with the other. Such harmonization of standards lessens the regulatory burdens on manufacturers desiring to market systems in the global market.

The proposed amendments would require particular x-ray equipment features reducing unnecessary radiation exposure and thereby yielding net benefits. The amendments are necessary because the market will not ensure that these equipment features will be adopted without a government mandate for such features. Purchasers in health care organizations have no incentive to demand the more expensive x-ray equipment that would be required by these new amendments because they perceive no institutional economic advantage in doing so as benefits accrue mainly to patients. Furthermore, purchasers are more responsive to physician attention to an immediate need for diagnostic and interventional efficacy from the equipment than to a prospective capability to reduce radiation-associated risk to patients many years in the future. Patients, also focused on their immediate medical needs, will not demand this equipment because they lack information and knowledge about long-term radiation risk and about the highly technical nature of x-ray equipment. Hence these proposed amendments are necessary to realize the net benefits described in the following analysis.

C. Risk Assessment

The risks to health that will be addressed by these amendments are the adverse effects of exposure to ionizing radiation that can result from procedures utilizing diagnostic x-ray equipment. These adverse effects are well known and have been extensively studied and documented. They are generally categorized into two types—''deterministic'' and ''stochastic.'' Deterministic effects are those that occur with certainty in days or weeks or months following irradiation whose cumulative dose exceeds a threshold characteristic of the effect. Above the threshold, the severity of the resulting injury increases as the radiation dose increases. Examples of such effects are the development of cataracts in the lens of the eye and skin ''burns.'' Skin is the tissue that often receives the highest dose from external radiation sources such as diagnostic or therapeutic x-ray exposure. Depending on the magnitude of the dose, skin injuries from radiation can range in severity from reddening of the skin and hair loss to more serious burn-like effects including localized tissue death that may require skin grafts for treatment or may result in permanent impairment. Stochastic effects are those that do not occur with certainty, but if they appear, they generally appear as leukemia or cancer one or several decades after the radiation exposure. The probability of the effect occurring is proportional to the magnitude of the radiation dose in the tissue.

The primary risk associated with radiation is the possibility of patients developing cancer years after exposure, and the magnitude of this cancer risk is generally regarded to increase with increasing radiation dose. Consistent with the conservative approach to risk assessment described by the National Council on Radiation Protection and Measurements (Ref. 32), we assume a linear relationship between cancer risk and dose. The slope of this relationship depends on age at exposure and on gender. Our benefits analysis presented in section VI.H is based on linear interpolations of cancer-mortality risk per dose derived from BEIR V table 4–3 (Ref. 22) values reduced by a dose-rate effectiveness factor of 2 for solid cancers (Ref. 30). The values used in our analysis are represented in the following graph in figure 1 of the excess lifetime-probability for death per dose associated with radiation exposure.

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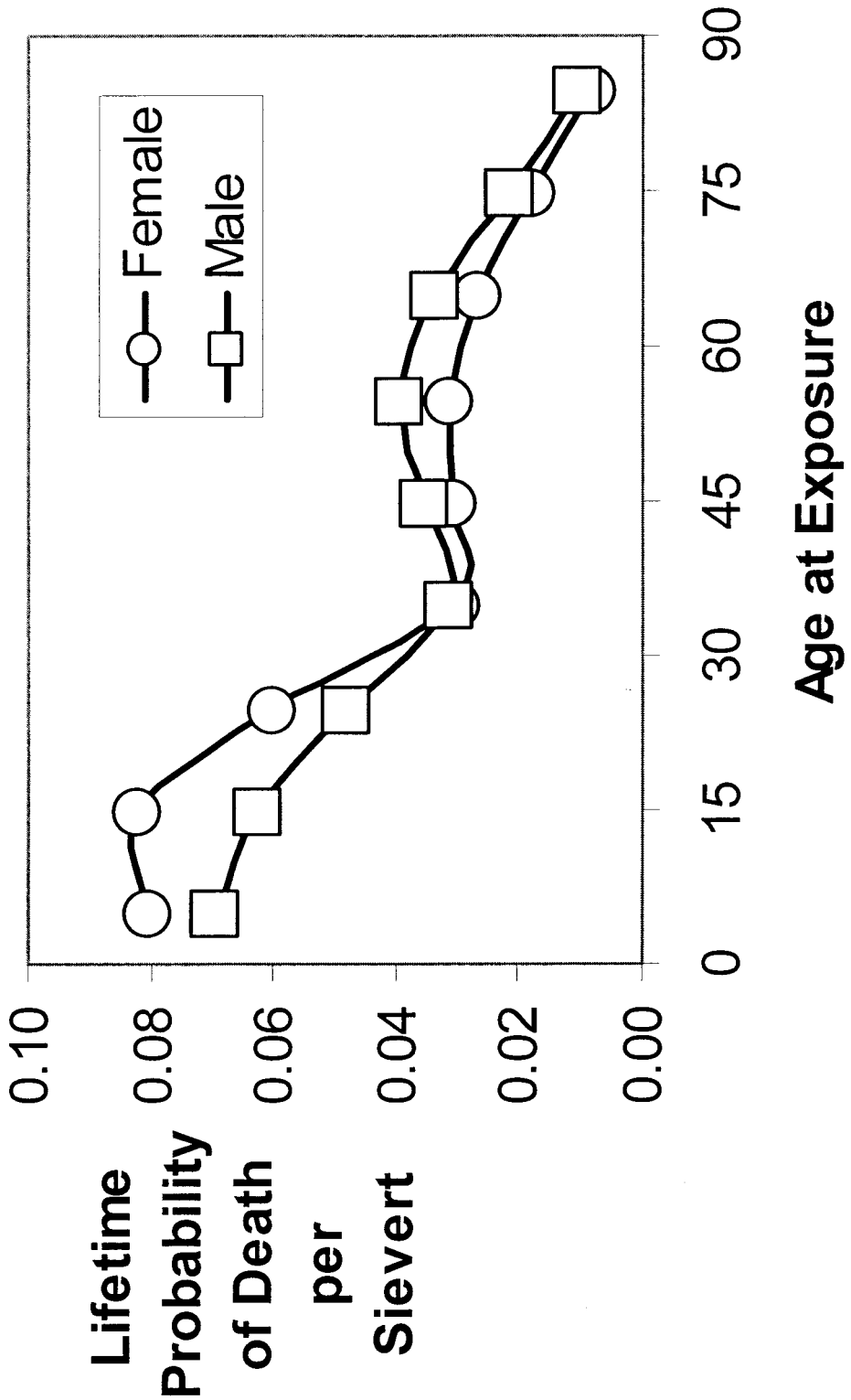

Figure 1. Mortality Risk per Sievert versus Age at Exposure

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FDA underscores the overarching uncertainty in these projections with the following statement adopted from CIRRPC Science Panel Report No. 9 (Ref. 30):

> The estimations of radiation-associated cancer deaths were derived from linear extrapolation of nominal risk estimates for lifetime total cancer mortality from doses of 0.1 Sv. Other methods of extrapolation to the low-dose region could yield higher or lower numerical estimates of cancer deaths. At this time studies of human populations exposed at low doses are inadequate to demonstrate the actual level of risk. There is scientific uncertainty about cancer risk in the low-dose region below the range of epidemiologic observation, and the possibility of no risk cannot be excluded.

We project that the equipment features that would be required by three of the proposed amendments will promote the bulk of radiation dose reduction and hence cancer risk reduction: (1) Displays of radiation time, rate, and dose values; (2) more filtration of lower-energy x rays; and (3) improved geometrical efficiency of the x-ray field achieved through tighter collimation. We assume that the display amendment would reduce dose on the order of 16 percent. This assumed value is one-half of a 32 percent dose reduction observed for several x-ray modalities in the United Kingdom (UK) between 1985 and 1995. We assume that one-half of the UK dose reduction was due to technology improvements alone, whereas the other half stemmed from the quality assurance use of reference dose levels and patient dose evaluation. The 16 percent dose reduction that we project for the display amendment thus presumes facility implementation of a quality assurance program making use of the displayed values. This analysis and other assumptions—6 percent dose reduction for the filtration amendment, 1 to 3 percent dose reduction for the collimation amendment—are detailed in Ref. 29. We invite comment on these assumptions.

