Tab B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 2001N–0275]

RIN 0910–AC34

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the Federal performance standard for diagnostic x-ray systems and their major components (the performance standard). The agency is taking this action to update the performance standard to account for changes in technology and use of radiographic and fluoroscopic x-ray systems and to fully utilize the International System of Units to describe radiation-related quantities and their units when used in the performance standard. For clarity and ease of understanding, FDA is republishing the complete contents, as amended, of three sections of the performance standard regulations and is amending a fourth section without republishing it in its entirety. 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: This rule is effective [*insert date 1 year after date of publication in the* **Federal Register**].

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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. As part of that program, FDA has authority to issue regulations prescribing radiation safety performance standards for electronic products, including diagnostic x-ray systems (sections 532 and 534 of the act (21 U.S.C. 360ii(a) and 360kk)).

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

In order for mandatory performance standards to continue to provide the intended public health protection, the standards must be modified when appropriate to reflect the changes in technology and product usage. When the performance standard was originally developed, the only means of producing a fluoroscopic image was either a screen of fluorescent material or an x-ray image intensifier tube. Therefore, the standard was written with these two types of image receptors in mind. A number of technological developments have been implemented for radiographic and fluoroscopic x-ray systems, such as solid-state x-ray imaging (SSXI) and new modes of image recording (e.g.,

digital recording to computer memory or other media). These developments have made the application of the current standard to systems incorporating these new technologies cumbersome and awkward. FDA is therefore amending the performance standard for diagnostic x-ray systems and their major components in §§ 1020.30, 1020.31, and 1020.32 (21 CFR 1020.30, 1020.31, and 1020.32) to address the recent changes in technology. In addition, we are amending § 1030.33(h) (21 CFR 1030.33(h)) to reflect the change in the quantity used to describe radiation.

These amendments will require that newly-manufactured x-ray systems include additional features that physicians may use to minimize x-ray exposures to patients. Advances in technology have made several of these new features feasible at minimal additional 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 (ANPRM) 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 the proposed amendments. In addition, the concepts embodied in the 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 that FDA is required to consult before the agency may prescribe any electronic product performance standard under the act (21 U.S.C. 360kk(f)(1)(A)). The proposed amendments themselves were discussed in detail with the TEPRSSC during a public meeting held on September 23 and 24, 1998. At that meeting, TEPRSSC approved the content of the proposed amendments and concurred with their publication for public comment.

FDA proposed the amendments for public comment in the **Federal Register** of December 10, 2002 (67 FR 76056). Interested persons were given until April 9, 2003, to comment on the proposal. FDA received comments from 12 organizations and individuals in response to the proposed amendments. These comments were generally supportive of the proposed changes to the performance standard, although some expressed concern about specific aspects of some of the proposed amendments.

II. Highlights of the Final Rule

In this final rule, FDA is making a number of changes to the performance standard for diagnostic x-ray systems and their components, including the following:

- In § 1020.30 of the performance standard, the final rule makes the following changes:

Adds a number of new definitions to address new technologies and to further clarify the regulations. One notable amendment to the definitions is the addition of the terms *air kerma* and *kerma* to reflect a change in the quantity used to describe radiation emissions from diagnostic x-ray systems (§ 1020.30(b));

Requires manufacturers to provide users (e.g., physicians) with certain information regarding the new features of fluoroscopic systems in order to better protect their patients from unnecessary x-radiation exposure (§ 1020.30(h));

Requires additional warning label language designed to alert users and facility administrators to the need to properly maintain and calibrate their diagnostic x-ray systems (§ 1020.30(j)); and

Modifies existing beam quality requirements by increasing the required minimum half-value layer (HVL) values for radiographic and fluoroscopic equipment. This increase in HVL values will bring FDA requirements into agreement with the performance already provided by systems that are compliant with corresponding international standards. Therefore, manufacturers currently complying with the international standards should not be impacted by this change (§ 1020.30(m)).

- In § 1020.31 of the performance standard, which addresses radiographic x-ray equipment, the following changes are being made:

A number of minor, technical corrections to sections applicable to mammographic x-ray systems that were made necessary by an oversight that occurred when this performance standard was amended in July 1999 (§ 1020.31(f)(3) and (m)).

- The provisions in § 1020.32 pertain to fluoroscopic equipment. Key changes being made to this section of the performance standard include the following:

Amending the x-ray field limitation and alignment requirements to promote the addition of features designed to reduce the amount of radiation falling outside the visible area of the image receptor, thereby preventing unnecessary patient exposure (§ 1020.32(b));

Amending the requirement concerning maximum limits on entrance air kerma rates (AKR) in order to clarify the circumstances under which the maximum limits would apply (§ 1020.32(d) and (e));

Establishing a minimum source-skin distance requirement for certain small "C-arm" type fluoroscopic systems. FDA traditionally has granted variances from minimum source-skin distance requirements for small, portable C-arm systems when such systems were intended only for the limited use of imaging extremities. The amendment establishes the conditions under which variances have been granted as part of the standard and removes the need for manufacturers to continue to request variances of this type and makes explicit the requirements for these systems (§ 1020.32(g));

Requiring the incorporation of a feature that will continuously display the last fluoroscopic image taken prior to termination of exposure (last-image-hold feature). This permits the user to conveniently view fluoroscopic images without continuously irradiating the patient (§ 1020.32(j)); and

Requiring the incorporation of a feature that will display critical information to the fluoroscopist regarding patient irradiation, including the duration, rate (AKR), and amount (cumulative air kerma) of exposure (§ 1020.32(k));

- Section 1020.33 addresses computed tomography (CT) equipment. With regard to CT systems, the final rule makes the following changes:

Amends the requirements pertaining to beam-on and shutter status indicators to reflect the change in quantity used to describe x-radiation from exposure to air kerma. This modification does not alter the level of radiation protection provided by the existing standard (§ 1020.33(h)).

III. Summary and Analysis of Comments and FDA's Responses

A. General Comments

(Comment 1) FDA received 12 comments on the proposed amendments to the performance standard, many of which addressed multiple issues. In general tone and content all 12 individuals or organizations that commented supported the need for amendments and the approach proposed by FDA. A number of the comments provided suggestions or critiques regarding specific aspects of the proposed changes or suggested additional changes or additions for FDA consideration that were not part of the FDA proposal. The specific comments and FDA's responses will be discussed in the following paragraphs for each section of the performance standard.

Seven of the comments provided general comments that did not address specific proposed changes. Some of them addressed the impact analysis or the estimate of the potential benefits that would likely result from the amendments. All seven comments were generally supportive of the changes proposed by FDA. Two comments suggested that the benefits of the proposed changes would be greater than estimated by FDA. One comment, from a State agency, suggested that the patient dose reductions would be greater than estimated by FDA, based on the State agency's experience with programs that have improved the information provided to facilities regarding patient

radiation doses. Another comment suggested that the benefit of any dose reduction resulting from the amendments would greatly exceed FDA's estimates and criticized FDA for suggesting that the risk from x-ray radiation is much less than the comment believes it to be. Two of the comments complimented FDA on its analysis of the potential impact of the regulation.

(Response) We acknowledge and appreciate the supportive comments. This rule includes important modifications to the Federal performance standard for diagnostic x-ray systems to address recent changes in the technology and usage of radiographic and fluoroscopic x-ray systems. These modifications will help ensure that the performance standard will continue to protect and improve the public health by reducing exposure to unnecessary ionizing radiation while assuring the continued clinical utility of images produced where these new technologies are in use.

(Comment 2) Two comments questioned the need to apply several of the requirements to all fluoroscopic x-ray systems, noting that the benefit of the requirements such as for display of dose information and a last-image-hold feature would largely result from fluoroscopic equipment used for interventional procedures. At least five other comments explicitly supported application of the requirements to all fluoroscopic systems.

(Response) FDA notes that performance requirements must be tied to equipment characteristics and not to the potential manner in which the equipment may be used. Because interventional procedures may be performed using many types of fluoroscopic equipment, and because the added costs of the requirements are not expected to be overly burdensome, FDA has determined that the requirements should apply to all fluoroscopic equipment as proposed.

(Comment 3) Two comments supported the change in the quantity proposed for the description of radiation in the standard from exposure to air kerma. One of these comments was fairly general, while the other expressed specific support for the approach taken in the proposal that will maintain all of the various limits on radiation contained in different requirements of the standard at the same effective level as in the limits in the current standard where they were expressed using the quantity roentgen.

(Response) FDA believes that the radiation limits contained in the existing requirements remain appropriate. Although the change from exposure to air kerma will result in different numerical values that may no longer be integer numbers or multiples of 5 or 10 as was previously the case, the level of radiation protection will effectively be the same.

(Comment 4) FDA received comments in response to questions posed by the agency in the preamble of the proposed rule. FDA invited comments on several questions regarding approaches that could be taken to assure the radiation safety of fluoroscopic systems through performance requirements. These questions, which were not associated with specific proposed amendments, were intended to gather information that might guide FDA in considering any future modifications to the performance standard. Among the questions FDA presented for comment was whether there are any clinical situations that could require entrance AKRs greater than those currently permitted. FDA also invited comment on whether limits should be established for the entrance AKR at the entrance surface of the fluoroscopic image receptor and, if so, how these limits might be determined and established.

FDA received three comments in response to the questions about entrance air kerma rates. Two comments recommended that limits should not be

established for the entrance air kerma rate at the entrance surface of the fluoroscopic image receptor. A third comment suggested that a mode of operation that would permit momentary imaging with entrance air kerma rates exceeding current limits should be considered if limits were to be established for the entrance air kerma rate at the entrance to the fluoroscopic image receptor. This comment also noted that any consideration of limits should involve the corresponding fluoroscopic image quality, and suggested that this is an area for further consideration by FDA in collaboration with interested parties. However, these comments did not make specific suggestions for requirements or provide data or evidence regarding such requirements.

(Response) FDA appreciates these suggestions. Although FDA has decided not to implement them at this time, FDA will involve interested parties in discussions about such requirements if modifications such as these are undertaken in the future.

(Comment 5) Two comments supported the need to modify the performance standard to address newly-evolving technologies. Although both comments agreed with FDA's proposed approach, they suggested that any future efforts to further address new technology with additional performance requirements, beyond the current proposed changes, would benefit from additional consultations between FDA and interested or affected parties. One of these comments suggested that consideration of further requirements to address additional characteristics of digital detectors or solid state x-ray imaging devices would benefit from interactive consultations with professional and scientific organizations. The other comment suggested that these areas could be addressed through the International Electrotechnical Commission's (IEC) standards development process.

(Response) FDA agrees with these suggestions and will encourage and facilitate such discussions should the future development of additional amendments be undertaken.

B. Comments on Proposed Changes to § 1020.30

1. Definitions (§ 1020.30(b))

As discussed in the preamble to the proposed rule, FDA proposed the inclusion of a number of new definitions in § 1020.30(b) to address new technologies and to further clarify the regulations. In addition to the changes to definitions proposed by FDA, a number of comments suggested modifications of additional, existing definitions or noted that new definitions were needed for clarity.

(Comment 6) One comment suggested that the definitions in the standard be harmonized to the extent possible with those used by the IEC.

(Response) FDA declines to make this change. The definitions in the U.S. standard were developed and finalized before the development of the IEC standards for x-ray equipment. Complete adoption of the IEC definitions would require FDA to overhaul the entire U.S. standard to bring it in line with the different structure and approach used in the IEC standards. In addition, the U.S. standard reflects differences in common usage. For example, the IEC standard uses the term "radioscopy" instead of the term "fluoroscopy" as commonly used in the United States. For these reasons, FDA does not believe that such wholesale revisions are warranted at this time.

(Comment 7) FDA received a comment concerning the definition of attenuation block that noted that the current size specified is not large enough to accommodate the large x-ray field sizes used in conjunction with some

current fluoroscopic image receptors that are significantly larger than earlier image receptors.

(Response) In response to this comment, FDA has modified the definition to indicate that an attenuation block with dimensions larger than currently specified is allowed. The new definition reads:

Attenuation block means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters. When used, the attenuation block shall be large enough to intercept the entire x-ray beam.

(Comment 8) One comment suggested the need for clarification of what the term C-arm fluoroscope means as used in the standard.

(Response) FDA agrees that clarification would be useful and has included a new definition for this term in the final rule. The new definition reads:

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Note that this definition will include some systems in which the x-ray tube and the fluoroscopic imaging assembly are not connected by a C-shaped mechanical connection. The distinguishing feature of a C-arm fluoroscope is the capability to change the orientation of the x-ray beam.

(Comment 9) In the preamble to the proposed rule, FDA noted that the word "exposure" is used in the standard with two different meanings. One comment suggested adding the second meaning of exposure to the definition for clarity.

(Response) FDA agrees with this comment. Accordingly, the definition of exposure is revised to read:

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. Exposure is also used with a second meaning to refer to the process or condition during which the x-ray tube produces x-ray radiation.

(Comment 10) One comment suggested that the definition of image intensifier be modified to add a comparison to a simple fluorescent screen.

