Assessment of the Impact of the Proposed Amendments to the Diagnostic X-ray Equipment Performance Standard addressing Fluoroscopic X-ray Systems

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Fluoroscopy Working Group

Center for Devices and Radiological Health
FDA

Note:

This is a draft of a document that is still under development. This assessment will not be completed until publication of a final rule, following the public comment period on a proposed rule to be published in the Federal Register at a future date. This draft is made available to any interested party via the FDA's web page in order to afford any interested party an opportunity to comment. Comments may be sent to the following address: CDRH Fluoroscopy Working Group, Mail Code HFZ-140, 9200 Corporate Boulevard, Rockville, MD 20850. Comments may also be sent by electronic mail to tbs@cdrh.fda.gov or by FAX to 301-443-9101.

Introduction to the Impact Assessment

The proposed amendments to the Federal Performance Standard for Diagnostic X-ray Systems and their Major Components (the Standard) will not significantly alter the manufacturing processes or distribution of diagnostic x-ray systems. The proposed new requirements will not require any significant changes, from an environmental or other standpoint, in the technology, manufacturing processes or use of natural resources during the production of x-ray equipment from current uses or practices.

The proposed changes to the standard will add additional requirements that manufacturers of fluoroscopic equipment must design systems to meet. These requirements address new performance features that all newly-manufactured systems must provide. In many cases, this will require some redesign of certain aspects of the system. The costs of any additional required features will very likely be passed on to the purchasers of these systems as increased costs. These costs to manufacturers will be of two types. The first are non-recurring costs associated with the development of new equipment designs to provide the required performance and features, including any new test instrumentation and administrative overhead associated with the regulatory processes and submissions for the new designs. The second cost is the increased cost of materials and production to provide the new features on each x-ray system marketed. Both of these costs will likely be reflected in the cost of equipment and be passed on to the ultimate purchasers. This analysis does not attempt to determine the parties that ultimately bear these costs, but to estimate their overall magnitude.

Some information and assumptions used in developing this analysis are given below. The information regarding the number of x-ray systems installed in the U.S. each year was obtained from information available in the FDA records of the annual installations of new diagnostic x-ray systems that are required to be reported to the FDA. The assumptions regarding the number of manufacturers of x-ray systems and distinct models of x-ray systems currently marketed by each manufacturer are based on this data and the experience of FDA staff. These numbers are, however, recognized as inexact due to the rapid change in the x-ray equipment market due to mergers between firms and frequent changes in product lines. The estimates are thought to be conservative for the purpose of this impact assessment in the sense that they will very likely overestimate the cost of the proposed amendments. As an example of this, many of the manufacturers will only have a few different models or distinct designs of fluoroscopic systems in current production, not the assumed 20 or 10 different models used in the estimates described below.

Information and assumptions used:

- There are approximately 40 manufacturers of diagnostic x-ray systems that manufacture system components that will be affected by these amendments and each manufacturer markets about 20 different models of x-ray systems.
- There are approximately 12,000 new medical (including dental systems with extraoral image receptors) x-ray systems sold and installed in the U.S. each year.
- There are approximately 20 manufacturers of fluoroscopic x-ray systems that market systems in the U.S.

- It is assumed that each manufacturer of fluoroscopic systems currently markets about 10 different, distinct models or designs of fluoroscopic x-ray systems that will be impacted by the new requirements
- Each year in the U.S. there are approximately 4200 new fluoroscopic x-ray systems sold and installed. Of these, the types of systems may be categorized roughly as follows:

Type of Fluoroscopic System	Number installed/yr
General purpose fluoroscopic (including R & F) systems	1100
Urologic systems	250
Angiographic (special procedures) systems	650
"C-arm" fluoroscopic systems (stationary and mobile)	2200
Total	4200

In addition to the increased cost of equipment that may be passed on to customers, there are costs to both the FDA and state and local governments associated with the establishment and enforcement of the radiation safety regulations contained in these amendments. Changes will be required to current programs of the FDA that are used to enforce the standard. Changes will be required to the inspectional and testing procedures used to evaluate compliance with Federal or state standards, as well as costs associated with training inspectors and other staff with respect to some of the new requirements. In many cases changes to state regulations will logically follow from the changes implemented in the Federal standard, due to the restriction that state standards, when established, be no different from the Federal standards. However, these changes are not required by the amendments and any costs associated with these changes to state programs should not be attributed to the cost of the Federal standard since the Federal standard does not require that state and local governments enforce the same requirements. The additions to the Federal standard do provide a benefit to manufacturers and others in that states are prohibited from establishing different requirements, thus preventing the excess costs that could arise to manufacturers if they had to comply with numerous different performance requirements imposed by each state.