Until recently, the principle radiation detriment for patients undergoing x-ray procedures was the risk of inducing cancer and, to a lesser extent, heritable genetic malformations. Since 1992, however, approximately 80 reports of serious radiation-induced skin injury associated with fluoroscopically-guided interventional therapeutic procedures have been published in the medical literature or reported to FDA. Many of these injuries involved significant morbidity for the affected patients. FDA's experience with reports of such adverse events leads the agency to believe that the number of these injuries is very likely underreported, given the total number of interventional procedures currently performed. Additionally, there is the lack of any clearly understood requirement or incentive for health care facilities to report such injuries. With the advance of fluoroscopic technology and the proliferating use of interventional procedures by practitioners not traditionally specializing in the field, and therefore not completely familiar with dose-sparing techniques, FDA expects an increasing risk of radiation burns that warrants the changes to the x-ray equipment performance standard through the proposed amendments.

D. Constraints on the Impact Analysis

It is FDA's opinion that the proposed amendments would offer public health benefits that warrant their costs. However, the agency has had difficulty thus far accessing pertinent information from stakeholders to help quantify the impact of the proposal and alternatives. In view of the limited information available with which to develop estimates of the costs and benefits, FDA solicits comments, data, and opinions as to whether the potential health benefits of the proposed amendments would justify their costs. FDA will use all information and comments received to revise the impact assessment in reaching a final determination as to the appropriateness of the proposed amendments.

The principal costs associated with the proposed amendments would be the increased costs to manufacturers to produce equipment that will have the features required by the amendments. FDA has made an estimate of potential cost. The cost estimate is based on a number of assumptions designed to assure that the potential cost is not underestimated. FDA anticipates that the actual costs of these amendments to be significantly less than the upper-limit estimate developed. Manufacturers of diagnostic x-ray systems are urged to provide detailed comments on the anticipated costs of these amendments that will enable refinement of these cost estimates.

The benefits that are expected to result from these amendments are reductions in acute skin injuries and radiation-induced cancers. The proposed amendments would have two types of impact that reduce patient dose and associated radiation detriment without compromising image quality.

The first type of change involves several newly required equipment features that would directly affect the intensity or size of the x-ray field. These are the requirements addressing x-ray beam quality, x-ray field limitation, limits on maximum radiation exposure rate, and MSSD for mini C-arm fluoroscopic systems. Almost all of the changes that directly affect x-ray field size or intensity would bring the performance standard requirements into agreement with existing international voluntary standards. To the extent that these requirements are included in voluntary standards that have a growing influence in the international marketplace, the radiological community has already recognized their benefit and appropriateness. Moreover, harmonization within a single international framework would obviate the expense for manufacturers to produce more than one line of products for a single global marketplace.

The second type of change that would be required by these amendments involves the information to be provided by the manufacturer or directly by the system itself that may be utilized by the operator to more efficiently use the x-ray system and thereby reduce patient dose. There is wide support for and anticipation of these new features by many knowledgeable users of fluoroscopic systems. Similar requirements were recently included in a new international voluntary standard.

E. Baseline Conditions

The cost of the proposed amendments to the x-ray equipment performance standard would be borne primarily by manufacturers of fluoroscopic systems. The cost for one of the nine proposed amendments would also affect manufacturers of radiographic equipment and is discussed in detail in Ref. 28. Therefore, this discussion will focus primarily on fluoroscopy (i.e., the process of obtaining dynamic, real-time images of patient anatomy).

X-ray imaging is used in medicine to obtain diagnostic information on patient anatomy and disease processes or to visualize the delivery of therapeutic interventions. X-ray imaging almost always involves a tradeoff between the quality of the images needed to do the imaging task and the magnitude of the radiation exposure required to produce the image. Difficult imaging tasks may require increased radiation exposure to produce the images unless some significant technological change provides the needed image quality. Therefore, it is important that users of x-ray systems have information regarding the radiation exposures required for the images that are being produced in order to make the appropriate risk-benefit decisions.

Equipment meeting the new standards in the proposed amendments would provide image quality and diagnostic information identical to equipment

meeting current standards. Therefore, the clinical usefulness of the images provided would not change. The amendments would not affect the delivery of x-ray imaging services because the reasons for performing procedures, the number of patients having procedures, and the manner in which procedures are scheduled and conducted would not be changed as a result of the amendments. In addition, nothing in these amendments would adversely affect the clinical information or results obtained from these procedures. These amendments would result in x-ray systems having features that automatically provide for more efficient use of radiation or features that provide the physicians using the equipment with immediate information related to patient dose, thus enabling more informed and efficient use of radiation. These amendments would provide physicians using fluoroscopic equipment with the means to actively monitor patient radiation doses and minimize unnecessary exposure or avoid doses that could result in radiation injury.

Estimates of the annual numbers of certain fluoroscopic procedures performed in the United States during the years 1996 or 1997 were developed, as described in Ref. 29, using data from several sources. These estimates of the annual numbers of specific procedures were used in the estimates of benefit from the proposed amendments. No attempt was made to account for changes in the annual numbers of procedures in future years, due to the large uncertainties in making such projections. FDA also estimates that over 3 million fluoroscopically guided interventional procedures are performed each year in the United States. These procedures are described as ''interventional procedures'' because they accomplish some form of therapy for patients, often as an alternative to more invasive and risky surgical procedures. Interventional procedures may result in patient radiation doses in some patients that approach or exceed the threshold doses known to cause adverse health effects. The high doses occur because physicians utilize the fluoroscopic images throughout the entire procedure, and such procedures often require exposure times significantly longer than conventional diagnostic procedures to guide the therapy.

FDA records indicate that about 12,000 medical diagnostic x-ray systems are installed in the United States each year. Of these, 4,200 are fluoroscopic system installations. The proposed amendments would apply only to those new systems manufactured after the effective date, therefore affecting the 4,200 new fluoroscopic systems installed annually and a small fraction of radiographic systems that do not currently meet the proposed standard for x-ray beam quality.

In modeling the x-ray equipment market in the United States for the purpose of developing estimates of the cost of these amendments, FDA estimates that there are approximately a total of 40 manufacturers of diagnostic x-ray systems in the United States and half of these (20) market fluoroscopic systems and radiographic systems. It is assumed that manufacturers of radiographic systems typically market 20 models of radiographic systems, while manufacturers of fluoroscopic systems market 10 different models of fluoroscopic systems.

F. The Proposed Amendments

As described in section II of this document, the proposed regulations may be considered as nine significant amendments to the current performance standard for diagnostic x-ray systems and other minor supporting changes to the standard. The nine principal amendments may be grouped into three major impact areas: (1) Amendments requiring changes to equipment design and performance that would facilitate more efficient use of radiation and provide means for reducing patient exposure, (2) amendments improving the use of fluoroscopic systems through enhanced information to users, and (3) amendments facilitating the application of the standard to new features and technologies associated with fluoroscopic systems.

Amendments requiring equipment changes include changes in x-ray beam quality; provision of a means to add additional filtration; changes in the x-ray field limitation requirements; provision of displays of values of irradiation time, AKR, and cumulative air kerma; the display of the last fluoroscopic image acquired (LIH feature); specification of the MSSD for mini C-arm systems; and changes to the requirement concerning maximum limits on entrance AKR. Amendments that would result in improved information for users are those requiring additional information to be provided in user instruction manuals. Amendments facilitating the application of the standard to new technologies include the recognition of SSXI devices, revisions of the applicability sections, and establishment of additional definitions.

G. Benefits of the Proposed Amendments

The proposed amendments would benefit patients by enabling physicians to reduce fluoroscopic radiation doses and associated detriment and, hence, to use the radiation more efficiently to achieve medical objectives. The health benefits of lowering doses are reductions in the potential for radiation-induced cancers and in the numbers of skin burns associated with higher levels of x-ray exposure during fluoroscopically-guided therapeutic procedures. FDA believes that the proposed amendments would not degrade the quality of fluoroscopic images produced while reducing the radiation doses.

There is widespread agreement in the radiological community that radiation doses to patients and staff should be kept ''as low as reasonably achievable'' (ALARA) as a general principle of radiation protection. In particular, moreover, recent experience has demonstrated that in some few cases of fluoroscopically-guided interventional procedures with especially long irradiation times, the magnitudes of the radiation doses are large enough to cause serious injury to the skin. A growing number of patients that are potentially at risk for acute and long-term radiation injury makes it important to provide fluoroscopic systems with features that will assist in reducing the radiation to patients while continuing to accomplish the medical objectives of the needed procedures.