(Response) FDA has concluded that such a change is not warranted. However, this comment prompted further review of the definition of fluoroscopy. As a result of this further review, FDA believes the proposed definition of fluoroscopy should be modified to remove the description that the images are presented instantaneously to the user. The word "instantaneously" is unnecessarily restrictive and ambiguous. It could result in confusion in certain situations such as when some short but finite time is required to process digital images before displaying them to the user. A further clarification has been added to note that, whereas "fluoroscopy" conforms to common usage in the United States, it has the same meaning as "radioscopy" in the IEC standards. Therefore, the definition of *fluoroscopy* is changed to read:

Fluoroscopy means a technique for generating a sequence of x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term 'radioscopy' in the standards of the International Electrotechnical Commission.

(Comment 11) One comment suggested that FDA clarify the meaning of the term "C-arm gantry" as used in the proposed definition of isocenter.

(Response) FDA agrees that clarification of this term would be useful and has revised the proposed definition of isocenter to read:

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

(Comment 12) Several comments suggested that FDA clarify the proposed definition of mode of operation.

(Response) FDA agrees that clarification is needed and has modified this definition. Mode of operation is defined for the purpose of assuring that adequate instructions are provided to the user on how to operate the fluoroscopic system. A mode of operation is intended to describe the state of system operation in which a set of several technique factors or other control settings are selected to perform a specific type of imaging task or procedure. Within a specific mode of operation, a variety of anatomical or examination-specific technique selections may be provided, either pre-programmed, under automatic control, or manually-selected.

(Comment 13) One comment suggested that the proposed definition of mode of operation would allow wide variations in AKR within a given mode of operation and that such variations would cause conflict with several items in § 1020.30(h). The comment suggested that FDA consider using the definition and information requirements of the IEC standard IEC 60601–2–43, "Particular Requirements for the Safety of X-Ray Equipment for Interventional Radiology" (Ref. 1).

(Response) FDA disagrees that the proposed definition will conflict with items of information required by § 1020.30(h). It is true that specification of a mode of operation does not in itself determine the AKR produced by the mode, as variations of technique factors or other controls within a given mode of operation can produce wide variations in the amount of radiation emitted by the system. Such variation, however, does not conflict with § 1020.30(h). Proposed § 1020.30(h)(5) would require a description of each mode of operation, and § 1020.30(h)(6) would require information about the AKR and cumulative air kerma displays. These sections do not require dose data for each mode in the information to be provided to users under § 1020.30(h). The IEC standard IEC 60601–2–43 does require providing certain dose information regarding some of the operating modes for fluoroscopic systems intended for interventional uses, but this IEC requirement would not conflict with the proposed changes to the performance standard.

FDA notes that the definition it is adopting for "mode of operation" differs from the definition used in paragraph 2.107 of the IEC standard IEC 60601–2–43. The IEC standard defines a mode of operation for interventional x-ray equipment as "* * * the technical state defined by a configuration of several predetermined loading factors, technique factors or other settings for radioscopy or radiography, selectable simultaneously by the operation of a single control." FDA does not think it necessary to limit a mode of operation to system operation selected by operation of a single control. The definition in this final rule includes methods of system operation that have specific or unique features or intended purposes about which the user should be informed in detail. The term mode of operation in this rule addresses only the information that must be provided to the user under § 1020.30(h)(5), which

requires that users receive complete instructions regarding the operation and intended function of each mode of operation.

FDA does not require information related to the reference AKR for modes of operation as does the IEC standard. FDA notes that the required display of AKR will directly inform users regarding actual entrance AKRs during use. FDA has determined that it is important that users receive complete descriptions in the user's manual of all the different modes of operation and their intended purposes or types of imaging procedures for which they are designed.

The definition of mode of operation has therefore been modified to read:

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), 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, 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.

(Comment 14) One comment suggested that FDA change the definition of a solid-state x-ray imaging device to make it less specific and therefore more likely to accommodate changes in technology.

(Response) FDA agrees. The definition has been modified to read:

Solid-state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray image. The electronic signal is then used to create an image for display and/or storage.

(Comment 15) One comment suggested that the existing definition of visible area needs clarification with respect to its use with solid-state x-ray imaging devices. The comment suggested that the definition clarify that the visible area can include both active and inactive elements of the detector when inactive elements are within the outer borders of the overall area.

(Response) FDA has determined that modification of this definition is not necessary. FDA notes that the "area" cited in this definition is the overall area defined by the external dimensions of the area over which photons are detected to form an image. It includes any inactive elements that might be located between active elements of the image receptor.

(Comment 16) FDA also received comments suggesting changes to some of the existing definitions that were not proposed for modification in the proposed amendments, including the definitions for beam axis, cradle, pulsed mode, source-image receptor distance (SID), portable x-ray equipment, and stationary x-ray equipment.

(Response) FDA carefully reviewed the suggestions and has determined that no changes to these definitions are warranted at this time. However, as FDA reviewed the comments received regarding proposed changes to the definitions, it became apparent to the agency that several additional definitions would be useful to further clarify some of the terms used in the performance standard. Therefore, FDA has added new definitions for the terms air kerma rate, cumulative air kerma, and fluoroscopic irradiation time. These definitions are not intended to impose any new requirements.

The new definitions read as follows:

• *Air kerma rate (AKR)* means the air kerma per unit time.

• *Cumulative air kerma* means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

• *Fluoroscopic irradiation time* means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device enabling x-ray tube activation in any fluoroscopic mode of operation.

2. Information to Be Provided to Users (§ 1020.30(h))

(Comment 17) Three comments suggested an expansion of the scope of information required to be provided to users by manufacturers. These comments suggested that the manufacturer be required to provide: (1) A full set of system schematics to permit the user or a third party to troubleshoot electronic problems and perform repairs; (2) system-specific hardware and software tools to permit a qualified individual to accomplish quality assurance tests without the need for service support; or (3) appropriate tools and instructions for their use, either as part of the system or as required accessories, to permit any "physics measurements" needed to assure system performance.

(Response) An expansion of existing information requirements was not contemplated in the proposed rule. Such requirements could have significant impact on manufacturers of diagnostic x-ray equipment and neither should be established without a full opportunity for affected parties to comment on specific proposals, nor should such requirements be established without a thorough assessment of the potential benefits and impacts of such requirements. Therefore, FDA is not incorporating the suggested requirements into the amendments at this time.

(Comment 18) One comment supported the proposed requirement that manufacturers provide additional, detailed information regarding the variety of fluoroscopic system modes of operation. This comment suggested that manufacturers be required to provide data on the entrance AKR for each mode of operation and further suggested that such a requirement could be less costly than the proposed requirement for a display of air kerma information on fluoroscopic systems. The comment suggested that users could infer approximate patient doses from such information with a degree of accuracy comparable to that of the displayed air kerma information.

(Response) FDA considered the approach described in this comment when developing the proposal and determined that providing the user with information on patient doses through data on typical entrance air kerma rates for each mode of operation was not practical and would not have the benefits associated with a real-time display of AKR and cumulative air kerma information. In FDA's opinion, either the entrance AKR is highly variable within a given mode of operation or there are so many different modes of operation, which would require separate AKR data, as to make this approach ineffective in informing physicians about the doses delivered to a patient in a procedure. For systems with a number of operating modes, it would be difficult for the user to remember all of the various entrance AKRs. The real-time display provides this information on a continuous basis for every patient, independent of the specific mode selected. For example, interventional procedures, with their associated long exposure times, may be undertaken on a variety of types of fluoroscopic systems. It does not appear feasible to distinguish the type of system that should have the real-time display from those for which such a display would not be useful.

The real-time displays are anticipated to have dose-reduction benefits even in noninterventional procedures. Providing users with immediate information related to patient doses is expected to have an impact on use of the equipment. In addition, the uncertainty in estimating an individual patient's specific radiation dose from a reference AKR provided for a mode of operation is expected, typically, to be much greater than the uncertainty in the real-time values displayed. This increased uncertainty is due to the wide variation in AKR possible within a given mode of operation because of variations in technique factors or other control factors, patient size and attenuation, and the specific beam orientations of an individual procedure.

(Comment 19) One comment suggested that the current wording of § 1020.30(h)(1)(i) be modified to emphasize that the adequate instructions required by the section be suitably written for physician operators.

(Response) FDA does not believe that modification of the current wording is needed. The requirement for adequate instructions embodies the concept of being adequate for the intended audience. Since diagnostic x-ray systems are prescription devices, there is a presumed level of knowledge regarding the use of x-ray equipment on the part of the users.

(Comment 20) A comment questioned the preamble statement regarding unique features of equipment that require adequate instructions regarding radiological safety procedures and the precautions needed because of these features. FDA noted that any mode of operation that yields an entrance AKR greater than 88 mGy/min should be considered a unique mode, and sufficient information should be provided to enable the user to understand the patient dose implications of using that mode. The comment questioned whether an 88 mGy/min threshold should be applied to radiographic modes and further

suggested that there be a requirement that any fluoroscopic mode capable of delivering more than 88 mGy/min be explicitly listed as a mode of operation and that standardized information regarding entrance AKR be provided for each such mode.

(Response) FDA disagrees with this comment. As noted in the preamble of the proposed rule, data regarding the doses from specific modes of operation are not being required in the information for users. Rather, the newly-required AKR and cumulative air kerma displays will be relied on to provide users real-time information on air kerma at the reference location which can be related to patient dose. Values of the AKR and cumulative air kerma displayed in real-time do not necessitate adjustments for particular imaging technique factors or patient size as would standardized tabulations of AKR information printed as user information for each mode.

(Comment 21) The same comment also suggested that manufacturers be required to provide standardized AKR data for fluoroscopic modes of operation as required in IEC standard IEC 60601–2–43, including information regarding the AKR for each available frame rate possible during the normal mode of operation.

(Response) FDA did not accept this suggestion, which is also addressed in the discussion in the previous paragraphs about the definition of mode of operation. FDA notes that proposed § 1020.32(k) is being revised as described in the following paragraphs to clarify the conditions under which the display of AKR is required. Proposed § 1020.30(h)(5) has been revised to require that information be provided to users for all modes of operation that produce images using the fluoroscopic image receptor regarding the impact of the mode

selected on the resulting technique factors. This includes any mode that produces radiographic images from the fluoroscopic image receptor.

(Comment 22) One comment suggested several changes to the performance standard that were not included in the proposed rule. These suggestions were that in several sections of the performance standard, where specification of the maximum kilovolts peak (kVp) or a specified kVp is stated, there should be a specification of the characteristics of the kV waveform. In particular, the comment suggested that a waveform having a voltage ripple of less than or equal to 10 percent be required. One of these sections is 1020.30(h)(2)(i), which requires the specification of the peak tube potential at which the aluminum equivalent of the minimum filtration in the beam is determined. The other is the requirement in § 1020.30(m) for the kVp at which the minimum HVL values are determined. The comment addresses the requirement that manufacturers provide information regarding the peak tube potential at which the aluminum equivalent of the beam filtration provided by the tube housing assembly or permanently in the beam is determined. The comment points out the fact that the determination of the aluminum equivalent is also dependent on the voltage waveform as well as the peak tube potential.

(Response) FDA will further consider this comment and if it determines that such a modification to the standard is warranted, a proposal will be published for public comment. Without specification of the waveform, uncertainty can be introduced into the specification of the aluminum equivalence of the filtration because this determination depends on the voltage waveform and the resulting energy spectrum of the beam. FDA notes that the IEC standard IEC 60601–1–3 (Ref. 2) that establishes the minimum HVL requirements for diagnostic x-ray systems does not specify the voltage

waveform as part of the test method for determining the aluminum equivalence. Rather, the requirement is specified as a function of the selected operating x-ray tube voltage over the normal range of use and is therefore dependent on the waveform of the specific x-ray generator being tested.

When the method for determining HVL was initially established, there were fewer generator designs and voltage waveforms than there are currently. It is correct that a complete specification of equivalent filtration would require a specification of the voltage waveform with which it was determined, as well as peak tube potential. However, there are no tolerances or specifications given in the standard regarding the accuracy with which the filtration equivalent is to be specified. FDA notes that one might conclude that since no requirements exist in the standard for the accuracy of the statement regarding filtration equivalent, it does not need to be so precise as to require description of or limitation on the waveform used. Note that a similar requirement exists in 1020.30(h)(4)(ii) for beam-limiting devices.

(Comment 23) One comment strongly supported the consolidation of instructions for use of the various modes of operation of fluoroscopic systems into a single section of the user's instructions. The comment further suggested that the instructions be required to include a description of all of the controls accessible to the operator at the normal working position.

(Response) FDA does not believe that such a requirement is necessary, as FDA expects that any user's instructions will include a complete description of all controls, including any controls available at the operator's working position.

(Comment 24) Three comments expressed concern regarding the requirement in proposed § 1020.30(h)(5) that manufacturers describe specific

clinical procedures or uses for which a specific mode of operation is designed or intended. The concern expressed was that the clinical use of the fluoroscopic system should not be limited by any statements required of the manufacturer regarding the purposes of any mode of operation.