Assessment of the Impact of Each Major New Requirement

In the following sections, each significant proposed change to the standard is reviewed and the impact of the change assessed.

1. Change in the Quantity Used to Describe X-Radiation from Exposure to Air Kerma

Requirement: This change does not impose any new requirement or change any of the limits in the current standard. The change brings the quantity and unit used to describe the radiation emitted by the x-ray tube into conformance with modern usage and the International System of Units. The quantity and unit used for this purpose is changed from "exposure" in roentgens to "air kerma" in gray.

Those Affected: Any party reading or using the standard will be impacted by this change and will need to be familiar with the new quantity and unit. However, this does not result in any significant impact as all professionals working in radiation protection should by now be conversant with this quantity and the means for conversion from the previous quantity exposure. The use of the new quantity in the standard does not require any changes by manufacturers with regard to test instrumentation as the previous methods can continue to be used. One would anticipate a gradual evolution to use of the new quantity in any product labeling or descriptive literature but such is not required.

Cost of the Change: Other than the small costs to the FDA to develop and promulgate this change, there will be no additional costs required by this change. The cost to the FDA is estimated to be less than 0.05 FTE and is considered negligible and included in the ongoing enforcement of the Standard.

Benefits: This change results in the use of the accepted quantity and unit in the standard, thus aligning the standard with the usage in other national and international standards.

Alternatives: The only alternative would be to leave the standard unchanged, perpetuating the use of an outdated quantity and unit in contradiction to the Federal and FDA policy to use the accepted "metric units" in standards and other activities. This alternative was unacceptable.

Manufacturers' costs		
Nonrecurring costs	No significant costs beyond those already associated with the standard and manufacture of a product subject to the standard.	
Annual costs to manufacturers based on per system production costs	None, beyond those associated with providing a certified component already required by the standard.	
Regulatory agency cost		
Nonrecurring FTE cost	0.05 FTE x $117K/FTE	$5,856
Other nonrecurring costs	None	
Annual FTE cost	Minimal	
Other annual cost	None	

2. Clarification of Applicability of Requirements to Account for Technological Developments in Fluoroscopic X-ray Systems such as Digital Imaging, Digital Recoding and New Types of Solid State X-ray Imaging Devices

Requirements: When the performance standard was originally developed, the only means for producing a fluoroscopic image was either a screen of fluorescent material or an x-ray image intensifier tube as the image receptor. The advent of new types of image receptors, such as solid-state x-ray imaging devices (SSXI), and new modes of image recording, such as digital recording to computer memory or other media, has made the application of the standard in its current format to those new fluoroscopic system components awkward. These amendments will modify the structure and organization of the standard to address the new types of image receptors and will clarify how the requirements of the standard apply in each case. In addition, the amendments will clarify the conditions defining the "record" mode of operations. The amendments will include new definitions for fluoroscopy and radiography to make a clearer distinction between these two modes of operation.

Those Affected: The addition will clarify that all manufacturers of fluoroscopic x-ray equipment incorporating new types of image receptors must meet the basic radiation protection and safety requirements already existing for equipment incorporating older image receptors. The proposed changes do not affect the requirements in the performance standard, but do change the spectrum of equipment to which the requirements will be applicable. It is estimated that less than five percent of the fluoroscopic x-ray equipment currently being sold incorporates these new types of image receptors. However, we expect the introduction into commerce of this type of equipment to continue to grow in the future.

Cost to Manufacturers: These changes to the standard do not establish specific performance requirements, resulting in changes in the design of equipment. These changes clarify the manner in which the standard will be applied to new types of image receptors that, as components of diagnostic x-ray systems, are already subject to the performance standard. These specific changes do not add to the existing requirements for testing and certification of components and systems already established by the standard. Manufacturers, as they introduce new designs or technologies under the existing Standard, and the Quality System Regulations applicable to all manufacturers of medical devices, are required to have appropriate design and test methods to assure a quality product. The costs associated with this testing do not arise from the proposed changes to clarify the applicability of the standard, but would be incurred without these changes.