The proposed amendments would require that fluoroscopic x-ray systems provide equipment features that directly enable the user to reduce radiation doses and maintain them ALARA. Furthermore, the amendments would require provision of information to the user of the equipment in the form of additional information in the user's manual or instructions to enable improved use in a manner that minimizes patient exposures and, by extension, occupational exposures to medical staff.

There is wide agreement that radiation exposures during fluoroscopy are not optimized. For example, data from the 1991 Nationwide Evaluation of X-ray Trends (NEXT) surveys of fluoroscopic x-ray systems used for upper gastrointestinal tract examinations (upper GI exam) indicate that the mean entrance AKR is typically 5 cGy/min for an adult patient (Ref. 28). Properly maintained and adjusted fluoroscopic systems are expected to be able to perform the imaging tasks associated with the upper GI exam with

an entrance AKR of 2 cGy/min or less (Ref. 8). The NEXT survey data indicate significant room for improvement in this aspect of fluoroscopic system performance. The total patient dose could be significantly reduced were the entrance AKR lowered to what is currently reasonably achievable, and the features required by the proposed amendments would facilitate this reduction.

The proposed features of LIH and real-time display of entrance AKR and cumulative entrance air kerma values are intended to provide fluoroscopists with means to better limit the patient radiation exposure. The LIH feature would permit decision-making regarding the procedure underway while visualizing the anatomy without continuing to expose the patient. The air kerma- and AKR-value displays would provide real-time feedback to the fluoroscopists and are anticipated to result in improved fluoroscopist performance to limit radiation dose based on the immediate availability of information regarding that dose. Realization of the potential dose-reduction benefits would require fluoroscopists to take advantage of these proposed features and optimize the way they use fluoroscopic systems.

The potential impact of the change in the beam quality requirement, which would apply to most radiographic and all fluoroscopic systems, can be seen from the data on beam quality obtained from the FDA Compliance Testing Program for the current standard. Since January 1, 1996, FDA has conducted 4,832 tests of beam quality, that is, measurement of the HVL of the beam for newly installed x-ray systems. Of these tests, only 15 systems did not meet the current HVL or beam quality requirement. If the requirements for HVL contained in these proposed amendments were used as the criteria for compliance, only 698 systems or 14.4 percent of the systems tested would have been found not to have complied. This result suggests that at a minimum approximately 15 percent of recently installed medical x-ray systems would have their beam quality improved and patient exposures reduced were the new requirement in place and applicable to them.

Numerous examples are available in the literature that illustrate the potential reduction in patient dose, while preserving image quality, that can result from increased x-ray beam filtration. Reference 7 demonstrates that the addition of 1.5 to 2.0 mm of aluminum (Al) as additional filtration, which is the change required to enable systems that just meet the current requirement to meet the proposed HVL requirement, would result in about a 30 percent reduction in entrance air kerma and about a 15 percent reduction in the integral dose for the fluoroscopic examination modeled in the paper at 80 kVp tube potential. Reduction in entrance skin dose (entrance air kerma) is relevant to reducing the risk of deterministic injuries to the skin, while a reduction in the integral dose is directly related to a reduction in the risk of stochastic effects such as cancer induction. Other authors have described dose reductions of a similar magnitude from increasing filtration for radiographic systems.

The requirements proposed in these amendments implement many of the suggestions and recommendations developed by members of the radiological community at the 1992 Workshop on Fluoroscopy sponsored by the American College of Radiology and FDA (Ref. 8). The recommendations from this workshop stressed the need to provide users of fluoroscopy with improved features enabling more informed use of this increasingly complex equipment. In addition, three radiological professional organizations indicated their opinions to FDA that radiologists would use the new features to better manage patient radiation exposure.

H. Estimation of Benefits

Projected benefits are quantified below in terms of: (1) Collective dose savings, (2) numbers of lives spared premature death associated with radiation-induced cancer, (3) collective years of life spared premature death, (4) numbers of reports of fluoroscopic skin burns precluded, and (5) pecuniary estimates associated with the preceding four items. The estimates represent average annual benefits projected to ramp up during a 10-year interval in which new fluoroscopic systems conforming to the proposed rules are phased into use in the United States. (FDA assumes that 10 years after the effective date of the proposed rules all fluoroscopic systems then in use would conform to those rules and that associated recurring benefits would continue to accrue at constant rates.) Annual pecuniary estimates that are averaged over the 10-year ramp-up interval and that are associated with prevention of cancer incidence, preclusion of premature mortality, and obviation of cancer treatment are based on the projected numbers of lives spared premature death. These pecuniary estimates are valued in current dollars using a 7 percent discount rate covering the identical 10-year evaluation period used in the cost analysis (see section VI.I). Based on an economic model of society's willingness to pay a premium for high-risk jobs, we associate a value of $5 million for each statistical death avoided, $25,000 for preclusion of each cancer treatment, and $5,000 for preclusion of cancer's psychological impact. Life benefits would be realized 20 years following exposure (after a period of 10 years of cancer latency followed by a period of 10 years of survival). Details, notes, and references for this analysis are provided in Ref. 29. The low, middle, and high estimates in table 6 of this document correspond respectively to the 5th, median, and 95th percentile points of nominal probability distributions. Estimation of the confidence intervals associated with these distributions is explained in the following paragraphs.

TABLE 6.—PROJECTIONS OF ANNUAL BENEFITS IN UNITED STATES FOR DISPLAY, COLLIMATION, AND FILTRATION RULES APPLIED TO PTCA, CA, AND UGI PROCEDURES[1]

	5th Percentile	Median	95th Percentile
Average Annual Dose and Life Savings in the First 10 Years After Effective Date of Proposed Rules			
Collective dose savings (person-sievert)	3,202	7,231	16,330
Number of lives spared premature death from cancer	62	223	808
Years of life spared premature death from cancer	1,131	4,094	14,818

TABLE 6.—PROJECTIONS OF ANNUAL BENEFITS IN UNITED STATES—Continued
FOR DISPLAY, COLLIMATION, AND FILTRATION RULES APPLIED TO PTCA, CA, AND UGI PROCEDURES[1]

	5th Percentile	Median	95th Percentile
Number of reported skin burns precluded	0.5	1.1	2.4
Average Annual Amortized Pecuniary Savings in the First 10 Years After Effective Date of Proposed Rules			
Prevention of premature death from cancer ($ millions)	78.61	285.03	1,032.75
Obviation of cancer treatment ($ millions)	9.71	35.21	127.56
Obviation of radiation burn treatment and loss ($ millions)	0.03	0.07	0.16
Total ($ millions)	88.35	320.31	1,160.48

[1] PTCA: percutaneous transluminal coronary angioplasty; CA: cardiac catheterization with coronary arterlography or angiography; UGI: upper gastrointestinal fluoroscopy

For the most part, these projections are based on a benefits analysis (Ref. 29, available at http://www.fda.gov/cdrh/radhlth/021501_xray.html) whose domain is intended to be representative but not exhaustive of prospective savings. To keep the analysis finite and manageable, it is limited to the three proposed amendments (sections II.E, II.F, and II.K of this document) that would most reduce radiation dose in several of the most common fluoroscopic procedures. The procedures considered are those of PTCA, CA, and UGI. There are other very highly utilized fluoroscopic procedures, for example, the barium enema examination, whose dose savings might be of comparable magnitude to those of UGI, that are not included at all in this analysis. The three amendments considered would require new fluoroscopic x-ray systems to: (1) Display the rate, time and cumulative total of radiation emission; (2) collimate the x-ray beam more efficiently; and (3) filter out more of the low energy x-ray photons from the x-ray beam. Proposed requirements for the source-skin distance for small c-arm fluoroscopes (section II.J of this document) and for provision of the last-image hold feature on all fluoroscopic systems (section II.L of this document) will also directly reduce dose, but their dose reductions are expected to be much smaller than those associated with the preceding proposed changes. The remaining amendments can be characterized as clarifications of the applicability of the standard, changes in definitions, corrections of errors, and other changes that contribute generally to the effectiveness of implementation of the standard.