(Response) FDA agrees that clinical use of the system should not be limited to the examples provided by the manufacturer. The manner of use and the decision to use a particular mode of operation are medical decisions. In addition, the requirements of the performance standard apply only to manufacturers and do not impose requirements on the users of such systems. The requirement at § 1020.30(h)(5)(ii) has been modified to reflect that a manufacturer's descriptions of particular clinical procedures exemplifying the use of specific modes of operation do not limit when or how any mode may be used in actual clinical practice.

In addition, FDA has revised § 1020.30(h)(5)(i) to further elaborate the type of information required to be provided to users with respect to the description of modes of operation. FDA believes it is important for users to understand the manner in which a given mode of operation controls the system technique factors and that this information should be included in the description of the mode of operation.

(Comment 25) An error in the proposed rule, which was detected by FDA following publication, was pointed out by one of the comments. Proposed § 1020.30(h)(6)(i) would have required a statement by the manufacturer of the maximum deviations of the values of AKR and cumulative air kerma from their displayed values.

(Response) This requirement should have been removed from the proposed rule as it was replaced by the requirement in proposed § 1020.32(k)(7)

specifying the maximum deviation allowed. Proposed § 1020.30(h)(6)(i) has been removed and § 1020.32(k)(7) has been revised to be § 1020.32(k)(6). This revision of § 1020.32(k) is described in section III.D.8 of this document.

(Comment 26) One comment suggested that, in addition to requiring instructions and schedules for calibrating and maintaining any instrumentation required for measurement or evaluation of the AKR and cumulative air kerma, § 1020.30(h)(6)(ii) should also require manufacturers to provide any hardware or software tools or accessories necessary to accomplish such calibration or maintenance.

(Response) FDA is not adding such a requirement to the standard at this time, but will consider it along with the other suggestion regarding information or equipment features that should be included in the performance standard.

3. Beam Quality—Increase in Minimum Half-Value Layer (§ 1020.30(m))

(Comment 27) One comment objected to the revision of the requirements for minimum half-value of the x-ray beam in § 1020.30(m)(1) on the grounds that the new minimum requirements for all systems should not be based on what the comment considered to be state-of-the-art equipment. The comment suggested a set of reduced minimum values.

(Response) It appears that the comment misunderstood the basis for the FDA proposal and the intent of the increased HVL values. Currently, to comply with paragraph 29.201.5 of the IEC standard IEC 60601–1–3, all x-ray systems other than mammographic and some dental x-ray systems must contain total filtration material in the x-ray beam that provides a quality equivalent filtration (using IEC terminology) of not less than 2.5 millimeters of aluminum (mm Al). Thus, all currently manufactured x-ray systems should be manufactured in a manner that assures this amount of filtration in the beam if compliance with

the IEC standard is claimed. The proposal to increase the HVL requirements in the FDA standard, which must be expressed as a performance standard rather than as a design standard for a given thickness of filtration, is intended to provide HVL values that correspond to those that result from the use of a filtration corresponding to the 2.5 mm Al required by the current IEC standard. Therefore, the changes proposed for HVL will simply bring FDA's requirements into agreement with the performance provided by systems complying with the IEC standards IEC 60601–1–3 and IEC 60601–2–43. Manufacturers currently complying with the IEC standard should experience no impact from this change as all of their production should already meet the requirement. Therefore, the change suggested by the comment is not necessary.

(Comment 28) In conjunction with the proposed revision of the requirements for the minimum HVL of the x-ray beam, one comment suggested a 60 kVp lower limit for intraoral dental x-ray systems. The comment suggested that systems with lower kVp capabilities are not dose efficient.

(Response) FDA notes that a previous amendment to the performance standard in 1979 increased the beam quality requirements for x-ray systems manufactured after December 1, 1980. The increased beam quality required of these systems was intended to preclude systems from operating below 70 kVp, while complying with the beam quality requirements. FDA believes that the modified requirements that became effective in 1980 limited the ability of dental intraoral x-ray systems to operate at lower voltages. FDA is not aware of information indicating that there are significant numbers of newly-manufactured systems that operate with such low voltage capability. Should FDA become aware that the current requirements are not effective in limiting

the beam quality of intraoral dental x-ray systems to appropriate values, future consideration will be given to proposing an appropriate amendment.

(Comment 29) Two comments suggested that § 1020.30(m)(2) contain a requirement that the system provide an indication to the user of the amount of additional filtration that is in the beam at any time during system use. The comments did not express a preference for the location for this display, indicating that it could be at the system control console or at the operator's location. A third comment supported the addition of § 1020.30(m)(2), noting the impact of the requirement in reducing patient dose and maintaining image quality.

(Response) FDA agrees that there should be a requirement for a display of the amount of additional filtration in use because it is important that the operator of the system be able to easily determine the added filtration that is currently in use during any procedure. An active display of this information will assist the operator. Manufacturers of systems that currently do not provide such a feature will be required to redesign to implement the capability to select and add filtration.

Accordingly, FDA has modified proposed § 1020.30(m)(2) to require an indication of the additional filtration in the beam. FDA has also clarified the requirement to state that the selection or insertion of the additional filtration can be either at the option of the user or automatically accomplished as part of the selected mode of operation. FDA notes that automatic selection and concurrent modification of the technique factors to maintain image quality is the preferred method of operation. Efficient manual use of additional filtration requires that the user make appropriate technique changes to preserve optimum image quality.

FDA notes that, through an oversight, no effective date was proposed for the new requirement in § 1020.30(m)(2). This new requirement was intended to become effective, along with all of the other new requirements, 1 year after the date of publication of the amendments in the **Federal Register**. FDA has modified proposed § 1020.30(m)(2) to reflect the effective date.

4. Aluminum Equivalent of Material Between Patient and Image Receptor (§ 1020.30(n))

(Comment 30) One comment noted that the values given in table 2 in § 1020.30(n) need to be revised as a result of the revision of § 1020.30(m)(1). According to the comment, if the values of the maximum aluminum equivalence given in table 2 are not revised to reflect the increased beam quality required by § 1020.30(m)(1) for the test voltage of 100 kVp for determining compliance with § 1020.30(n), the current requirements of table 2 in § 1020.30(n) would in effect require that items between the patient and the image receptor provide less attenuation than currently required.

(Response) The comment is correct that FDA's proposal was not intended to reduce the limits on the maximum allowed aluminum equivalence of materials between the patient and the image receptor. The comment is also correct that the values in table 2 in § 1020.30(n) were based on the beam qualities associated with the current values in table 1 in § 1020.30(m)(1), reflecting a beam quality of 2.7 mm of aluminum HVL, and not the beam quality described in the proposed revision of § 1020.30(n), which is an HVL of 3.6 mm Al at 100 kVp. However, the comment's reference to the values in table 2 in § 1020.30(n) as HVL values was incorrect, although that does not invalidate the concern raised by the comment. Therefore, FDA is revising the values in table 2 in § 1020.30(n) for the maximum aluminum equivalent of

materials between the patient and image receptor to reflect requirements that are met by current products that comply with the present standard. These revised limits are consistent with the maximum limits used in current IEC standard IEC 60601–1–3 (Ref. 2). This change continues the current requirement for maximum aluminum equivalence, but has no impact on current products and will not require changes in design.

5. Modification of Certified Diagnostic X-Ray Components and Systems (§ 1020.30(q))

(Comment 31) Two comments suggested that a party other than the owner be required to certify the continued compliance of any certified system that is modified in accordance with § 1020.30(q).

(Response) The current requirement was not proposed for change and no change is considered necessary by FDA. As discussed in the preamble to the proposed rule, the requirement in § 1020.30(q)(2) states that the owner of an x-ray system may modify the system, provided that the modification does not result in a failure of the system to comply with an applicable requirement of the performance standard. In accomplishing such a modification, the owner may employ a third party with the requisite skills and knowledge to accomplish the modification in a manner that does not result in noncompliance. As the responsible party, the owner should assure that any modifications are accomplished appropriately. This can be done through contractual arrangements with the party performing the modifications to assure compliance is maintained or through any other means that satisfies the owner that compliance has not been compromised by the modification. Section 1020.30(q) does not require that owners themselves perform the modification,

but rather that owners be responsible for assuring the compliance of the modified system.

(Comment 32) One comment suggested that the party performing the modification be required to certify and report the modification in a manner similar to that required of an assembler of a new x-ray system. Another recommended that the party performing the modification submit a report as required by subpart B of 21 CFR part 1002 to the owner of the x-ray system.

(Response) FDA does not see a need for the reporting of such a modification. The reporting of the assembly of an x-ray system is required to provide a mechanism for the assembler of the system to complete the certification that the system has been assembled according to the manufacturer's instructions and therefore complies with the standard. The compliance of any modified system can be verified during a routine inspection by Federal or state authorities. FDA also notes that the contractual arrangement between the owner and a party engaged by the owner to perform a modification can be structured to provide the owner with the necessary assurances that the party performing the modifications is responsible to the owner for assuring the continued compliance of the system. FDA concludes that there is no need to describe these arrangements in the standard beyond the requirement that the owner be responsible for assuring the continued compliance of any modifications to its system.

Upon reviewing the comments relating to § 1020.30(q), FDA decided, on its own initiative, to add a phrase to § 1020.30(q)(2) that was not described in the proposed rule. This phrase clarifies where the recorded information regarding an owner-initiated modification is to be maintained. The phrase specifies that the information is to be maintained with the system records.

C. Comments on Proposed Changes to § 1020.31—Radiographic Equipment

1. Field Limitation and Post Exposure Adjustment of Digital Image Size

(Comment 33) One comment suggested a change in the requirement for beam limitation on radiographic x-ray systems that was not proposed. This comment recommended that automatic collimation be required for digital radiographic systems to preclude what it referred to as "digital masking" of images obtained with the x-ray beam limiting device (collimator) adjusted to produce an x-ray field larger than the sensitive area of the digital image receptor. This comment expressed a concern about the operation of digital radiographic systems and the manner in which the x-ray field size is adjusted. Because digital radiographic systems permit the opportunity for post-exposure image manipulation, the comment expressed concern that adjustment following image acquisition of the area imaged or "image cropping" might occur, obscuring the fact that the x-ray field was not adjusted appropriately and therefore not limited to the clinical area of interest.

(Response) FDA agrees that digital image cropping in lieu of appropriate x-ray field limitation could be a concern for systems that produce digital radiographic images with a digital image receptor used in place of a film/screen cassette, or for fluoroscopic systems when used to produce a radiographic image via the fluoroscopic image receptor, analogous to use of a photospot camera for analog images. For fluoroscopy and radiography using the fluoroscopic imaging assembly, proposed § 1020.32(b)(4) and (b)(5) require that the x-ray field not exceed the visible area of the image receptor by more than specific tolerances. These requirements for the fluoroscopic imaging assembly are intended to prevent imaging with the x-ray field adjusted to a size greater than the selected visible area of the image receptor. However, it may not be

clear how this requirement applies to radiographic images at the time of later storage or display.

For radiographic images, obtained directly using a digital radiographic image receptor, such as a solid-state x-ray imaging device, or from the fluoroscopic image receptor, the comment raised the question of whether some control is needed to assure that x-ray fields are not used when they are larger than necessary for the ultimate size of the either stored or displayed image.

Neither the current standard nor the proposed amendments address the issue of post-exposure image cropping of the original image at the time of image display or image storage. In the case of a radiographic system, including a purely digital system, the current standard requires that the x-ray field size not exceed the size of the image receptor, meaning that portion of the image receptor area that has been preselected during imaging such as when using a spot-film device.

The comment addresses the concern that the x-ray field might be larger than necessary to capture the area of clinical interest and that the individual obtaining the image could "hide" this fact by electronically cropping the digital image for storage and display. Thus, it would not be possible for someone reviewing the image later to determine that the image was obtained with an x-ray field size larger than necessary, resulting in unnecessary patient exposure. The comment suggests some type of automatic collimation to prevent this possibility, but does not describe the automatic system envisioned. If electronic cropping of digital imaging is available post exposure, it does not appear possible to have an automatic collimation system that could anticipate how such cropping might be done to the exposure.

FDA notes that the question of electronic image cropping is a question that requires further exploration and discussion with the equipment users to determine if a requirement to address this issue is needed. The agency will review this issue and determine what the current equipment design and usage practices are. If FDA determines that a limitation on the ability to crop digital images is warranted and feasible, it will be addressed in a future proposed amendment.

2. Policy Regarding Disabled Positive Beam Limitation Systems

(Comment 34) One State radiation control agency submitted a comment expressing disappointment that FDA did not propose an amendment that would have codified its policy regarding application of the standard to x-ray systems that are reassembled and that contain positive beam limitation systems that may have previously been disabled by the owner of the system.

(Response) FDA did not propose amending the standard to include this clarification because it is not a performance requirement and the standard clearly states the performance required of stationary, general-purpose systems and the obligations of assemblers to install certified components according to the manufacturer's instructions. The performance standard originally required that stationary, general-purpose x-ray systems be equipped with beam limiting devices that provided positive beam limitation (PBL). The standard was amended in 1993 (58 FR 26386) to remove the requirement that stationary, general-purpose systems be equipped with a beam limiting device providing PBL and permitting instead beam limiting device that provides continuous adjustment of the x-ray field. Questions arose regarding the performance required of beam limiting devices that were designed and certified to provide

PBL when assembled into x-ray systems that were no longer required to provide PBL.