Currently there are only two models of fluoroscopic systems cleared for marketing that use rectangular image receptors and very few of these have been sold. These products were required to meet requirements for rectangular field limitation as a condition for market clearance. Thus, manufacturers are currently designing SSXI systems with rectangular image receptors to meet the proposed requirement. Clarification of the requirement will assure that, as manufacturers bring additional models to market, the requirements are known at the beginning of the design process.

Because all x-ray systems must have means to limit the size of the x-ray field to the area of clinical interest, systems will be equipped with some type of adjustable collimation in order to meet basic radiation safety principles. Any costs resulting from the clarification of the field limitation requirements for SSXIs will be very marginal and can be incorporated from the initial design, obviating the need for any design changes for these systems that are currently under development. For this reason, no significant costs to manufacturers can be attributed directly to the clarification of applicability.

Cost to Regulatory Agencies: These changes will require minimal changes to FDA programs to enforce the standard. Minor changes may be required to inspector training programs, report submission guidance for manufacturers or to compliance testing programs to reflect the clarified applicability. These efforts are estimated to require less than 0.2 FTEs on a non-recurring basis.

These changes to the Federal standard may result in the desire of State or local radiation control programs to modify their existing regulations to conform. While States are not required to make such changes, some may choose to do so. Such changes may be implemented as a special change or incorporated into scheduled revisions or updates of State regulations. Such costs, if incurred, are not required by the change to the Federal standard and are expected to be minimal.

Benefits: The primary benefit of these amendments is the application of a set of basic radiation protection and safety requirements to systems incorporating new types of image receptors. The beneficial aspects of these requirements to the exposed population have been recognized for many years.

Alternatives: The only reasonable alternative to the proposed changes to clarify the applicability of the standard would be to make no changes. This would continue the current situation in which the application of the standard to these new technologies is unclear, resulting in confusion for manufacturers and State regulatory agencies and the likely possibility of inadequate radiation safety performance for some new systems. It would not be reasonable from a radiation safety standpoint to exempt the new types of image receptors from the controls in the Standard, as this could lead to system designs that do not prevent unnecessary radiation exposure to patients.

Manufacturers' costs		
Nonrecurring costs	No significant costs beyond those already associated with the standard and manufacture of a product subject to the standard.	
Annual costs to manufacturers based on per system production costs	None, beyond those associated with providing certified components already required by the standard.	
Regulatory agency cost		
Nonrecurring FTE cost	Additional one-time costs to revise programs to account for changes. 0.2 FTE x $117K	$23,400
Other nonrecurring costs	None	
Annual FTE cost	None	
Other annual cost	None	

3. Changes in §1020.30(h) – Information to be Provided to Users

Requirement: Amendment to §1020.30(h) adds new paragraphs 1020.30(h)(5) and (h)(6) to require provision of additional information regarding fluoroscopic x-ray systems in the instructions to users.

With so many optional modes of operation for fluoroscopic x-ray systems and accessory components available, many users of the equipment may be confused over the use of some of the available modes of operation. While there may be a brief description of how to engage a mode in the current user's manual or information, there may not be a clear description of how that mode operates by changing the parameters of the system. More explanation is needed on the intended use of each particular fluoroscopic mode. The proposed amendments also require additional information be provided regarding the new display of values of air kerma rate and cumulative air kerma that will be required.

Those Affected: This amendment requires manufacturers of fluoroscopic x-ray systems to provide additional specific information in the written instructions (User's Instruction Manual) normally provided to users on the operation of the x-ray system. The proposed changes do not affect the equipment performance requirements in the standard, but require the addition of new information.

Cost to Manufacturers: This addition to the regulations will include recurring and non-recurring costs to the manufacturer. The non-recurring costs are the one-time costs associated with the development of information and format for distribution. This cost will occur regardless of the number of systems produced by a manufacturer. Manufacturers are already required to provide certain information for users and they also provide additional information and instructions to enable proper operation of the x-ray systems. This requirement will necessitate additions to this information that is currently provided to users. Manufacturers will have to develop specific sections in the Instructions for Users to describe the system modes of operation. Although manufacturers currently provide instructions for use of their equipment, this information may not be detailed enough to meet the proposed requirement, requiring that the Instructions for Users be revised. Most of the information should already be in the user manual provided with the equipment but not necessarily centrally located nor sufficiently detailed.