Most of the assumptions, rationales, and data sources underlying the benefit projections are explicitly detailed in Ref. 29 and its notes and references. That analysis, however, is incomplete insofar as it refers only to a single set of point estimates. In order to develop a range of projections with a nominally high level of confidence, several additional assumptions are needed. Among the most important of the underpinnings of the analysis are: (1) The projected percentage dose reductions corresponding to the three amendments considered and (2) the dependence on the risk estimates for cancer mortality from the U.S. National Research Council Committee on the Biological Effects of Ionizing Radiation (BEIR V) (Ref. 22). For the former, FDA assumes a relative uncertainty of a factor of 2 (lower or higher) to represent the range in projected dose reductions consistent with a range of confidence of about 90 percent in the findings and assumptions (Ref. 29).

With respect to the dependence on the BEIR V estimates, FDA follows two recommendations of the Office of Science and Technology Policy (OSTP) Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) Science Panel Report No. 9 (Ref. 30) that represent the Federal consensus position for radiation risk-benefit evaluation: First, we apply a value of 2 as the dose-rate effectiveness factor (DREF) in the projections of numbers of solid, non-leukemia cancers. Adopting a DREF value of 2 in the analysis nearly halves the Ref. 29 modal point projections of the numbers of lives and years of life spared premature death from cancer. A DREF value of 2 implies that diagnostic or interventional fluoroscopy is a relatively low dose-rate modality. There are ambiguous assessments of that proposition: Although BEIR V (Ref. 22, pp. 171, 220) considers most medical x-ray exposures to correspond to high-dose rates (for which the DREF is assumed to equal 1 for solid cancers), ICRP Publication 73 (Ref. 16, p. 6) states just as unequivocally that risk factors reduced by a DREF larger than 1 (i.e., for low dose-rate modalities) ''are appropriate for all diagnostic doses and to most of the doses in tissues remote from the target tissues in radiotherapy.'' Recognizing these contrary views of the detrimental biological effectiveness associated with the rates of delivery of fluoroscopic radiation, we assume a factor of 2 uncertainty in the DREF to span a 90 percent range of confidence. The second recommendation that FDA adopts from CIRPPC Panel Report No. 9 (Ref. 30) is the interpretation that a factor of 2 relative uncertainty represents the BEIR V Committee's estimation of the 90 percent confidence interval for mortality risk estimates (Ref. 22). The latter value also agrees with that in the recent review of the United Nations Scientific Committee on the Effects of Atomic Radiation in the ''UNSCEAR 2000 Report'' (Ref. 31).

All of the contributions of relative uncertainty appropriate for the projections of collective dose savings, lives and years of life spared premature death associated with radiation-induced cancer, numbers of reports of fluoroscopic skin burns precluded, and associated pecuniary estimates are summed in quadrature. For the projected collective dose savings, the root quadrature sum yields an overall relative uncertainty of a factor of 2.3 lower and higher than the modal point estimates and corresponding respectively to the 5th and 95th percentiles of a nominal distribution of confidence; for the projected numbers of lives and years of life spared premature death, the overall relative uncertainty is a factor of 3.6 lower and higher.

I. Costs of Implementing the Proposed Regulations

Costs to manufacturers of fluoroscopic and radiographic systems would increase due to these proposals. FDA would also experience costs for increased compliance activities. Some costs represent one-time expenditures to develop new designs or manufacturing processes to incorporate the regulatory changes. Other costs are the ongoing costs of providing improved equipment performance and features with each installed unit. FDA developed unit cost estimates for each required activity and multiplied the respective unit cost by the relevant variables in the affected industry segment. One-time costs are amortized over the estimated useful life of a fluoroscopy system (10 years) using a 7 percent discount rate. This allows costs to be analyzed as average annualized costs as well as first year expenditures.

FDA developed these cost estimates based on its experience with the industry and its knowledge regarding design and manufacturing practices of the industry. Initially, gross, upper-bound estimates were selected to ensure that expected costs were adequately addressed. The initial assumptions and estimates were posted on FDA's Web site and circulated to the affected industry for comment in July 2000. FDA received no comments on these initial, upper-bound estimates and therefore believes that they were generally in line with industry expectations. Since then, in order to refine the estimates to provide a more accurate representation of the upper-bound costs of the proposed amendments, FDA re-examined its estimating assumptions and reduced some unit cost figures based on the expectation that future economies of scale would reduce the expense of some required features. This section presents a brief discussion of the cost estimates. A detailed description of this analysis is given in Ref. 33.

FDA has no information, indication, or economic presumption that costs estimated to be borne by manufacturers would be passed on to purchasers. The cost analysis therefore is limited to those parties who would be directly affected by the adoption of the proposed amendments, namely, manufacturers and FDA itself. FDA requests any information on the costs that would be imposed by these new requirements that would aid in refining the cost estimates.

1. Costs Associated With Requirements Affecting Equipment Design

The agency estimates that approximately one-half (20) of the manufacturers of x-ray systems will have to make design and manufacturing changes to comply with the revised beam quality requirements. It is estimated that a total of 200 x-ray models would be affected, with a one-time cost of at most $20,000 per model. These numbers result in an estimated first year expenditure of $4.0 million to redesign systems to meet the new beam quality requirement.

It will be necessary for manufacturers of fluoroscopic systems equipped with x-ray tubes with high heat capacity to redesign some systems to provide a means to add additional beam filtration. FDA estimates a design cost of $50,000 per model. A total of 100 models are likely to be affected for a one-time cost of $5.0 million to fluoroscopic system manufacturers. In addition, each system would cost more to manufacture because of the increased costs for components to provide the added feature. The increased cost of this added feature is estimated at $1,000 per fluoroscopic system. A total of 650 fluoroscopic systems are estimated to be installed annually with high heat capacity x-ray tubes, resulting in a total of $0.65 million in increased annual costs.

Modification of x-ray systems to meet the revised requirement for field limitation will entail either changes in installation and adjustment procedures, or redesign of systems. Each fluoroscopic system would need either modification in the adjustment procedure for the collimators (for which new installation and adjustment procedures would be developed at an estimated one-time cost of $20,000 per model) or collimators would need to be redesigned at an estimated cost of $50,000 per model. FDA has assumed that one-half of all flouroscopic x-ray system models (5 models each for 20 manufacturers) would need modifications to meet the new requirement, while the remainder would either meet the new requirement or could meet it through very minor modifications in the collimator adjustment procedure. For those system models not meeting the new requirement, it is assumed that a redesign of the collimator system is required at a cost of about $50,000 per model, leading to an upper-bound estimate of the total redesign cost of $5.0 million (20 manufacturers x 5 models x $50,000). All stationary fluoroscopic systems would most likely need redesigned collimators that would add an additional $2,000 per new system due to increased complexity of the collimator. An annual industry cost increase of $5.0 million accounts for all 2,500 annual installations of systems with these more expensive collimators.

The proposals to modify the requirement limiting the maximum entrance AKR and to remove the exception to the limit during recording of images in analog format using a video recorder will only affect the adjustment of newly installed systems having such recording capability. This requirement is not expected to impose significant costs.

FDA is proposing that all fluoroscopic systems include displays of irradiation time, AKR, and cumulative air kerma to assist operators in keeping track of patient exposures and avoiding overexposures. Each model of fluoroscopic system would need to be redesigned (at a maximum estimated cost of $50,000 per model) for a one-time estimated cost of $10.0 million (200 models x $50,000). Accessory or add-on equipment for existing fluoroscopic systems that provide similar information are currently available for an additional cost of over $10,000 per system. However, FDA expects the average manufacturing cost of including such a feature as an integral feature of a fluoroscopic system to be less than $4,000 per system, due to achievable economies of scale and integration with other system computer capabilities. This assumption results in annual cost increases of $16.8 million (4,200 annual installations x $4,000).

The proposed amendments would require that all newly manufactured fluoroscopic systems be provided with LIH capability. FDA expects that 10 fluoroscopic system manufacturers would need to redesign their systems to include this technology at a maximum cost of $100,000 per manufacturer. Total one-time design costs would equal $1.0 million for the industry (10 manufacturers x $100,000). It is estimated that about half of the new systems installed would already be equipped with this feature. Thus, about half of the newly installed systems that currently do not provide this feature would need it. FDA estimates that the cost would be an additional $2,000 for each system required to have this feature. Thus, annual costs would increase by $4.2 million (2,100 annual systems x $2,000).

The amendment clarifying the requirement for MSSD for small C-arm systems is anticipated to require redesign of several of these systems. As there are only three manufacturers of these systems, and the redesign costs are estimated to be no more than $50,000 per system, the total one-time cost for this change would be $0.2 million. The

average annualized cost of this proposed change would be negligible.