The standard requires, in § 1020.30(d), that assemblers of diagnostic x-ray systems must install certified components according to the instructions of the component manufacturer when these certified components are installed in an x-ray system. Thus, the standard requires that, when an assembler installs a beam limiting device, including one designed to provide PBL, the beam limiting device must be installed according to the manufacturer's instructions. That is, the beam limiting device must be installed such that the PBL system functions as designed and according to the manufacturer's instructions. FDA clarified this issue via communications to manufacturers, State radiation control agencies and others that emphasized the continuing requirement that any certified component be installed according to the manufacturer's instructions. Although the installation of a beam limiting device providing PBL became optional for stationary general-purpose systems, FDA noted that the requirement to install any certified component according to manufacturer's instructions remained. Thus, a PBL system, if installed, must be installed in a manner such that it functions as designed, even though there is no longer a requirement that all stationary, general-purpose x-ray systems be provided with PBL. FDA, therefore, has concluded that the suggested amendment is not appropriate for a performance standard.

D. Comments on Proposed Changes to § 1020.32—Fluoroscopic Equipment

1. Testing for Attenuation By the Primary Protective Barrier

(Comment 35) One comment on § 1020.32(a)(2) pointed out differences between FDA's testing procedures for determining compliance with the requirements for a primary protective barrier as part of the fluoroscopic

imaging assembly and the testing procedure described in paragraph 29.207.2 of IEC standard IEC 60601–1–3. The comment noted that the area of the attenuation block may be insufficient for some modern fluoroscopic image receptors that accommodate x-ray field sizes greater that 20 centimeters (cm) by 20 cm.

(Response) FDA acknowledges there may be a need for a larger attenuation block in some circumstances and, as described previously in the discussion of changes to definitions in § 1020.30(b), has modified the definition to accommodate a larger size for the attenuation block.

(Comment 36) The comment also expressed concern that, because FDA and IEC compliance testing procedures are different, manufacturers will need to perform two separate tests in order to meet both standards.

(Response) FDA notes that its performance standard does not require the manufacturer to determine compliance in any particular way. Section 1020.32(a)(2) describes how FDA will measure compliance. The manufacturer is free to use any test method that provides assurance that the product complies and is free to develop a single testing procedure that would assure compliance with both standards. The comment is incorrect, therefore, in stating that the manufacturer is required to perform two different sets of measurements to satisfy both standards.

FDA also notes that the requirements for the thickness of the attenuation block and the quantitation of the amount of radiation transmitted by the protective barrier are different in the performance standard and the IEC standard. The thickness differences most likely arise from the conversion of linear dimensions in inches (as originally used in the standard) to centimeters.

FDA considers these differences minor and notes that a manufacturer may develop a single test method that assures compliance with both requirements.

(Comment 37) The comment also suggested that FDA adopt the complete wording from the IEC standard related to the attenuation of the primary beam by the primary protective barrier in lieu of the current FDA standard.

(Response) FDA does not believe that adoption of the IEC wording regarding the attenuation of the primary beam by the primary protective barrier is necessary. Although the two standards employ different approaches, including different terms, definitions, and organizational structure, there does not appear to be a significant conflict between the two standards with regard to this issue.

2. Field Limitation for Fluoroscopic Systems

(Comment 38) One comment opposed proposed § 1020.32(b)(4) and FDA's intent to promote continuously adjustable, circular field limitation in all types of fluoroscopic systems. The comment expressed doubts about the need for such a requirement, especially for systems designed for extremity imaging only, and was concerned that the requirement would add to maintenance costs. The comment suggested that a stricter requirement would be effective only if States modify their regulations to enforce identical requirements during the useful life of the equipment.

(Response) The proposal encouraged the provision of circular or nearly circular collimation for fluoroscopic systems having circular image receptors, but does not require it. The comment provided no information about why a collimator providing nearly circular collimation would be more expensive to maintain than rectangular collimation. If adopted, the proposed requirement in § 1020.32(b)(4) would apply to affected equipment, regardless of when

inspected or who is performing the inspection. FDA does not understand the assertion made in the comment that, under State regulations, the under-framed fluoroscopic field would be enlarged to fill the input phosphor. Review of the State regulations of the party who submitted the comment indicates no such requirement. Rather, this State's regulations require that the x-ray field not exceed the visible area of the image receptor. There is no requirement that the field be enlarged to match the size of the image receptor. The State's regulations do not appear to prohibit an under-framed image. FDA expects that State regulations will be modified to conform to the Federal standard because, under section 542 of the act (21 U.S.C. 360ss), States may not impose different requirements on an aspect of performance of an electronic product that is addressed by the Federal standard. FDA acknowledges that the benefit of the requirement will not be as great for fluoroscopic systems intended for examination of extremities only as it will be for general-purpose fluoroscopic systems. Nevertheless, improved collimation for these systems can reduce operator exposures from scattered radiation and improve image quality. The proposal does not require circular collimation for equipment designed only for extremity use. Systems with rectangular collimation will meet the requirement of this standard. Accordingly, no change to the proposed requirement was made in response to this comment.

(Comment 39) One comment from a radiology professional organization stated that the proposed requirements for field limitation and alignment of fluoroscopic systems were acceptable. Another comment which specifically addressed § 1020.32(b)(4)(ii)(A) and (b)(4)(ii)(B) asserted that the clarity of these proposed requirements would be improved by the addition of the words "any linear dimension of" before the words "the visible area."

(Response) FDA agrees with the suggestion to add these words and has incorporated the change into the final performance standard.

3. Air Kerma Rates

(Comment 40) One comment suggested a change to the wording of proposed § 1020.32(d)(2)(iii)(B). The comment suggested adding the phrase "archive of the" before the words "image(s) after termination of exposure" to clarify that the presence of a last-image-hold feature is not sufficient to invoke the exception to the limit on maximum entrance AKR.

(Response) FDA agrees that suggested language more accurately reflects the intent of the proposed paragraph. The presence of the last-image-hold feature, without storage of the images for later viewing, is not sufficient for the exception to apply. The wording of proposed § 1020.32(d)(2)(iii)(B) has been modified accordingly.

The agency has also decided to remove the proposed requirement that the limitation on the maximum AKR apply when images are recorded in analog format with a videotape or video-disc recorder. The proposed limitation on maximum AKR cannot be justified solely on the basis of recording technology used. The display of air kerma information will directly inform the user of the AKRs delivered by different modes. Because of the different methods and mechanisms for recording fluoroscopic images and the differences in the amount of incident radiation on the image receptor required for different clinical tasks, there is no consensus on appropriate maximum AKRs during recording of fluoroscopic images. FDA has concluded that, until such a consensus is developed, it is not appropriate to establish such limits. Therefore, the list of exceptions in § 1020.32(d)(2)(iii) specifying when the limitation on maximum AKR does not apply has been modified to remove the

exclusion of analog recording. Thus, the limit on maximum AKR in the amended standard does not apply to any mode of operation involving recording from the fluoroscopic image receptor for fluoroscopic systems manufactured after the effective date of the amendments.

(Comment 41) One comment supported what it described as the attempt to establish an upper limit on AKRs during both normal and high-level control modes of fluoroscopy.

(Response) This comment reflects confusion regarding the proposed amendments and the revision of § 1020.32(d) and (e). Limits already exist on AKRs during normal and high-level control fluoroscopy. The sections are being revised for clarity; the only change is to the applicability of the exception to the maximum AKR limit to systems operated in a pulsed mode as described in the following paragraphs.

(Comment 42) One comment noted that the distinction between recording fluoroscopic images via analog or digital means is not a reasonable means of differentiating between recording methods that could have different patient dose implications.

(Response) FDA agrees that this is a legitimate concern. The limitation on the exception to the maximum AKR limit originally proposed in § 1020.32(d)(2)(iii)(B) would not be an effective way to limit AKR as there are now available digital recording products that could perform the function of previous analog recording devices. The requirements of current § 1020.32(e)(2)(i) and proposed § 1020.32(d)(2)(iii)(B) were intended to prevent bypassing the limits on maximum entrance AKRs by the addition of image recording devices to fluoroscopic systems. Rather than attempting to limit entrance AKRs in this manner, FDA has concluded that the display of AKR

and cumulative air kerma will inform operators about the amount of radiation being delivered during fluoroscopic procedures and that limits during recording cannot be appropriately justified at this time. FDA has therefore revised proposed § 1020.32(d)(2)(iii)(B) to remove the last sentence that would have imposed limits during recording of fluoroscopic images with an analog format. The standard, as amended, will not place any limits on AKR during the recording of images from the fluoroscopic image receptor. Instead, the display of AKR and cumulative air kerma at the reference location, as required by § 1020.32(k), will be relied on to inform the user regarding radiation incident on the patient during fluoroscopic procedures.

(Comment 43) One comment noted that the value for the maximum limit on AKR given in proposed § 1020.32(d)(2)(iii)(C) was expressed as 180 mGy per minute, not 176 mGy per minute, which is twice the rate of 88 mGy per minute as specified for normal fluoroscopy mode.

(Response) FDA agrees with this comment and has revised the limit to be 176 mGy per minute for consistency.

(Comment 44) One comment suggested that additional information be provided to permit the AKR at the reference location for the AKR display to be determined for the maximum permitted AKRs where the latter are determined at the measurement points specified in § 1020.32(d)(3). The comment also suggested that the measurement point for mini C-arm systems be specified at the minimum source-skin distance (SSD), which is, in fact, the measurement point specified in proposed § 1020.32(d)(3)(iv).

(Response) The requirements in § 1020.32(d) address the limit on the maximum AKR permitted for fluoroscopic x-ray systems. There is no requirement that the values obtained for AKR at the compliance measurement

points specified in § 1020.32(d)(3) be provided or displayed to the user. The comment appears to request that some comparison be made available to the user regarding the AKR at the compliance measurement point and the reference location for the AKR that is displayed according to proposed § 1020.32(k). Providing information to the user regarding the maximum AKR that could result at the fluoroscopic reference location could provide additional information to the user prior to the use of a system. However, as this information will be displayed in real-time to the user during the use of the system, FDA does not see the need to add an additional requirement of the type suggested.

(Comment 45) One comment suggested that additional language be added to ensure that the entrance AKR limits are met at all times by systems that permit variation in the source-image receptor distance.

(Response) FDA notes that the current standard already includes such a requirement and, like all other requirements in § 1020.32, this requirement applies to all fluoroscopic systems unless there is a specific exception stated. FDA, therefore, does not believe the suggested addition is needed.

4. Minimum Source-Skin Distance

(Comment 46) One comment noted the difference in limits on the minimum source-skin distance permitted in the FDA performance standard and the limits specified in IEC standard 60601–1–3. The requirements addressed by the comment are those for fluoroscopic systems not intended for special surgical applications. Since its inception in 1974, the performance standard has required a minimum source-skin distance of 38 cm for stationary fluoroscopes. The IEC standard has a minimum of 30 cm for fluoroscopic systems that are not intended for use during surgery. The comment suggested

a limit of 30 cm for systems labeled for interventional uses. It was suggested that a minimum of 38 cm for the source-skin distance can limit the manner of clinical use of C-arm fluoroscopes. The comment also acknowledged the provisions in both the U.S. performance standard and the IEC standard for a smaller minimum source-skin distance of 20 cm for systems intended for surgical applications. The comment noted that, although interventional uses might be considered surgical applications, the limit of 20 cm for surgical systems was too short for interventional uses.

(Response) FDA did not propose a change to the minimum source-skin distance. Furthermore, no other comments suggested that the current minimum source-skin distance should be modified. FDA will consider the issue further and, if it determines that the standard should be modified, the agency will propose the amendment at a future time.

5. Display of Cumulative Irradiation Time

(Comment 47) Six comments expressed very different views on the requirement to display the cumulative irradiation time at the fluoroscopist's position, as proposed in § 1020.32(j)(2). Two comments from manufacturers and one from a State suggested that such information was not needed at the user's working position and, in fact, could be confusing to the user. In contrast, comments from two medical professional associations whose members are users of fluoroscopy systems, a medical physicist, and a State agency strongly endorsed the proposed requirements to display the cumulative irradiation time, along with the AKR and cumulative air kerma, at the user's working position.

(Response) FDA agrees with the comments from the users of fluoroscopic systems and, accordingly, the final standard retains this requirement.

(Comment 48) One comment emphasized the importance for the user of the uniformity and consistency of the display of information and two comments suggested that FDA require that the units of measurement and manner of display be specified.

(Response) In response to these comments, FDA has revised § 1020.32(h)(2) to specify the following requirements: The display must show the irradiation time in minutes and tenths of minutes and such information must be displayed continuously; updated every 6 seconds, displayed within 6 seconds of termination of exposure, and displayed until reset. In addition, as noted in the discussion of *Definitions* mentioned previously in the document, FDA has added a definition of "fluoroscopic irradiation time" to § 1020.30(b) to further clarify the meaning of this term.