For the new dose display feature, the manufacturer will have to develop user instructions to accompany this new feature. The costs for developing the instructions and information will be included in the cost of the requirements for display of cumulative exposure time, patient dose rate and cumulative dose described below.

Cost to Regulatory Agencies: The cost to the FDA for this requirement is that associated with assuring the adequacy of the information after the regulations become effective. This will require additional effort in the review of manufacturer reports but not a significant effort per individual report. The annual cumulative effort associated with this is estimated to be no more than 0.1 FTE. This requirement will not impact state or local agencies.

Benefits: The primary benefit of these amendments is the provision of improved information to the users of fluoroscopic x-ray systems. Such information should allow for improved and safer operation by more informed operators.

Alternatives: Several alternatives to the proposed change were considered and dismissed as follows:

- Making no change to 1020.30(h).

  This alternative was dismissed as not providing the necessary information needed by users for safe operation of the equipment. Although one might argue that manufacturers would always provide sufficient and detailed information for these new features, this has not been the case to date. The new requirements for display of air kerma rate and cumulative air kerma require explanation for users to assure that the purpose and operation of these new features are understood.

- Requirement for additional, detailed information on potential patient dose from each specific mode of operation.

  This alternative was considered and rejected in view of the new requirement for display of air kerma rate and cumulative air kerma. For safe and appropriate use of fluoroscopic systems, users should be aware of the patient dose implications of each mode of operation selected. It had been proposed that manufacturers be required to provide specific dose information for each unique mode of operation. This requirement would provide users with detailed information on the patient dose impacts of the selected mode of operation prior to its use. Provision of this information would require extensive expansion of the user information and measurements and provision of data by manufacturers. In view of the requirement for display of air kerma information, this amount of detailed information was judged to be unnecessary.

- Another alternative to increasing the amount and type of information required to be provided to purchasers of fluoroscopic x-ray systems would be for the agency and state radiation control agencies to work cooperatively with medical professional associations, medical educational institutions and the manufacturers of fluoroscopic x-ray systems to improve the training and awareness of the users of fluoroscopic x-ray systems as to the proper operation and use of these systems. For this alternative to be effective, users of fluoroscopic x-ray systems would have to insist, as part of their purchase specifications, that manufacturers provide the detailed information that will be required by these amendments and manufacturers would have to provide adequate information and training for users in the operation of their systems, including descriptions of the new features required by these amendments. Without the proposed amendments, it is unlikely that all manufacturers will provide all of the information in sufficient detail to satisfy this need.

  FDA has no regulatory authority to require any actions of the state agencies or professional organizations but could work cooperatively to accomplish the goal of improved user knowledge. FDA has and will continue to work with states and professional organizations to

improve the use of fluoroscopic systems. However, this was judged to be most effectively accomplished if the users have the basic information proposed to be required in the proposed amendments. For this reason, this alternative was rejected.

Manufacturers' costs		
Nonrecurring costs	Estimate of 10 models of x-ray systems impacted initially for each of 20 manufacturers with a cost of $5,000 per model of system for revision of user instructions. 10 models x 20 manuf. X $5,000 per model = $1,000,000 cost	$1,000,000
Annual costs to manufacturers based on per system production costs	Per system cost of $20 for revised user instructions and 4,200 systems sold per year. 4,200 x $20 = $84,000	$84,000
Regulatory agency cost		
Nonrecurring FTE cost	None	
Other nonrecurring costs	None	
Annual FTE cost	Slight increase in annual FDA effort to review manufacturer initial reports for adequacy of information. Estimate 0.1 additional FTE x $117K / FTE = $11,700	$11,700
Other annual cost	None	

4. Increase Minimum Half-Value Layer for Most Diagnostic X-ray Systems

Requirement: These amendments will increase the minimum half-value layer (HVL) for radiographic and fluoroscopic x-ray systems to recognize changes in x-ray tube and x-ray generator technology over the last few decades. The amendments also prescribe an additional requirement for fluoroscopic x-ray systems incorporating x-ray tubes of high heat-load capacity. The manufacturers of these systems will have to provide a means, to be used at the user's option, of adding x-ray filtration over and above the amount needed to meet the proposed new minimum HVL values. This additional requirement is predicated on the assumption that x-ray tubes of high heat-load capacity to which it will apply are associated with interventional procedures where it is important to take measures to spare the skin of patients from high levels of radiation dose.