In summary, total industry costs for compliance with the amendments in the area of equipment design include one-time costs of $25.2 million. This total equals an average annualized cost (7 percent discount rate over 10 years) of $3.6 million. In addition, annual recurring costs for new equipment features associated with these proposed provisions are expected to equal $26.7 million.

2. Costs Associated With Additional Information for Users

The proposed amendments would require that additional information be provided in the user instructions regarding fluoroscopic systems. FDA has estimated that each model of fluoroscopic system would need a revised and augmented instruction manual at a cost of less than $5,000 per model. This is equal to a maximum one-time cost of $1.0 million (200 models of fluoroscopic systems x $5,000) and implies maximum average annualized costs of $0.14 million. In addition, each newly installed system would include an improved instruction manual. FDA estimates a cost of $20 per manual for printing and distribution of the required additional information. Each of the 4,200 installed fluoroscopy systems would include a revised manual for an annual cost of approximately $0.1 million.

Related to the requirements for additional information is the proposal to change the quantity used to describe the radiation produced by the x-ray system. Because the change to use of the quantity air kerma does not require any changes or actions on the part of manufacturers or users, there is no significant cost associated with it.

3. Costs Associated With Clarifications and Adaptations to New Technologies

The new definitions and clarifications of applicability proposed for the standard do not pose any significant new or additional costs on manufacturers.

4. FDA Costs Associated With Compliance Activities

FDA costs would increase due to the increased compliance activities that would result from these proposed regulations. In addition, FDA would experience implementation costs in developing and publicizing the new requirements. FDA has estimated that approximately five full-time equivalent employees (FTEs) would be required to implement the proposed regulations and conduct training of field inspectors. Using the current estimate of $117,000 per FTE, the one-time cost of implementation to FDA is approximately $0.6 million. Amortizing this cost over a 10-year evaluation period using a 7 percent discount rate results in average annualized costs of about $0.1 million. Ongoing costs of annual compliance activities are expected to require about three FTEs, or a little more than $0.3 million per year.

5. Total Costs of the Proposed Regulation

The estimated costs of the amendments identified as having any significant cost impact are summarized in table 7 of this document. The costs are identified as non-recurring costs that must be met initially or as annual costs associated with continued production of systems meeting the proposed requirements or additional annual enforcement of the amendments. The total annualized cost of the proposed regulations (averaged over 10 years) equals $30.8 million, of which $30.4 million would be borne by manufacturers. The annualized estimate of $30.8 million represents amortization of first year costs of $53.8 million and expenditures from years 2 through 10 of $27 million annually.

TABLE 7.—SUMMARY OF COSTS OF AMENDMENTS

Amendment Described in Section	Non-recurring Costs to Manufacturers ($ millions)	Non-recurring Costs to FDA ($ millions)	Annual Costs to Manufacturers ($ millions)	Annual Costs to FDA ($ millions)
II.A	none	0.0059	none	none
II.B	none	0.0324	none	none
II.D	1.0	none	0.084	0.0117
II.E	9.0	0.0117	0.650	none
II.F	5.0	0.0468	5.0	none
II.G, II.H, and II.I	none	none	none	none
II.J	0.150	0.0234	none	none
II.K	10.0	0.4680	16.8	0.2340
II.L	1.0	0.0234	4.2	none
Total	26.150	0.6026	26.734	0.2457

Therefore, during the first 10 years after the effective date of the proposed amendments, the average annual cost is estimated to be $30.8 million, compared to a projected average annual benefits of $320 million, within a range estimated between $88 million and $1.2 billion.

J. Small Business Impacts

FDA believes that it is likely that the proposed rule will have a significant impact on a substantial number of small entities and has conducted an IRFA. This analysis is designed to assess the impact of the proposed rule on small entities and alert any impacted entities of the expected impact.

1. Description of Impact

The objective of the proposed regulation is to reduce the likelihood of adverse events due to unnecessary exposure to radiation during diagnostic x-ray procedures, primarily fluoroscopic procedures. The amendments would accomplish this by requiring performance features on all fluoroscopic

x-ray systems that would protect patients and health personnel while maintaining image quality.

Manufacturers of diagnostic x-ray systems, including fluoroscopy equipment, are grouped within the North American Industry Classification System (NAICS) industry code 334517 (Irradiation Apparatus Manufacturers)[1]. The Small Business Administration (SBA) classifies as ''small'' any entity with 500 or fewer employees within this industry. Relatively small numbers of employees typify firms within this NAICS code group. About one-half of the establishments within this industry employ fewer than 20 workers, and companies have an average of 1.2 establishments per company. The manufacturers are relatively specialized, with about 84 percent of company sales coming from within the affected industry. In addition, 97 percent of all shipments of irradiation equipment originate by manufacturers classified within this industry.

The Manufacturing Industry Series report on Irradiation Apparatus Manufacturing for NAICS code 334517 from the 1997 Economic Census indicates 136 companies having 154 establishments for this industry in the United States. This report also indicates that only 15 of these establishments have 250 or more employees, with only 5 establishments having more than 500 employees. Therefore, this industry sector is predominately composed of firms meeting the SBA description of a ''small entity.'' Of the total value of shipments of $3,797,837,000 for this industry, 73 percent are from the 15 establishments with 250 or more employees. Thus, for the purposes of the IRFA, most of the diagnostic x-ray equipment manufacturing firms that will be affected by these proposed amendments are small entities.

The impact of the proposed amendments will be similar on manufacturers of diagnostic x-ray systems, whether or not they are small entities. This impact is the increased costs to design and manufacture x-ray systems that meet the new requirements. For those manufacturers that produce smaller numbers of systems per year, the impact of the cost of system redesign to meet the new requirements will result in a greater per unit cost impact than for manufacturers with a high volume of unit sales over which the development costs may be spread. This may have a disproportionate impact on the very small firms with a low volume of sales.

FDA considered whether there were approaches that could be taken to mitigate this impact on the firms producing the smaller numbers of systems. FDA, however, identified no feasible way to do this and also accomplish the needed public health protection. The proposed radiation-safety-related requirements are appropriate for any x-ray system, independent of the circumstances of the manufacturer. FDA considers it appropriate for any firm producing x-ray systems to provide the level of radiation protection that will be afforded by the revised standard. Patients receiving x-ray examinations or procedures warrant the same degree of radiation safety regardless of the circumstances of the manufacturer of the equipment.

2. Analysis of Alternatives

FDA examined and rejected several alternatives to proposing amendments to the performance standard. One alternative was to take no actions to modify the standard. This option was rejected because it would not permit clarification of the manner in which the standard should be applied to the technological changes occurring with fluoroscopic x-ray system design and function. This option was also rejected as failing to meet the public expectation that the federal performance standard assures adequate radiation safety performance and features for fluoroscopic x-ray systems. The changes that have occurred since the standard was developed in the early 1970s necessitate modification of the standard to reflect current technology and to recognize the increased radiation hazards posed by new fluoroscopic techniques and procedures.

A portion of the concern and the unnecessary radiation exposure resulting from current fluoroscopic practices might be addressed through the establishment of controls and requirements regarding the qualifications and training of physicians permitted or allowed to use fluoroscopic systems. Such requirements could assure that, contrary to the current situation, all physicians using fluoroscopy are adequately trained regarding radiation safety practices, proper fluoroscopic system use, and methods for assuring that patient doses are maintained as low as possible. This alternative was rejected because FDA does not have the authority, under current law, to establish such requirements. To be effective, such a program would have to be established by States or medical professional societies or certification bodies. While recognizing that encouragement of such activities by FDA is worthwhile, reliance on such efforts alone would not result in the needed performance improvement of fluoroscopic x-ray systems. FDA concluded that improved use of fluoroscopy requires the dose reduction features and operator feedback mechanism regarding patient doses that would be provided by the proposed amendments.

Alternatives to the specific amendments proposed were also considered in developing these proposals. These alternatives are described in detail in the assessment report developed and filed as part of the information supporting these amendments (Ref. 33). FDA requests comments on alternatives to these proposed amendments that would accomplish the needed public health protection and, in particular, any alternatives that could mitigate the impact of the proposed amendments on small businesses.

3. Ensuring Small Entity Participation in Rulemaking

FDA believes it is possible that the proposed regulation could have a significant impact on small entities. The impact would occur due to increased design and production costs for fluoroscopy systems. FDA solicits comment on the nature of this impact and whether there are reasonable alternatives that might accomplish the intended public health goals.