6. Audible Signal of Irradiation Time

(Comment 49) Five comments addressed the proposed requirement that an audible signal sound every 5 minutes during fluoroscopy to alert the fluoroscopist to the passage of irradiation time. Three of these comments supported the proposed approach of a fixed, 5-minute interval between audible signals. Two of the comments specifically addressed the question of whether the interval between audible signals should be selectable by the user and recommended against such an approach, suggesting that a variable interval could lead to confusion. One comment from a manufacturer's association suggested complete elimination of the audible signal in view of the display of the AKR and cumulative air kerma to the operator and the potential for the audible signal to be distracting to the user. However, users of fluoroscopic systems supported retaining the requirement of an audible signal as a feature of the equipment. One manufacturer commented that the proposed

requirement of an audible signal would lead to a potential conflict with the IEC standard 60601–2–7, "Particular Requirements For the Safety of High-Voltage Generators of Diagnostic X-Ray Generators," which contains a requirement for an audible signal that sounds continuously until reset. The manufacturer's comment also raised a question regarding the specification of the interval between reset of the signal and the time of the next audible signal.

(Response) FDA notes the potential conflict with IEC standard 60601–2–7, and further notes that this requirement for an audible warning of elapsed fluoroscopic time predates the use of fluoroscopy in interventional procedures, which often require much more than 5 minutes of irradiation time. The need to continually reset the 5-minute timer and the lack of information about the cumulative fluoroscopic time under those circumstances indicate that the current IEC requirement should also be revised. FDA will work with the appropriate IEC committee responsible for the maintenance of IEC 60601–2–7 to encourage that it be revised to be consistent with the FDA proposal.

(Comment 50) One comment suggested that the audible signal should be required to be reset manually because a signal of 1-second duration would likely be ignored.

(Response) In view of the additional requirement for a display of air kerma information during a procedure, FDA does not think that a manual reset of the audible signal is needed or that such a requirement would add significantly to the safety of these systems. The users of fluoroscopic systems will have both the display of air kerma information and the periodically recurring audible signal to remind them of the passage of fluoroscopic irradiation time. Nevertheless, the standard should not prohibit a manual reset if the user desires such a feature. Therefore, § 1020.32(j)(2) has been modified to permit,

at the option of the manufacturer, the signal to be automatically terminated after 1 second or to continue sounding until manually reset. Manufacturers may provide both options for user selection if they wish.

7. Last-Image-Hold (LIH) Feature

(Comment 51) Six comments supported the proposed requirement for the LIH feature on fluoroscopic systems. One of these comments questioned whether the LIH feature was necessary for small, extremity-only fluoroscopic systems, in view of their low radiation output.

(Response) FDA believes that, even for the small, extremity-only fluoroscopic systems, the LIH feature can reduce exposure to the patient and operator. Many of the current extremity-only systems, which are digital systems, already provide the LIH feature. FDA has determined that this requirement should apply to all fluoroscopic systems.

(Comment 52) In response to the proposed requirement that images that are the result of the LIH display be clearly labeled as LIH images, two comments stated that there are other conditions during which confusion might exist regarding whether a displayed image is the result of concurrent fluoroscopic irradiation or is a display of a stored image. This could be a concern with systems with more than one image-display device. A similar concern expressed in the comments was that, when systems may display stored images, there may be no clear indication of when the fluoroscopic x-ray tube is activated. These comments suggested that the standard include additional requirements, not contained in the proposal, for a visible indication of when fluoroscopic irradiation is initiated and when irradiation is occurring. In addition, the comments suggested that the replay of stored images also be

accompanied by a clear indication that the image is a replay of a stored image and not a live fluoroscopic image.

(Response) FDA agrees it is important that the fluoroscopic system provide a clear indication of when x-rays are being produced. FDA notes that § 1020.31(j) requires radiographic systems provide a visual "beam-on" indicator whenever x-rays are produced. Such a requirement was not included in the performance standard applicable to fluoroscopic systems in the past because the production of the fluoroscopic image was previously a direct indication of the production of x-rays. However, with the introduction of LIH features and the serial replay of stored images, the display of an image on the fluoroscopic display is not necessarily an indication of x-ray production.

FDA also agrees it is important that users be able to easily distinguish between display of a previously recorded image(s) and live-time image. It could be a safety issue if a recorded image were mistaken for a "live" image (or vice versa). However, FDA needs to further consider whether the requirements suggested by the comments should be added to the performance standard.

The relevant IEC standard 60601–2–7, "Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators" (Ref. 3) (see 29.2.102 Indication of Operational States, (b) Loading state) requires a yellow light on the control panel of the high voltage generator that indicates the loading state and that there be a means for connecting a remote indication of the loading state in continuous mode. This IEC standard also requires that there be a means of connecting an audible signaling device to indicate the instant of termination of loading (radiation exposure). However, these IEC requirements do not address the comment's concern that there be a requirement for a visual signal visible from anywhere in the room.

The adequacy of the approach taken in the IEC standard is open to question if, in fact, there is a need for an indication of x-ray production during fluoroscopy at the user's position. One could ask if it is sufficient for systems to provide only the means for connecting a signal device that would be visible in the procedure room or if means for actually producing such a signal should be required as part of the system. If only the means for connection is provided, State or local authorities would have to require that it be used.

The cost of adding such a display would also have to be considered, although FDA expects that the cost would be minor because the change would only require adding an indicator if the "means for connection" required by the IEC standard is already incorporated in the design. Manufacturers are encouraged to provide such indicators, and FDA will urge the development of an appropriate requirement in an IEC standard. In addition, FDA will consider whether such a feature should be included in any future amendments to the performance standard that FDA may develop.

8. Display of Values of Air Kerma Rate and Cumulative Air Kerma

(Comment 53) Eight comments addressed the proposed requirement for the display of AKR and cumulative air kerma at the fluoroscopist's working position. None of these comments opposed the proposed requirement. One of the comments supported the concept, but questioned whether it is necessary to impose the requirement on small, extremity-only fluoroscopes. One professional association specifically suggested that the requirement should apply to all fluoroscopic systems.

(Response) FDA notes that even small, extremity-only systems can be used for extended surgical or interventional procedures and that the radiation output of some of these systems currently is significantly larger than the output

from early versions of these types of systems. For these reasons, FDA has concluded that the requirement for air kerma display is appropriate for all fluoroscopic systems.

(Comment 54) Four of the comments raised questions or made suggestions regarding the technical details and specifics of how the air kerma information should be described or displayed. One of the comments referenced the IEC standard 60601–2–43 and the manner of air kerma display required by that standard, but it incorrectly cited the requirements of that standard.

(Response) In response to these comments, FDA has modified proposed § 1020.32(k) to require display of the AKR at the fluoroscopist's working position when the x-ray tube is activated and the number of images produced is greater than six images per second. Furthermore, the value displayed is required to be updated at least once every second. The value of the cumulative air kerma will be required to be displayed either within 5 seconds of termination of an exposure, or it can be displayed continuously and updated at least once every second. The displayed values of AKR and cumulative air kerma must be clearly distinguishable from each other. The details of the specific display means are left to the manufacturer, except that the AKR must be displayed in units of mGy/min and the cumulative air kerma in mGy.

(Comment 55) A comment from a radiology society suggested that the cumulative air kerma be displayed continuously at the operator's position at all times while fluoroscopy is used.

(Response) This comment, from an organization representing users of fluoroscopic systems, indicates that these users desire a simultaneous display of both AKR and cumulative air kerma. FDA originally had envisioned a single display that would alternate between AKR and cumulative air kerma,

depending on the state of the x-ray generator. However, this physician group indicates a preference for continuous update and display of the cumulative air kerma. FDA agrees that such a display is feasible and not likely to add significant costs to meeting the requirement.

There is a potential advantage to displaying the cumulative air kerma only at the termination of exposure. This would provide an incentive to stop or interrupt the exposure to learn or view the cumulative exposure and thereby perhaps minimize exposure time. However, during most fluoroscopic procedures, the exposure is continually interrupted and thus the cumulative air kerma would often be displayed.

After reviewing the comments received from the radiology society and others regarding the proposed requirement for the display of AKR and cumulative air kerma at the fluoroscopist's working position, FDA has determined that the method of display of cumulative air kerma can be left to the manufacturer. Either a continuous display of cumulative air kerma or a display following termination of exposure will provide the user with the necessary information.

(Comment 56) One comment suggested that a statement be added to explain that the information displayed would represent the air kerma measured without scatter.

(Response) FDA notes that this information was contained in the proposed requirement and is in revised § 1020.32(k)(4).

(Comment 57) One comment suggested that an alternative requirement was needed for the description of the reference location for fluoroscopic systems that have variable source-image receptor distance.

(Response) FDA notes that the reference location is specified with respect to the table or the isocenter for a C-arm system and that, under § 1020.32(k)(4)(ii), a manufacturer may describe an alternate reference location if appropriate. Therefore, FDA has concluded that the addition suggested by this comment is not needed.

(Comment 58) One comment recommended that manufacturers be permitted to adjust or change the reference location for AKR and cumulative air kerma to a point specified by the clinical user of the system.

(Response) This comment appears to suggest that some clinical users might wish to have the air kerma display indicate the air kerma at locations other than the location identified by the manufacturer in the initial design of the system. Users might desire this alternative if they consider some other point to be more representative of the dose to the patient. FDA notes that the air kerma at any other location can be obtained by the use of a multiplicative factor that is the square of the ratio of distance from the source to the reference location to the distance from the source to the new location. Such a factor can be easily calculated. Also, it is permissible for the owner of an x-ray system to modify (or cause to be modified) the x-ray system as long as the modification does not cause the system to fail to comply with the performance standard. Therefore, an owner could request that a system be modified to display the air kerma at a point different from that originally specified by the manufacturer, under § 1020.30(q), provided the user instructions for that specific system are also appropriately modified to indicate the location of the new reference location to which the air kerma display is referenced. FDA would encourage that, for any system so modified, the modification be clearly posted or labeled so that all users are aware of the modification. Such a

modification would be possible only if the manufacturer's design of the air kerma display system provides a means by which the calibration of the air kerma display could be adjusted by a factor to provide the requested display. FDA does not believe that it is necessary to require that all systems have such a capability.

(Comment 59) Four comments expressed concern about the tolerance of ±25 percent for the deviation of the displayed values of AKR and cumulative air kerma from the actual values. Several of these comments asserted that the accuracy of the corresponding display requirement in IEC standard 60601–2–43 is ±50 percent. They also pointed out that accuracy required of ionization-chamber-based dose-area-product meters specified by IEC standard IEC 60580 (Ref. 4) is ±25 percent, and that other sources of error would combine with the basic uncertainties of a measuring instrument such as a dose-area-product meter to determine the air kerma at the reference location.

(Response) FDA agrees that the standard should not require accuracy greater than is technically feasible. FDA discussed this tolerance with the TEPRSSC advisory committee during a public meeting and members of the committee expressed the opinion that the display of dose information should be as accurate as possible to provide a meaningful indication of the patient dose. These members suggested that an accuracy of better than ±50 percent should be possible. After considering factors that could contribute to the uncertainty of the display of AKR and cumulative air kerma, and the importance of having as accurate an indication as technically feasible, FDA has concluded that a tolerance of ±35 percent is appropriate. Accordingly, proposed § 1020.32(k)(7) has been revised as § 1020.32(k)(6) and specifies a maximum uncertainty of ±35 percent and a range of AKRs and cumulative air

kerma over which this accuracy is to be met. Manufacturers will need to provide a schedule of maintenance sufficient to keep the air kerma display values within these tolerances.

Also, in conjunction with considering the accuracy of the dose display, FDA noted a need to better describe the conditions under which compliance would be determined. Therefore, FDA has also included in § 1020.32(k)(6) a specification that compliance with the accuracy requirement shall be determined with measurements having an irradiation time greater than three seconds. This condition is sufficient to allow for any minimum response times associated with measuring instruments.

IV. Additional Revisions of Applicability Statements and Other Corrections

In section II.B of the proposed rule (62 FR 76056 at 76059), FDA described the need to modify the applicability statements in §§ 1020.31 and 1020.32 to clearly distinguish between radiographic and fluoroscopic imaging and to identify the type of equipment to which each section applies. This clarification was needed in conjunction with modifying the performance standard to address the new types of image receptors that have been introduced for fluoroscopy and radiography. As part of this clarification, definitions of radiography and fluoroscopy were also proposed.

Although no comments were received on the proposed modifications to the applicability statements for §§ 1020.31 and 1020.32, FDA has concluded that additional modifications of the applicability statements for both sections are necessary for clarity. These changes, which are described in the following paragraphs, are not substantive changes to the wording of both sections as contained in the proposed rule.

The proposed rule contained a proposed § 1020.30(a)(1)(i)(F) that added image receptors that are electrically powered or connected to the x-ray system, to the list of components to which the performance standard applies. This addition was proposed because FDA determined that it was necessary to include new solid-state x-ray imaging devices, which are being used for both radiography and fluoroscopy, in the list of components subject to the requirements of the performance standard.