The proposed regulation will be available on the Internet at http://www.fda.gov for review by all interested parties, and all comments will be considered prior to final implementation of the regulation. In addition, FDA will communicate the proposed regulation to manufacturer organizations and trade associations as well as parties that have previously indicated an interest in amendments to the diagnostic x-ray equipment performance standard. The proposed amendments will also be brought to the attention of relevant medical professional societies and organizations whose members are likely to use fluoroscopic x-ray systems. FDA will solicit the assistance of the SBA during the comment period to assure that all small manufacturers impacted by the proposed amendments are aware of the opportunity to comment on the proposal, possible alternatives and its impact.

[1]NAICS has replaced the Standard Industrial Classification (SIC) codes. NAICS Industry Group 334517 (Irradiation Apparatus) coincides with SIC Group 3844 (X-Ray Apparatus and Tubing).

K. Reporting Requirements and Duplicate Rules

FDA has concluded that the proposed rule imposes new reporting and other compliance requirements on small businesses. In addition, FDA has identified no relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule. The cost in the labeling is addressed previously.

L. Conclusion of the Analysis of Impacts

FDA has examined the impacts of the proposed amendments to the performance standard. Based on this evaluation, an upper-bound estimate has been made for average annualized costs amounting to $30.8 million, of which $30.4 million would be borne by the manufacturers of this equipment. FDA believes that the reductions in acute and long-term radiation injuries to patients that would be facilitated by the proposed amendments would appreciably outweigh the upper-bound costs estimated for compliance with the rules. Finally, FDA has concluded that it is likely that this proposal would have a significant impact on a substantial number of small entities.

FDA solicits comment on all aspects of this analysis and all assumptions used.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Submission of Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposal. Two copies of any mailed 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.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Allisy, A. et al., ''Fundamental Quantities and Units for Ionizing Radiation,'' ICRU Report No. 60, International Commission on Radiation Units and Measurements, Bethesda, MD, December 1998.
2. FDA Guidance Document, ''Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices,'' Food and Drug Administration, August 6, 1999.
3. National Council on Radiation Protection and Measurements, ''Medical X-Ray and Gamma-Ray Protection for Energies Up to 10 MeV, Equipment Design and Use,'' NCRP Report No. 33, Bethesda, MD, February 1, 1968.
4. International Standard, International Electrotechnical Commission (IEC) 601–1–3, ''Medical Electrical Equipment—Part 1: General Requirements for Safety. 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment,'' 1994.
5. Cranley, K., B. J. Gilmore, and G. W. A. Fogarty, ''Data for Estimating X-Ray Tube Total Filtration,'' Institute of Physical Sciences in Medicine, Report No. 64, *Institute of Physical Sciences in Medicine*, York, England, 1991.
6. Shope, T. B., ''Radiation-Induced Skin Injuries From Fluoroscopy,'' *RadioGraphics*, vol. 16, pp. 1195–1199, September 1996.
7. Gagne, R. M., P. W. Quinn, and R. J. Jennings, ''Comparison of Beam-Hardening and K-Edge Filters for Imaging Barium and Iodine During Fluoroscopy,'' *Medical Physics*, vol. 21, pp. 107–121, 1994.
8. *Proceedings of the ACR/FDA Workshop on Fluoroscopy*, ''Strategies for Improvement in Performance, Radiation Safety and Control,'' Dulles Hyatt Hotel, Washington, DC, October 16 and 17, 1992, American College of Radiology, Merrifield, VA, 1993.
9. Stern, S. H. et al., ''Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries,'' HHS Publication FDA 95–8288, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, 1995.
10. Rudin, S. and D. R. Bednarek, ''Spatial Shaping of the Beam: Collimation, Grids, Equalization Filters, and Region-of-Interest Fluoroscopy,'' *A Categorical Course in Physics, Physical and Technical Aspects of Angiography and Interventional Radiology* (syllabus). Eds. S. Balter and T. B. Shope, presented at the 81st Scientific Assembly and Annual Meeting of the Radiological Society of North America, Chicago, IL, November 1995.
11. Solomon, E. et al., ''Low-Exposure Scanning-Beam X-Ray Fluoroscopy System,'' *SPIE*, vol. 2708, pp. 140–149, 1996.
12. National Council on Radiation Protection and Measurements, ''Quality Assurance for Diagnostic Imaging Equipment,'' NCRP Report No. 99, Bethesda, MD, December 30, 1988.
13. National Council on Radiation Protection and Measurements, ''Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV,'' NCRP Report No. 102, Bethesda, MD, June 30, 1989.
14. Beninson, D. et al., ''1990 Recommendations of the International Commission on Radiological Protection,'' *Annals of the ICRP*, ICRP Publication 60, vol. 21, Nos. 1–3, Pergamon Press, Oxford, UK, 1991.
15. Thornbury, J. R. et al., ''An Introduction to Efficacy in Diagnostic Radiology and Nuclear Medicine (Justification of Medical Radiation Exposure),'' NCRP Commentary No. 13, National Council on Radiation Protection and Measurement, Bethesda, MD, August 1995.
16. Zuur, C. and F. Mettler, ''Radiological Protection and Safety in Medicine,'' *Annals of the ICRP*, ICRP Publication 73, vol. 26, No. 2, Pergamon Press, Oxford, UK, 1996.
17. ''Council Directive 97/43/Euratom of 30 June 1997 on Health Protection of Individuals Against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/Euratom,'' *Official Journal of the European Communities*, No. L 180, pp. 22–27, July 9, 1997.
18. Food and Drug Administration, ''Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures,'' Food and Drug Administration Important Information for Physicians and Other Health Care Professionals, September 9, 1994.
19. Food and Drug Administration, ''Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures,'' *FDA Public Health Advisory*, September 30, 1994.
20. Food and Drug Administration, ''Recording Information in the Patient's Medical Record That Identifies the Potential for Serious X-Ray-Induced Skin Injuries Following Fluoroscopically-Guided Procedures,'' Food and Drug Administration Important Information for Physicians and Other Health Care Professionals, September 15, 1995.
21. Rosenstein, M. et al., ''Handbook of Selected Tissue Doses for the Upper Gastrointestinal Fluoroscopic Examination,'' U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, FDA Publication 92–8282, Rockville, MD, 1992.
22. Upton, A. C. et al., ''Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V,'' Committee on the Biological Effects of Ionizing Radiations, Board on Radiation Effects Research, Commission on Life Sciences, National Research Council, National Academy of Science, National Academy Press, Washington, DC, 1990.
23. Bäuml, A. et al., Eds., Proceedings of the ''Joint WHO/ISH Workshop on Efficacy and Radiation Safety Interventional Radiology,'' Munich-Neuherberg, Germany, October 9 to 13, 1995, BfS-ISH Report 178/

97, Bundesamt für Strahlenschutz, Fachbereich Strahlenhygiene, Institut für Strahlenhygiene, Neuherberg, Germany, 1997.

24. International Standard, International Electrotechnical Commission (IEC) 60601–2–43, ''Medical Electrical Equipment-Part 2–43: Particular Requirements for the Safety of X-Ray Equipment for Interventional Procedures,'' edition 1, 2000.

25. Gkanatsios, N. A. et al., ''Evaluation of an On-Line Patient Exposure Meter in Neuroradiology,'' *Radiology*, vol. 203, pp. 837–842, 1997.

26. Geise, R. A. et al., ''Radiation Doses During Pediatric Radiofrequency Catheter Ablation Procedures,'' *PACE*, Part 1, vol. 19, pp. 1605–1611, 1996.

27. Transcript of Proceedings, Twenty-fifth Meeting of the Technical Electronic Product Radiation Safety Standards Committee, vol. 1, pp. 118–121, Gaithersburg, MD, September, 1998.

28. Suleiman, O. H. et al., ''Nationwide Survey of Fluoroscopy: Radiation Dose and Image Quality,'' *Radiology*, vol. 203, pp. 471–476, 1997.

29. Stern, S. H. et al., ''Estimated Benefits of Proposed Amendments to the FDA Radiation-Safety Standard for Diagnostic X-ray Equipment,'' Poster presented at the 2001 FDA Science Forum, Washington, DC, February 15–16, 2001. Also available at http://www.fda.gov/cdrh/radhlth/021501xray.html.

30. Rosenstein, M. et al., Committee on Interagency Radiation Research and Policy Coordination Science Panel Report No. 9, ''Use of BIER V and UNSCEAR 1988 in Radiation Risk Assessment, Lifetime Total Cancer Mortality Risk Estimates at Low Doses and Low Dose Rates for Low-LET Radiation,'' (ORAU 92/F–64), OSTP, EOP, Washington, DC, December 1992.

31. ''Sources and Effects of Ionizing Radiation,'' United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, New York: United Nations, 2000.

32. National Council on Radiation Protection and Measurements, ''Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation,'' NCRP Report 136, Bethesda, MD, June 2001.

33. ''Assessment of the Impact of the Proposed Amendments to the Performance Standard for Diagnostic X-Ray Equipment Addressing Fluoroscopic X-ray Systems,'' Food and Drug Administration, pp. 1–28, November 15, 2000. Also available at http://www.fda.gov/cdrh/radhealth/fluoro/amendxrad.html

List of Subjects in 21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1020 be amended as follows:

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

1. The authority citation for 21 CFR part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360gg–360ss, 371, 381.

2. Revise §1020.30 to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability*—(1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(F) Image receptors which are electrically powered or connected with the x-ray system manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**].

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32, which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and § 1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) ''Technique factors'';

(iii) Section 1020.30(b) ''CT,'' ''Dose,'' ''Scan,'' ''Scan time,'' and ''Tomogram'';

(iv) Section 1020.30(h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33(a) and (b);

(vii) Section 1020.33(c)(1) as it affects § 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and § 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions*. As used in this section and §§1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Air kerma means kerma in air (see kerma).

Aluminum equivalent means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in ''Aluminum Standards and Data'' (1969). Copies may be obtained from The Aluminum Association, New York, NY.

subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters by 20 centimeters by 3.8 centimeters.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of the x-ray field.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 centimeters beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}}\left[\sum_{i=1}^{n}\frac{\left(X_i - \overline{X}\right)^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

X_i = ith observation sampled.

n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of $d\varepsilon$ by dm, where $d\varepsilon$ is the mean energy imparted to matter of mass dm; thus $D=d\varepsilon/dm$, in units of J/kg, where the special name for the unit of absorbed dose is gray (Gy).

Equipment means x-ray equipment.

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopy means a technique for generating x-ray images and presenting them instantaneously and continuously as visible images for the purpose of providing the user with a visual display of dynamic processes.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term ''image receptor'' shall mean the preselected portion of the device.

Image receptor support device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

Isocenter means the center of the smallest sphere through which the beam axis passes for a C-arm gantry moving through a full range of rotations about a common center.

Kerma means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as ''air kerma.''

Last-image hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

Leakage radiation means radiation emanating from the diagnostic source assembly except for:

(1) The useful beam; and

(2) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

Percent line-voltage regulation = $100(V_n - V_i) / V_i$

where:

V_n = No-load line potential and

V_i = Load line potential.

Maximum line current means the root mean square current in the supply line of an x-ray machine operating at its maximum rating.

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography selected with a set of technique factors or other control settings uniquely associated with the mode. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog), digital cineradiography, digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses per exposure series, SID, or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Nonimage-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Quick change x-ray tube means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or § 1020.31 or § 1020.32;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§1020.31 and 1020.32.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Solid state x-ray imaging device means an assembly, typically in a rectangular panel configuration, consisting of:

(1) A transducer layer that intercepts x-ray photons and through a single or multistage process converts the photon energy into a modulated signal representative of the x-ray image, and

(2) A matrix of integration and switching elements that are coupled to the transducer layer. An electrical signal representing the x-ray image is generated by a charge generation and transfer process within the integration and switching matrix. The electrical signals may undergo analog-to-digital conversion before leaving the panel to provide either a digital radiographic or fluoroscopic image.

Source means the focal spot of the x-ray tube.

Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to

its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperes-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) *Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) *Portable x-ray equipment* means x-ray equipment designed to be hand-carried; and

(3) *Stationary x-ray equipment* means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility*. Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Compliance of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility*. An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by § 1020.31, § 1020.32, or § 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly*. All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, Center for Devices and Radiological Health. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements*. Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to the Center for Devices and Radiological Health in the report required under § 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and

reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word ''model'' or ''type'' shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels, that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users.* Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) *Tube rating charts.* If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the

rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device*. For each variable-aperture beam-limiting device, there shall be provided;

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) *Imaging system information*. For x-ray systems manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a description of any specific clinical procedure(s) and clinical imaging task(s) for which the mode is recommended or designed and how each mode should be used.

(6) *Displays of values of AKR and cumulative air kerma*. For fluoroscopic x-ray systems manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], the following shall be provided:

(i) A statement of the maximum deviations of the AKR and cumulative air kerma from their respective displayed values;

(ii) Instructions, including schedules, for calibrating and maintaining any instrumentation associated with measurement or evaluation of the AKR and cumulative air kerma;

(iii) Identification of the spatial coordinates of the irradiation location to which displayed values of AKR and cumulative air kerma refer according to § 1020.32(k)(5);

(iv) A rationale for specification of a reference irradiation location alternative to 15 centimeters from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to § 1020.32(k)(5)(ii).

(i) [Reserved]

(j) *Warning label*. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

(k) *Leakage radiation from the diagnostic source assembly*. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly*. The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 μGy (vice 2 mR exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Beam quality*—(1) *Half-value layer*. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table 1 of this section under "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under "I—Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before [date 1 year after date of publication of the final rule in the **Federal Register**]; and under "II—Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**]. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1 of this section, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

[2]In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 1.

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (millimeters of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[1]	I—Other X-Ray Systems[2]	II—Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.4
	80	2.3	2.3	2.8
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	4.1
	120	3.2	3.2	4.5
	130	3.5	3.5	5.0
	140	3.8	3.8	5.4
	150	4.1	4.1	5.9

[1]Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
[2]Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before or on [date 1 year after date of publication of the final rule in the **Federal Register**].
[3]All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured after [date 1 year after date of publication of the final rule in the **Federal Register**].

(2) *Optional filtration*. Fluoroscopic systems incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of selecting and adding x-ray filtration to the diagnostic source assembly over and above the amount needed to meet the half-value layer provisions of § 1020.30(m)(1). The selection of this additional x-ray filtration shall be at the option of the user.

(3) *Measuring compliance*. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor*. Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table 2 of this section, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has a HVL specified in table 1 of this section for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

TABLE 2.

Item	Aluminum Equivalent (millimeters)
Front panel(s) of cassette holders (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Cradle	2.0
Tabletop, stationary, without articulated joints	1.0
Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.5
Tabletop, with radiolucent panel having one articulated joint	1.5
Tabletop, with radiolucent panel having two or more articulated joints	2.0
Tabletop, cantilevered	2.0
Tabletop, radiation therapy simulator	5.0

(o) *Battery charge indicator*. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems*—(1) Diagnostic x-ray components and systems certified in accordance with § 1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with § 1010.4 of this chapter or an exemption under section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of § 1020.31, § 1020.32, or § 1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification, and provided the modification of the x-ray system does not result in a failure to comply with § 1020.31, § 1020.32, or § 1020.33.

3. Revise § 1020.31 to read as follows:

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except equipment for fluoroscopic imaging and for radiographic imaging when images are recorded from the fluoroscopic image receptor or computed tomography x-ray systems manufactured on or after November 28, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication*. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers*. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls*. When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy*. Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3);

(b) *Reproducibility*. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3);

(1) *Coefficient of variation*. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

(2) *Measuring compliance*. Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity*. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Equipment having independent selection of x-ray tube current (mA)*. The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1+X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive tube current settings or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) *Equipment having selection of x-ray tube current-exposure time product (mAs)*. For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1-X_2| \leq 0.10(X_1+X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) *Measuring compliance.* Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

(d) *Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.* Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters.

(2) *Visual definition.* (i) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

(e) *Field indication and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(3) Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(4) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 centimeters and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 centimeters and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for mammography*—(i) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with the means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(iii) Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and

permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems*. Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Positive beam limitation (PBL)*. The requirements of this paragraph shall apply to radiographic systems which contain PBL.

(1) *Field size*. When a PBL system is provided, it shall prevent x-ray production when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

(iii) The beam limiting device is at an SID for which PBL is not designed for sizing.