FDA inadvertently failed to discuss the addition of proposed § 1020.30(a)(1)(i)(F) in the preamble to the proposed rule. However, the application of the performance standard to the new types of image receptors was extensively discussed in sections II.B and II.C of the preamble of the proposed rule. Thus, FDA believes that its intention to apply the standard to these types of x-ray system components was made clear. No comments were received concerning this addition to § 1020.30(a); therefore, FDA has retained this proposed paragraph in the final rule.

The application of solid-state x-ray imaging devices as the image receptors for both radiographic and fluoroscopic x-ray systems requires additional clarification in the performance standard regarding the specific requirements that apply to these components and systems containing them. Previously, the requirements of § 1020.31 for radiographic systems were understood to apply to systems when x-ray film was used to obtain static radiographic images. The requirements of § 1020.32 applied to fluoroscopic x-ray systems, including when the fluoroscopic image receptor, primarily the x-ray image intensifier tube, was used to record images such as during cineradiography or when photospot images were made. With the introduction of solid-state x-ray imaging devices, we now have the situation where image receptors with the

same or very similar technology may be used in both radiographic and fluoroscopic x-ray systems. The solid-state x-ray imaging device used for fluoroscopy may also produce digital radiographic images that are essentially equivalent to images produced by solid-state x-ray imaging devices used as the image receptor in digital radiographic x-ray systems. Such similarities can raise questions about when the requirements of §§ 1020.31 or 1020.32 apply to a system using a solid-state x-ray imaging device to produce digital images.

To date, this question has not received very much, if any, discussion in the radiology community. Contrary to the situation involving x-ray film and intensifying screens in an imaging cassette, the introduction of solid-state x-ray imaging devices, which are integral parts of the electronic x-ray system, raises questions as to what are appropriate performance requirements for these systems. FDA notes that there has been no consensus developed about how requirements such as x-ray system linearity, reproducibility, and x-ray field indication and alignment may need to be modified to appropriately assure the radiation safety performance of systems using a solid-state x-ray imaging device. FDA did not specifically raise these issues in the preamble to the proposed rule.

As discussed previously in section III.A of this document (comment 5), two of the organizations commenting on the proposed rule suggested that additional action may be needed to determine appropriate performance requirements for solid-state x-ray imaging devices. FDA agrees that further investigation and development of consensus on appropriate requirements for systems using solid-state x-ray imaging devices is needed and will pursue further discussions and interactions with the radiology community to better define what these requirements should be. However, in the meantime,

clarification is needed regarding how the requirements of the current standard apply to systems using new types of x-ray image receptors. FDA has modified the introductory applicability statements of §§ 1020.31 and 1020.32 to clarify how these requirements apply to such systems.

In the proposed rule, the applicability statements of §§ 1020.31 and 1020.32 were revised to replace the reference to the x-ray image intensifier tube with a reference to the fluoroscopic image receptor.

In this final rule, the applicability statements have been further revised to use the new definitions of radiography and fluoroscopy and to indicate that, when images are recorded using the fluoroscopic image receptor, the requirements of § 1020.32, not § 1020.31, will apply. Thus, if an image receptor is used for fluoroscopic imaging, the requirements of § 1020.32 apply even when radiographic images are produced using the fluoroscopic image receptor. When the image receptor "irrespective of whether it is film-based, computed radiographic, or solid-state x-ray imaging digital technology" is used only for radiographic imaging, the requirements of § 1020.31 will apply. FDA notes that, if new combination radiographic and fluoroscopic system designs are developed that use the same image receptor for both fluoroscopic and all conventional radiographic images, the modified applicability statements would apply only the requirements of § 1020.32 to these types of systems. FDA recognizes that this particular application of requirements may not be the optimum approach or the most appropriate control for systems using new types of image receptors. However, until a consensus is developed regarding a different approach or different requirements, FDA has concluded that this approach to applying the requirements of §§ 1020.31 and 1020.32 is appropriate. FDA will initiate efforts to develop a consensus in the radiology

community regarding the appropriate requirements that should be applied to systems using solid-state x-ray imaging devices and, if warranted, propose future revisions to the performance standard established by this final rule.

FDA also notes that a typographical error regarding the statement of effective date in the introductory paragraph of § 1020.31 has been corrected to read November 29, 1984, rather than November 28, 1984. This date was originally established as November 29, 1984 in the final rule published in the **Federal Register** of August 31, 1984 (49 FR 34698) but was incorrectly printed as November 28, 1984, in the revision of the standard published on May 3, 1993 (58 FR 26386).

In addition, there was a typographical error in the text of proposed § 1020.32(k)(5)(ii), which was intended to describe the alternate location for the reference location that manufacturers might choose to designate. This text has been corrected, so that § 1020.32(k)(4)(ii) now reads as intended, "Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin."

V. 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.

VI. Paperwork Reduction Act of 1995

A. Summary

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3502). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting 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.

FDA received no comments related to the information collection requirements or the estimate of burden in response to the proposed rule. FDA, therefore, concludes that readers of the proposed rule recognized the necessity of the information to be collected, did not disagree with FDA's estimate of the burden, and had no suggestions of alternate approaches to accomplishing the goals of the proposal.

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

Description: FDA is amending 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 rule established by this document will add to § 1020.30 paragraphs (h)(5) and (h)(6) describing additional information that must be included in these manuals or instructions. In addition, § 1020.32(j)(4) specifies additional descriptive information to be included in the user manuals for fluoroscopic

x-ray systems required by § 1020.30(h). This additional information contains descriptions of features of the x-ray equipment required by the 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 these amendments. FDA estimates the burden of this collection of information as follows:

TABLE 1.—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 2.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN FOR THE 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 amendment (Ref. 5), 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 amendments, for each model of fluoroscopic x-ray system that manufacturers continue to market, each manufacturer will have to supplement the user instructions to include the additional information required by the 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 § 1020.30(h). Therefore, it is assumed that no significant

additional capital, operating, or maintenance costs will be incurred by 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 amendments is expected to only add a few printed pages to these already extensive manuals or documents.

The burden that will be imposed on manufacturers by 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) will 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 will be required to draft, edit, design, layout, review, and approve the new portions of the user's manual or information required by the amendments. Hence, FDA estimates a total of 360 hours to prepare the new user information that will 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 requirement

for display of exposure time, AKR, 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. FDA expects that the average burden will be reduced from 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 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 will be required is 36,000 hours, as shown in table 1 in the preamble 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 2 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 amendments, as shown in table 2 of this document. The information collection burden of the current performance standard at §§ 1020.30 and 1020.32 is approved and reported under an existing information collection clearance (OMB control number 0190–0025).

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The information collection requirements in this final rule have been approved ~~The information collection provisions of this final rule have been~~ under OMB control number 0910-0564. This approval expires December 31, 2006. ~~submitted to OMB for review. Before the effective date of this final rule, FDA~~

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

~~will publish a document in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.~~

OMB

VII. Analysis of Impacts

A. Introduction

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4) . 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is a significant regulatory action as defined by Executive Order 12866 and, therefore, is subject to review.

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 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. No comments were

received regarding the impact on small entities, and the IRFA became the final regulatory flexibility analysis without further revision (see section VII.J of this document).

Section 202(a) of the UMRA requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing any rule that includes any Federal mandate that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The agency has conducted analyses of the final rule, including a consideration of alternatives, and has determined that the final rule is consistent with the principles set forth in the Executive order and in these statutes. The costs and benefits of the rule have been assessed in two separate analyses that are described in this section of the document and that were made available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. As reviewed in the following paragraphs, these 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 amendments using a 7-percent annual discount rate and $30.1 million using a 3-percent annual discount rate. 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 $88.3 million and

$1.160 billion using a 7-percent annual discount rate. The same analysis of benefits using a 3-percent annual discount rate resulted in annualized benefits of $715 million, with a 90-percent confidence interval of between $197.3 million and $2.593 billion. Table 2a of this document shows the annualized costs, benefits, and net benefits of the final regulation. FDA believes this analysis of impacts complies with Executive Order 12866 and OMB Circular A-4, and that the rule is a significant regulatory action as defined by the Executive order. Because of the preliminary nature of the initial cost and benefit analyses and estimates, FDA requested comments on any aspect of their methodologies, assumptions, and projections in the proposed rule. The only comments received on any aspect of these analyses were two comments that suggested, for two different reasons, that FDA had underestimated the benefits that will result from the amendments. FDA considered these comments and determined, due to the inherent uncertainty in the benefits cited, that revision of the estimated benefits analysis is not warranted.

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TABLE 2a.—SUMMARY OF ANNUALIZED COSTS, BENEFITS, AND NET BENEFITS OF THE FINAL RULE
(in millions of dollars)

Discount Rate	Annualized Costs	Annualized Benefits	Range of Annualized Benefits	Net Annualized Benefits (Modal)
3% Annual discount rate	$30.1	$715.6	$197.4 to $2,592.8	$685.5
7% Annual discount rate	$30.8	$320.3	$88.4 to $1,160.5	~~$284.5~~ $289.5

FDA

B. Objective of the Rule

The primary objective of the 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 rule will 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 rule are to bring the performance standard up to date with recent and emerging technological advances in the design of fluoroscopic and radiographic x-ray systems and to assure appropriate radiation safety for these designs. The amendments will also align the performance standard with performance requirements in current international standards that were developed after 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 changes will 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 amendments will require particular x-ray equipment features reducing unnecessary radiation exposure FDA believes the ~~and thoroby yielding net benefits. The~~ amendments are necessary because the private market ~~will~~ may not ensure that these equipment features will be adopted without a government mandate for such features. Purchasers in health care organizations may ~~have~~ ~~no~~ insufficient incentive to demand the more expensive x-ray equipment that will be required by these new amendments because ~~they perceive no institutional economic advantage in doing so as~~ and health care providers many years in the future 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~~ may ~~will~~ not demand this

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equipment because they lack information and knowledge about long-term radiation risk and about the highly technical nature of x-ray equipment. Hence, these amendments are necessary to realize the net benefits described in the following analysis.

(FDA believes)

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C. Risk Assessment

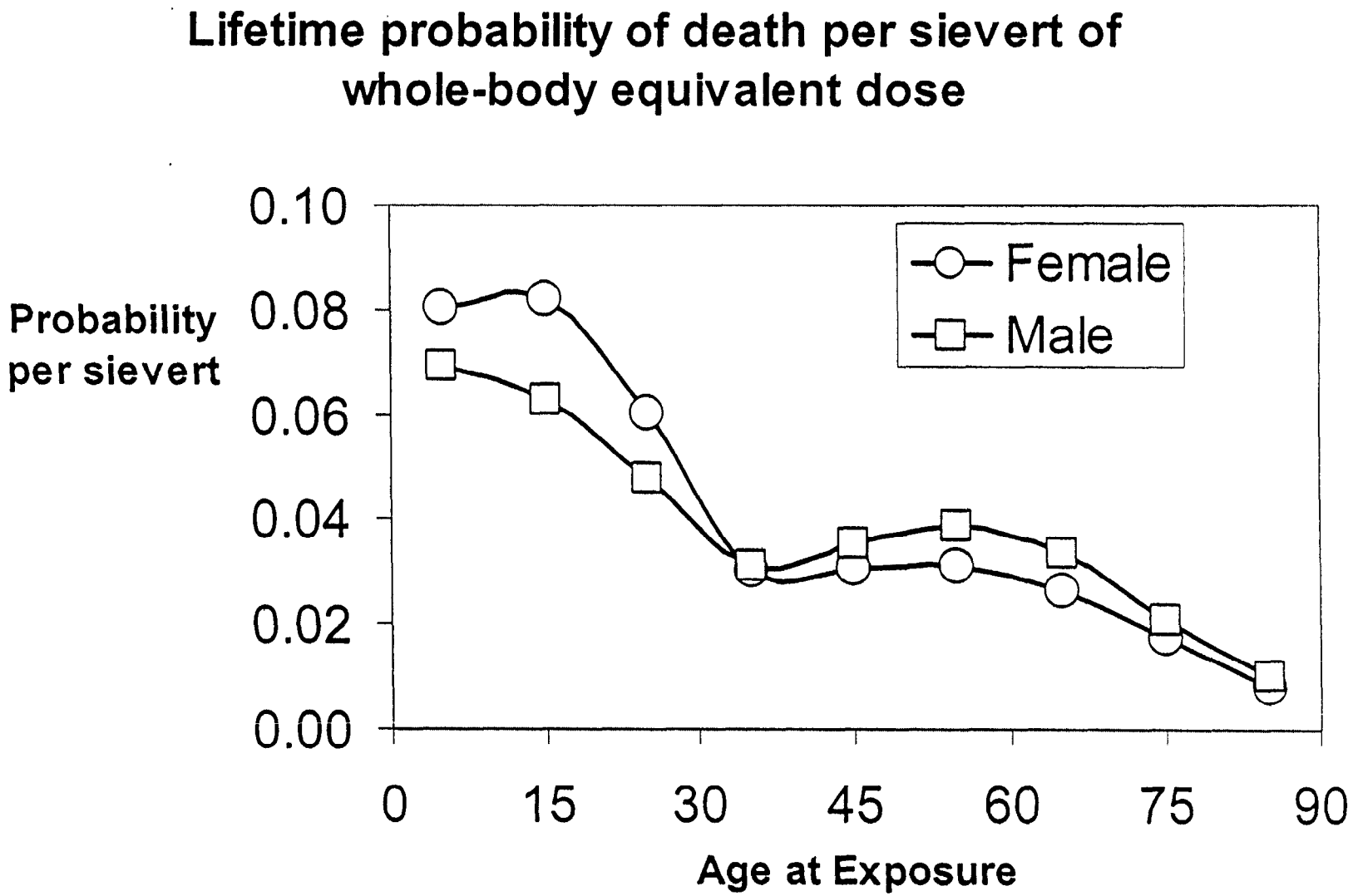
The risks to health that are addressed by these amendments are the adverse effects of exposure to ionizing radiation that can result from procedures utilizing diagnostic x-ray equipment. These adverse effects are well-known and have been extensively studied and documented. They are generally categorized 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. 6), 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 VII.H of this document is based on linear interpolations of cancer mortality risk per whole-body equivalent dose derived from table 4-3 of the fifth report of the Committee on the Biological Effects of Ionizing Radiations (BEIR) of the National Research Council (Ref. 7). (This report is commonly known as "BEIR V" and henceforth will be abbreviated that way in this document.) For reasons detailed in section VII.H of this document, in the estimations of cancer mortality risk these interpolated values are reduced by a dose-rate effectiveness factor (DREF) of 2 for solid cancers (Ref. 8). The values used in our analysis are represented in the following graph of the excess lifetime probability of death per sievert of whole-body equivalent dose (figure 1 of this document). Equivalent dose is determined from the average radiant energy absorbed per mass of tissue or organ exposed, where this average is multiplied by a dimensionless radiation weighting factor whose magnitude accounts for the detrimental biological effectiveness of the type of radiation; the value of the radiation weighting factor is unity for x rays emitted by the equipment covered in these regulations (Ref. 13). In the International System of Units, the unit of measurement of equivalent dose is joule per kilogram (J/kg) and is given the special name "sievert" (Sv) (Ref. 7). "Whole-body" means that all of the organs and tissues of the body receive the same dose.