(2) *Conditions for PBL*. When provided, the PBL system shall function as described in paragraph (g)(1) of this section whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than 50 centimeters;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(3) *Measuring compliance*. Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) *Operator initiated undersizing*. The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) *Override of PBL*. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(h) *Field limitation and alignment for spot-film devices*. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(i) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square centimeters; or

(ii) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(i) *Source-skin distance*—(1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kVp; or

(ii) Ten centimeters if not operable above 50 kVp.

(2) Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 centimeters.

(j) *Beam-on indicators*. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes*. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment*. Radiation emitted from the x-ray tube shall not exceed:

(1) An air kerma of 0.26 mGy (vice 0.03 mR exposure) in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters; and

(2) An air kerma of 0.88 mGy (vice 100 mR exposure) in 1 hour at 100 centimeters from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Primary protective barrier for mammography x-ray systems*—(1) For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 μGy (vice 0.1 mR exposure) for each activation of the tube.

(2) For mammographic x-ray systems manufactured on or after September 30, 1999:

(i) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(ii) The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(2)(i) of this section.

(iii) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 μGy (vice 0.1 mR exposure) for each activation of the tube.

(3) Compliance with the requirements of paragraphs (m)(1) and (m)(2)(iii) of this section for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

4. Revise § 1020.32 to read as follows:

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopic imaging and for radiographic imaging when images are recorded from the fluoroscopic image receptor except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam*. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic image receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, under § 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance*. The AKR shall be measured in accordance with paragraph (d) of this section. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Angulation.* For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with paragraphs (b)(4) and (b)(5) of this section shall be determined with the

beam axis indicated to be perpendicular to the plane of the image receptor.

(2) *Further means for limitation.* Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of paragraphs (b)(4) and (b)(5). Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or the capability of a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square centimeters shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 centimeters by 5 centimeters. This paragraph does not apply to nonimage-intensified fluoroscopy.

(3) *Nonimage-intensified fluoroscopy.* The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(4) *Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.* (i) For fluoroscopic equipment manufactured before [date 1 year after date of publication of the final rule in the **Federal Register**], other than radiation therapy simulation systems, the following applies:

(A) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(B) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(ii) For fluoroscopic equipment manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], other than radiation therapy simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

(A) When the visible area of the image receptor is less than or equal to 34 cm in any direction: (1) At least 80 percent of the x-ray field overlaps the visible area of the image receptor, or (2) at least 80 percent of the air kerma integrated over the x-ray field is incident on the area of the image receptor.

(B) When the visible area of the image receptor is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the visible area of the image receptor by more than a total of 2 cm.

(5) *Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently rectangular image receptors.* For x-ray systems manufactured after [date 1 year after date of publication of the final rule in the **Federal Register**]:

(i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(ii) The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(6) *Override capability.* If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(c) *Activation of tube.* X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(d) *Air kerma rates.* For fluoroscopic equipment, the following requirements apply:

(1) *Fluoroscopic equipment manufactured before May 19, 1995*— (i) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(1)(v) of this section.

(ii) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(1)(v) of this section.

(iii) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(1)(v) of this section.

(iv) Equipment may be modified in accordance with § 1020.30(q) to comply with § 1020.32(d)(2). When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

''Modified to comply with 21 CFR 1020.32(d)(2).''

(v) Exceptions:

(A) During recording of fluoroscopic images, or

(B) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in § 1020.32(d)(1)(i), (d)(1)(ii), or (d)(1)(iii) at the measurement point specified in § 1020.32(d)(3), unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) *Fluoroscopic equipment manufactured on or after May 19, 1995*— (i) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3). Provision for manual selection of technique factors may be provided.

(ii) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10

R/min exposure rate) at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(2)(iii) of this section:

(iii) Exceptions:

(A) For equipment manufactured prior to [date 1 year after date of publication of the final rule in the **Federal Register**], during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(B) For equipment manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with an image(s) after termination of the exposure. However, the archiving of fluoroscopic or radiographic images through the recording of such images in analog format with a video-tape or video-disc recorder does not qualify as an exception.

(C) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 180 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in §1020.32(d)(3). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) *Measuring compliance.* Compliance with paragraph (d) of this section shall be determined as follows:

(i) If the source is below the x-ray table, the AKR shall be measured at 1 centimeter above the tabletop or cradle.

(ii) If the source is above the x-ray table, the AKR shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the AKR shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(iv) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(v) In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

(4) *Exemptions.* Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph (d) of this section.

(e) [Reserved]

(f) *Indication of potential and current.* During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with § 1020.30(h)(3).

(g) *Source-skin distance.* (1) Means shall be provided to limit the source-skin distance to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(2) For mobile or portable C-arm fluoroscopic systems manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], having a maximum source-image receptor distance of less than 45 centimeters, means shall be provided to limit the source-skin distance to not less than 19 centimeters. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(h) *Fluoroscopic irradiation time, display, and signal.* (1)(i) Fluoroscopic equipment manufactured before [date 1 year after date of publication of the final rule in the **Federal Register**], shall be provided with means to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with § 1020.30(q) to comply with the requirements of § 1020.32(h)(2). When the equipment is modified, it shall bear a label indicating the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)."

(ii) As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

(2) For x-ray controls manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], there shall be provided for each fluoroscopic tube:

(i) A display of the value and units of the irradiation time from the beginning of a patient examination or procedure. This display shall be visible at the fluoroscopist's working position throughout the examination or procedure and after it ends. The display shall be able to be reset to zero prior to the commencement of a new examination or procedure, and it shall function independently of the audible signal described in § 1020.32(h)(2)(ii).

(ii) A signal audible to the fluoroscopist shall indicate the passage of irradiation time during an examination or procedure. The signal shall sound for at least one second at each interval of 5-minutes duration of irradiation time.

(i) *Mobile and portable fluoroscopes.* In addition to the other requirements of this section, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

(j) *Display of last image hold (LIH).* Fluoroscopic equipment manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], shall be equipped with means to display an LIH radiograph following termination of the fluoroscopic exposure.

(1) For an LIH radiograph obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

(2) For an LIH radiograph obtained by initiating a separate radiographic exposure, if the techniques factors for the radiographic exposure are selectable prior to the exposure, the combination selected must be indicated prior to initiation of the fluoroscopic exposure.

(3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with reinitiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

(4) The predetermined or selectable options for producing the LIH radiograph shall be described in the information required by § 1020.30(h). The information shall include a description of any applicable technique factors for the selected option and the impact of the selectable options on image characteristics and radiation dose.

(k) *Displays of values of AKR and cumulative air kerma.* Fluoroscopic equipment manufactured on or after [date 1 year after date of publication of the final rule in the **Federal Register**], shall display at the fluoroscopist's working position values of AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

(1) The value displayed for AKR shall be in units of mGy/min and shall represent the air kerma per unit time during fluoroscopy and while recording during fluoroscopy.

(2) The value displayed for cumulative air kerma shall be in units of mGy; shall include all contributions generated from fluoroscopic and radiographic radiation; shall represent the total air kerma accrued from the commencement of an examination or procedure and shall be updated during the examination or procedure each time that fluoroscopic or radiographic x-ray production is deactivated.

(3) During fluoroscopy and while recording during fluoroscopy, the value and units of the AKR shall be displayed. Following fluoroscopy or radiography, the value and units of the cumulative air kerma shall be displayed.

(4) The display of the value of the AKR shall be clearly distinguishable from the display of the value of the cumulative air kerma.

(5) Values displayed for the AKR and cumulative air kerma shall be determined for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in information provided to users according to § 1020.30(h)(6)(iii).

(i) For fluoroscopes with x-ray source below the table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in § 1020.32(d)(3)(i), (d)(3)(ii), or (d)(3)(v) for measuring compliance with air-kerma rate limits.

(ii) For C-arm type fluoroscopes, the reference location shall be 15 centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be along the beam axis at a point deemed by the manufacturer to represent the intersection of the x-ray beam entrance surface and the patient skin.

(6) Means shall be provided to reset to zero the values of AKR and cumulative air kerma prior to the commencement of a new examination or procedures.

(7) The AKR and the cumulative air kerma shall not deviate from their respective displayed values by more than ±25 percent.

5. Amend § 1020.33 by revising paragraph (h)(2) to read as follows:

§ 1020.33 Computed tomography (CT) equipment.

* * * * *

(h) * * *

(2) For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-ray with a shutter, the radiation emitted may not exceed 0.88 milligray (vice 100 milliroentgen exposure) in 1 hour at any point 5 centimeters outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements average over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

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Dated: July 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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