[INSERT Figure 1]

Figure 1.


Lifetime probability of death per sievert of whole-body equivalent dose
Probability per sievert
0.10
0.08
0.06
0.04
0.02
0.00
0
15
30
45
60
75
90
Age at Exposure
Female
Male

Based on Science Panel Report No. 9 (Ref. 8) of the Committee on Interagency Radiation Research and Policy (CIRRPC) of the Office of Science Technology and Policy of the Executive Office of the President, FDA underscores the overarching uncertainty in these projections with the following statement:

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 will be required by three of the amendments will promote the bulk of radiation dose reduction and hence cancer risk reduction: (1) Displays of irradiation time, rate, and air kerma 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 will 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. 9. We invited comment on these assumptions in the proposed rule and received no objections to this approach. One comment suggested, based on a State's experience, that greater dose reductions would result from facilitating quality assurance programs by the requirement for air kerma display. Until recently, the principal 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 obtained through the amendments.

D. Constraints on the Impact Analysis

It is FDA's opinion that the amendments will offer public health benefits that warrant their costs. However, the agency had difficulty 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 solicited comments, data, and opinions about whether the potential health benefits of the amendments would justify their costs. FDA received only the two limited comments cited previously on this question and, therefore, has reached a final affirmative determination as to the appropriateness of the amendments based on the earlier analyses.

The principal costs associated with the amendments will be the increased costs 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 were urged to provide detailed comments on the anticipated costs of these amendments that would enable refinement of these cost estimates. No additional information was received on this topic during the comment period.

The benefits that are expected to result from these amendments are reductions in acute skin injuries and radiation-induced cancers. These benefits will result from two types of changes to the performance standard that should reduce patient dose and associated radiation detriment without compromising image quality.

The first type of change involves several new equipment features that will 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 the minimum source-skin distance for mini C-arm fluoroscopic systems. Almost all of the changes that directly affect x-ray field size or intensity will 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 will eliminate the need for manufacturers to produce more than one line of products for a single global marketplace.

The second type of change that will 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. These new features are widely supported and anticipated by many knowledgeable users of fluoroscopic systems. Similar requirements were recently included in a new international voluntary standard.

There is a third type of change being made to the standard. These changes will not have a direct benefit in terms of a reduction in radiation dose. Rather, they clarify the applicability of the standard, clarify definitions, and facilitate the application of the standard to new technology and x-ray system designs.

E. Baseline Conditions

The cost of the amendments to the x-ray equipment performance standard will be borne primarily by manufacturers of fluoroscopic systems. The cost for one of the nine amendments will also affect manufacturers of radiographic equipment and is discussed in detail in Ref. 5. 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 amendments will provide image quality and diagnostic information identical to equipment meeting current standards. Therefore, the clinical usefulness of the images provided will not change. The amendments will 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 will adversely affect the clinical information or results obtained from these procedures. These amendments will 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 will provide physicians using fluoroscopic equipment with the means to actively monitor the amount

of radiation incident on patients 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. 9, using data from several sources. These numbers of specific procedures were used in the estimates of benefit from the amendments. To keep the estimations relatively simple and conservative, no attempt was made to project the future growth in the numbers of procedures suggested by some of the literature (Ref. 9, note 27, and Ref. 25). FDA 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, about 4,200 are fluoroscopic system installations. The amendments will 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 current models of radiographic systems that do not meet the 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. These estimates were developed by FDA in 2000. These estimates have not been updated since publication of the proposed rule as the size of the radiographic and fluoroscopic x-ray equipment is not expected to have changed significantly in the period since 2000 and in view of the uncertainty in the original estimates.

F. The Amendments

The changes to the 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 the following: 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 last-image-hold feature; specification of the minimum source-skin distance 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 SSIX devices, revisions of the applicability sections, and establishment of additional definitions.

G. Benefits of the Amendments

The amendments will 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 amendments will 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. The introduction of an increasing variety of new, fluoroscopically-guided interventional procedures, as alternatives to more invasive surgical procedures or as totally new therapies, and the use of a variety of new devices and therapies that are used with fluoroscopic guidance are resulting in significant increases in the number of fluoroscopically-guided interventional procedures

with long irradiation times. Thus, the 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 amendments will 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 will 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 also is widespread 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. 10). 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. 11). 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 amendments will facilitate this reduction.

The new, required features of last-image-hold 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 last-image-hold feature will permit decisionmaking regarding the procedure underway while visualizing the anatomy without continuing to expose the patient. The air kerma- and AKR-value displays will 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 will require fluoroscopists to take advantage of these new features and optimize the way they use fluoroscopic systems.

The potential impact of the change in the beam quality requirement, which will apply to most radiographic and all fluoroscopic systems, can be seen from the data on beam quality obtained from FDA's Compliance Testing Program for the current standard. Between January 1, 1996, and December 31, 2000, FDA 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 amendments had been 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 12 demonstrates that the addition of 1.5 to 2.0 mm Al as additional filtration, which is the change

required to enable systems that just meet the current requirement to meet the new HVL requirement, will 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 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. 11). 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 in table 3 of this document 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 new rules

are phased into use in the United States. (FDA assumes that 10 years after the effective date of the new rules all fluoroscopic systems then in use will conform to those rules and that associated recurring benefits will 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 and, separately, using a 3-percent discount rate covering the identical 10-year evaluation period used in the cost analysis. (See section VII.I of this document.) 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).

TABLE 3.—PROJECTIONS OF ANNUAL BENEFITS IN THE UNITED STATES

FOR DISPLAY, COLLIMATION, AND FILTRATION RULES APPLIED TO PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), CARDIAC CATHETERIZATION WITH CORONARY ARTERIOGRAPHY OR ANGIOGRAPHY (CA), AND UPPER GASTROINTESTINAL FLUOROSCOPY (UGI) PROCEDURES

	5th Percentile	Mode	95th Percentile
Average Annual Dose and Life Savings in the First 10 Years After Effective Date of Rule			
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
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 Rule	7% Discount Rate		
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 precluded ($ millions)[1]	0.03	0.07	0.16
Total ($ millions)	88.35	320.31	1,160.00
Average Annual Amortized Pecuniary Savings in the First 10 Years After Effective Date of Rule	3% Discount Rate		
Prevention of premature death from cancer ($ millions)	178.99	649.02	2,351.60
Obviation of cancer treatment ($ millions)	18 34	66.52	241.01
Obviation of radiation burn treatment and loss precluded ($ millions)[1]	0.03	0.07	0.16
Total ($ millions)	197.36	715.61	2,592.77

[1] There is no amortization for savings associated with obviation of radiation burn treatment and loss because the interval for latency, presentation, and treatment of skin injury generally occurs within a year of radiation exposure.

Columns in table 3 of this document labeled "Mode," "5th Percentile," and "95th Percentile" categorize the results of a sensitivity analysis performed to account for uncertainties in the principal variables used to compute the data contained in the rows of table 3. The columns correspond to the expected (mode) and extremum values of 90-percent confidence intervals associated with the estimated benefits. Estimation of these uncertainties is discussed following descriptions of the row categories in table 3.

Collective dose savings (quantified in units of person-Sv) are the estimated reductions in radiation dose to the U.S. population projected to result following implementation of the amended regulations. Collective dose savings are evaluated in terms of the number of persons receiving a procedure (Ref. 9, notes 26 and 29, and Ref. 24) multiplied by the associated effective dose reduction (quantified in units of Sv) per procedure (Ref. 9, notes 28 and 42). The unit "person-Sv" is a product of the number of persons receiving a procedure and the number of Sv per procedure, where Sv is the unit of measurement of effective dose as well as equivalent dose, defined previously. Effective dose is the weighted sum of equivalent doses in all of the organs; it represents a level of radiation detriment equal to that for whole-body irradiation (Ref. 13), and we use it as an approximation of whole-body equivalent dose. Estimates of effective dose reduction from current levels that will result from the amendments are 16 percent for the air-kerma rate and cumulative air-kerma display requirement, 6 percent for the requirement for increased minimum x-ray filtration, and 1 to 3 percent for the requirement that would improve collimation of the x-ray field (Ref. 9, notes 9 through 13 and 18 through 25, and Refs. 12 and 15 through 23).

The number of lives spared premature death is the number of statistical deaths projected to be avoided as a result of the collective dose savings. It is essentially the product of the estimated collective dose savings described in the preceding paragraph and the radiation-associated mortality risk per Sv, represented in figure 1 of this document, summed for each gender over all ages at exposure. As illustrated in the Ref. 9 slide entitled "Annual Life Benefit Projections in the U.S.," age and gender dependences are incorporated into the estimation of the number of lives spared premature death as well as into the estimation of collective dose savings and years of life spared premature death from cancer.

The years of life spared premature death from cancer is a projection evaluated as the product of the number of lives spared premature death from cancer and the difference between the actuarial number of years of life remaining and the 20-year combined interval of cancer latency and survival.

The number of skin burns precluded is projected as the percentage dose reduction multiplied by the number of skin burns reported to FDA annually, which averages approximately 8.6 reports. It is assumed that the fraction of skin doses exceeding the threshold for skin injury would be reduced in proportion to the effective-dose reduction (approximately 25 percent) projected for procedures of PTCA and CA and that therefore the number of skin burns would be reduced in the same proportion.

Estimates of average annual amortized pecuniary savings in the first 10 years after the effective date of the rule are evaluated as the respective products of two factors: (1) The projected numbers of lives spared premature death from cancer (with which obviation of cancer treatment is also associated) and (2) the monetary savings per single case associated with either prevention of

premature death from cancer or obviation of cancer treatment. Pecuniary savings associated with obviation of radiation burn treatment and loss are evaluated simply as the product of the projected number of reported skin burns precluded and the estimated pecuniary savings associated with each case of radiation burn treatment and loss precluded; although the savings associated with radiation burns are averaged over the first 10 years after the effective date of the rule, they are not amortized because the interval for latency, presentation, and treatment of skin injury generally occurs within a year of radiation exposure.

Based on an economic model of society's willingness to pay (WTP) a premium for high-risk jobs, FDA associates a value of $5 million for each statistical death avoided (Ref. 9, notes 54 through 56 and Refs. 26 through 28).

Savings of $25,000 for preclusion of each cancer treatment are estimated as follows: According to data of the U.S. National Cancer Institute (Ref. 9, note 59, and Ref. 29), 75 percent of all cancers are either stage 1 or 2 at the time of presentation. Per Ref. 9, note 60 (Ref. 30), these cancers have annual treatment costs of $23,000 to $28,000. In situ cancers are less expensive, and stage 3 and 4 cancers cost $50,000 to $60,000 annually to treat. (Also see Ref. 9, note 61, and Ref. 31.) For the FDA analysis, the annual treatment cost is estimated to be that associated with the modal stage and was estimated to be $25,000.

Savings of $5,000 for precluding each case of cancer's psychological impact are estimated as follows: Psychological impact of dread, anxiety, or depression has long been noted in cancer treatment research (e.g., see Ref. 9, notes 63 through 65, and Refs. 32 through 34). This literature indicates that symptoms associated with mental well-being contribute as much as 8 percent

to one's overall sense of health. Of the sense of psychological well-being, depression scales have shown that worries about personal health account for approximately one sixth of the 8 percent contribution, where other contributors include factors associated with family, finances, work, relationships, etc. Therefore, worries and concerns about personal health contribute approximately 1.3 percent to one's sense of personal well-being. Another way to put it is that society's WTP to avoid such worries is approximately 1.3 percent of overall health costs. The WTP for overall health is derived from the estimated annual WTP of $5 million to avoid a statistical death (Ref. 9, notes 54 through 56, and Refs. 26 through 28). This value was derived from blue-collar males of about 30 years of age whose life expectancy is 41.3 years (adjusted for future expected bed and nonbed disability per Ref. 9, notes 66 and 67, and Refs. 35 and 36). Amortization of $5 million across 41.3 years at a discount rate of 7 percent implies a WTP of $373,000 per quality adjusted life-year (QALY). 1.3 percent of this QALY is approximately $5,000 per year for society's WTP to avoid the sense of psychological dread associated with concerns about personal health generated by cancer treatments.

Savings of $67,600 for each case of radiation burn treatment and loss precluded are estimated as follows: Survey data on radiation burns indicate an average medical treatment cost of $23,000 and an average work-loss cost of $20,700 (Ref. 9, note 69, and Ref. 37). Costs of pain and suffering are estimated from an index of the quality of well-being, where 1.0000 indicates perfect health, 0.0000 death (Ref. 9 notes 63, 66, and 70, and Refs. 32, 35, and 38). Relative functionality is first based on mobility (ranging from driving a car without help to being in a special care unit), social activity (ranging from working to needing help with self-care), and physical activity (ranging from

walking without problems to staying in bed). Each state has been assigned a relative wellness and is adjusted according to the cause of the state (e.g., bedridden with a stomach ache versus bedridden with a broken leg). For the purpose of this analysis, FDA assigns two functional states to radiation burns: (1) Two weeks of serious debilitation (relative wellness value 0.3599) and (2) four weeks of functional distress with some activity (relative wellness value 0.5108). An annual amortized average value of $373,000 for the societal WTP for a QALY equals about $7,200 per week for a quality adjusted life week, which corresponds to the base 1.0000 in the well-being index. The estimate of the expected WTP to avoid a radiation burn is [2 x $7,200 x (1.0000 - 0.3599)] + [4 x $7,200 x (1.0000 - 0.5108)] = $23,200. Adding this value to medical treatment and work-loss costs results in a cost per burn of $67,600.

For the most part, these projections are based on a benefits analysis (Ref. 9, available at *http://www.fda.gov/cdrh/radhlth/scifor01f.pdf* or *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 amendments (see sections II.E, II.F, and II.K of the proposed rule) 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. New requirements for the source-skin distance for small C-arm fluoroscopes (see section II.J of the proposed rule) and for provision of the last-image-hold feature on all fluoroscopic systems (see section II.L of the proposed rule) will also directly reduce dose, but their dose reductions are expected to be much smaller than those associated with the preceding 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. 9 and its notes. That analysis, however, is incomplete insofar as it refers only to a single set of point estimates employing the BEIR V mortality risk estimates, which presume a dose-rate effectiveness factor (DREF) equal to unity; the DREF is defined as "a factor by which the effect caused by a specific dose of radiation changes at low as compared to high dose rates" (Ref. 7). For the sensitivity analysis whose results are tabulated in table 3 of this document, several additional assumptions are invoked. Among the most important of the underpinnings of the analysis are the projected percentage dose reductions corresponding to the three amendments considered and the dependence on the risk estimates for cancer mortality from BEIR V (Ref. 7). 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. 9).

With respect to the dependence on the BEIR V estimates, FDA follows two recommendations of the Office of Science and Technology Policy (OSTP)

CIRRPC Science Panel Report No. 9 (Ref. 8) that represent the Federal consensus position for radiation risk benefit evaluation: First, we apply a value of 2 as the DREF in the projections of numbers of solid, non-leukemia cancers. Adopting a DREF value of 2 in the analysis nearly halves the Ref. 9 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. 7, pp. 171 and 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), International Commission on Radiological Protection (ICRP) Publication 73 (Ref. 13, 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 and incorporate that uncertainty into the sensitivity analysis. The second recommendation that FDA adopts from CIRPPC Panel Report No. 9 (Ref. 8) 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. 7). 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. 14).

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 estimated relative uncertainty of a factor of 2.3 lower and higher than the modal point estimates of the projected savings. These values represent, respectively, the 5th and 95th percentile points of a 90 percent confidence interval. For the projected number of lives and years of life spared premature death, the overall estimated relative uncertainty is a factor of 3.6 lower and higher spanning a 90 percent confidence interval. Hence, these factors account for the principal sources of uncertainty in the projected dose reductions, in DREF, and in the mortality risk estimates. Applied to the sensitivity analysis, these relative factors of uncertainty comprise the bounds of variability within which the true values of table 3 quantities reside, at a 90-percent confidence level and under the modeling assumptions and discount rates indicated in preceding paragraphs of this document.

I. Costs of Implementing the Regulation

Costs to manufacturers of fluoroscopic and radiographic systems will increase due to these proposals. FDA will 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 amendments, FDA reexamined 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. 5.

FDA has no information, indication, or economic presumption on whether 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 amendments, namely, manufacturers and FDA itself. In the proposed rule, FDA requested information on the costs that would be imposed by these new requirements that would aid in refining the cost estimates. FDA received no comments or additional information on these costs.

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 will 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 will 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 will need either modification in the adjustment procedure for the collimators (for which new installation and adjustment procedures will be developed at an estimated one-time cost of $20,000 per model) or collimators will need to be redesigned at an estimated cost of $50,000 per model. FDA has assumed that half of all fluoroscopic x-ray system models (5 models each for 20 manufacturers) will need modifications to meet the new requirement, while the remainder will 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 will most likely need redesigned collimators that will add an estimated 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 modification of the requirement limiting the maximum entrance AKR and removal of the exception to the limit during recording of images will only affect the adjustment of newly-installed systems having such recording capability. This requirement is not expected to impose significant costs.

FDA is requiring 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 will need to be redesigned (at a maximum estimated cost of $50,000 per model) for an estimated one-time 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 produces an annual cost increase of $16.8 million (4,200 annual installations x $4,000).

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

The clarification of the requirement for minimum source-skin distance 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 will be $0.2 million. The average annualized cost of this change will be negligible.

In summary, total industry costs for compliance with the amendments in the area of equipment design include onetime costs of $25.2 million. This total equals an average annualized cost (7-percent discount rate over 10 years) of $3.6 million. The average annualized cost using a 3-percent discount rate over 10 years equals $3.0 million. In addition, annual recurring costs for new equipment features associated with these provisions are expected to equal $26.7 million.

2. Costs Associated With Additional Information for Users

The amendments will require that additional information be provided in the user instructions regarding fluoroscopic systems. FDA has estimated that each model of fluoroscopic system will 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 (7-percent discount rate) or $0.12 million (3-percent discount rate). In addition, each newly-installed system will 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 will include a revised manual for an annual cost of approximately $0.1 million.

Related to the requirements for additional information is the change of 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 for the performance standard do not pose any significant new or additional costs on manufacturers.

4. FDA Costs Associated With Compliance Activities

FDA costs will increase due to the increased compliance activities that will result from these regulations. In addition, FDA will experience implementation costs in developing and publicizing the new requirements. FDA has estimated that approximately five full-time equivalent employees

(FTEs) will be required to implement the 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 7- and 3-percent discount rates 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 Regulation

The estimated costs of the amendments identified as having any significant cost impact are summarized in table 4 of this document. The costs are identified as nonrecurring costs that must be met initially or as annual costs associated with continued production of systems meeting the requirements or additional annual enforcement of the amendments. The total annualized cost of the regulations (averaged over 10 years using a 7-percent discount rate) equals $30.8 million, of which $30.4 million will 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. If costs are amortized using a 3-percent discount rate, annualized costs equal $30.1 million. The sections listed in the left-hand column of table 4 of this document refer to sections of the proposed rule.

TABLE 4.—SUMMARY OF COSTS OF AMENDMENTS

Section of the Proposed Rule Preamble Describing the Amendment	Nonrecurring Costs to Manufacturers ($ millions)	Nonrecurring 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

TABLE 4.—SUMMARY OF COSTS OF AMENDMENTS—Continued

Section of the Proposed Rule Preamble Describing the Amendment	Nonrecurring Costs to Manufacturers ($ millions)	Nonrecurring Costs to FDA ($ millions)	Annual Costs to Manufacturers ($ millions)	Annual Costs to FDA ($ millions)
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 amendments, using a 7-percent discount rate, the average annual cost is estimated to be $30.8 million, compared to projected average annual benefits of $320 million, within a range estimated between $88 million and $1.2 billion. A comparison of costs and benefits using a 3-percent discount rate results in annualized costs of $30.1 million and average annual benefits of about $716 million, within an expected range of $197 million to $2.6 billion.

J. Cost-Effectiveness of the Regulation

We evaluated the cost-effectiveness of the final regulation using the cost per incidence of cancer avoided due to lower exposure over the 10-year evaluation period. The annual numbers of future-avoided cancers due to reduced radiation doses are compared to the present values of the costs for the evaluation period. We used projections of the annual number of cancer cases that would be avoided due to the final regulation. The cases that would be avoided because of exposure reductions during the first year (as improved systems are installed) are assumed to present themselves after a 10-year latency period. We expect the overall exposure reduction attributable to this final regulation to increase by 10 percent each year as currently installed x-ray systems are replaced by systems meeting the new performance standards. The most likely estimate for reductions in the number of premature cancers resulting from reduced unnecessary exposures during the first compliant year is 66 fewer incidents of cancer. By the 10th year, the exposure reductions are

expected to preclude 664 annual cancers according to the modal dose-response relationship. Table 5 of this document shows the annual decrease in cancer incidence expected for the modal relationship, as well as for the low and high range of estimated reductions.

TABLE 5.—EXPECTED ANNUAL REDUCTIONS IN CANCER INCIDENCES BY YEAR
(MODAL, LOW, AND HIGH ESTIMATES)

Compliance Year	Modal Estimate	Low Range Estimate	High Range Estimate
1	66	18	241
2	133	37	482
3	199	55	722
4	266	73	963
5	332	92	1,204
6	399	110	1,445
7	465	128	1,686
8	532	147	1,926
9	598	165	2,167
10	664	183	2,408

Although the reductions in cancers would continue beyond the evaluation period, we have analyzed only through the 10th year.

While the dose reduction attributable to the final regulation during the first year is expected to avoid 66 future cancers, those cancers have an assumed latency of 10 years and would not be discovered until the 11th year. Therefore, while reduced exposures during year 1 are expected to avoid 66 cancers, those avoided cancers would not have occurred until year 11. Each year's expected number of future avoided cancers is discounted to arrive at an equivalent number of avoided cancers during the first year. The present equivalent number of annual cancers avoided are estimated using both 7- and 3-percent annual discount rates. These equivalent numbers are shown in table 6 of this document.

TABLE 6.—EXPECTED EQUIVALENT NUMBER OF CANCERS AVOIDED DISCOUNTED TO YEAR 1 DUE TO REGULATION

Annual Discount Rate	Modal Estimate	Low Estimate	High Estimate
3 Percent	2,217	612	8,034

TABLE 6.—EXPECTED EQUIVALENT NUMBER OF CANCERS AVOIDED DISCOUNTED TO YEAR 1 DUE TO REGULATION—Continued

Annual Discount Rate	Modal Estimate	Low Estimate	High Estimate
7 Percent	1,173	324	4,252

The present value of the regulatory costs, when divided by the equivalent number of avoided cancers, will result in the expected cost per cancer avoided. Annualized costs using a 3-percent discount rate equaled $30.1 million and result in a present value of $256.8 million for the evaluation period. Using a 7-percent annual discount rate, annualized costs of $30.8 million result in a present value of $216.3 million. The cost per avoided cancer is shown in table 7 of this document.

TABLE 7.—REGULATORY COST-EFFECTIVENESS PER INCIDENCE OF CANCER AVOIDED DUE TO REGULATION

Annual Discount Rate	Modal Estimate	Low Estimate	High Estimate
3 Percent	$115,800	$419,600	$32,000
7 Percent	$184,400	$667,600	$50,900

The cost-effectiveness of the final regulation using a 7-percent discount rate has a modal value of $184,400 within an estimated range of between $50,900 and $667,600 per cancer avoided. If a 3-percent annual discount rate is used, the regulation will cost an estimated $115,800 per avoided cancer within an estimated range of $32,000 to $419,600.

K. Small Business Impacts

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

1. Description of Impact

The objective of the regulation is to reduce the likelihood of adverse events due to unnecessary exposure to radiation during diagnostic x-ray procedures,