Those Affected: These amendments would apply to all radiographic and fluoroscopic x-ray systems and require changes for those systems currently marketed that do not meet the new requirements. Manufacturers who only reload previously manufactured x-ray tube housing assemblies will also be impacted in that they will have to assure that all newly reloaded x-ray tube housings meet the new requirements and certify the reloaded tube housings to the new requirements.

Cost to Manufacturers: This change to the Standard will impact manufacturers in two ways -- additional costs to meet the new requirement for minimum HVL, and for some fluoroscopic systems, the cost to provide the option of increasing the amount of beam filtration. The first requirement will apply to all systems, other than dental systems used with intraoral image receptors. However, many systems currently marketed are expected to meet the new requirement, as it is similar to the current international standard. For those systems that require modification to meet the new requirement, the extent of the modification is expected to be slight, simply involving an increase in the thickness of the material used as a filter with no significant increase in the cost of this material or manufacturing costs. It is estimated that these costs will be minimal for several reasons. First, test protocols and test instrumentation are already available for testing systems to this particular requirement. Second, the proposed changes bring the requirements of the Standard for x-ray beam quality to the same level as the current international standard. Thus, manufacturers of radiographic and fluoroscopic x-ray systems already have to meet the proposed requirement in order to market their products where the international standard is used outside the United States. Lastly, meeting the requirements can simply be met by increasing the thickness of the x-ray filtration currently in the x-ray beam. This modification of filter thickness is not expected to require significant redesign or changes to production. For systems that require a change in filter thickness, the manufacturer will have to modify the testing program used to assure compliance with the new requirements.

As an estimate of the upper limit to the cost resulting from this requirement, it is estimated that 20 manufacturers (about one half of all manufacturers of diagnostic x-ray systems) will have to make changes to add filtration (increase filter thickness) and modify testing programs. Each of these manufacturers are estimated to have 10 different models of collimators or tube-housing designs for which this change is necessary. It is estimated that for each model the one time cost

for these changes is no more than about $20,000. This results in an estimate of $4,000,000 as the upper limit to the one time cost to manufacturers for this change.

This requirement is not expected to add significant costs to those manufacturers that reload x-ray tube housing assemblies. Those manufacturers already use the specifications provided by the original manufacturers along with their own testing programs to assure that reloaded tube housing assemblies meet the standard. Based on compliance testing performed by FDA, only about 15 percent of the currently installed x-ray tube housing assemblies will not comply with the new requirement. Manufacturers reloading such x-ray tube housings will have to assure, as they currently do, that any reloaded tube housing assembly has adequate filtration to meet the requirements of the standard. Any modifications required to increase the added filtration for previously manufactured tube housing assemblies are expected to add a negligible cost to the reloading process over current activities.

For fluoroscopic x-ray systems incorporating x-ray tubes of high heat-load capacity, it is estimated that the cost to the manufacturer to provide a means, at the user's option, of adding x-ray filtration over and above the amount needed to meet the proposed new minimum HVL values will consist of the following:

- One time cost of the system redesign required to provide this feature, including the development of any new test procedures and user instructions for the feature.
- The per system cost for the additional feature resulting from additional material or production costs for each system produced.

A number of manufacturers of fluoroscopic systems already provide the means to add additional filtration on some of their models. These manufacturers will not have to make changes to meet this requirement for those systems. As an estimate of an upper limit for the cost of system redesign to meet this new requirement, it is estimated that there are ten manufacturers of fluoroscopic systems that have high heat capacity x-ray tubes that will require redesign to meet this requirement. It is assumed that each of these manufacturers will have ten models of systems requiring redesign and that the cost of this redesign is $50,000 per model. This results in an estimate of a one-time cost of $5,000,000 for this requirement.

There are currently about 650 new angiographic x-ray systems installed in the U.S. each year. Many of these are already equipped with the means for adding additional optional filtration. The exact number of fluoroscopic systems sold each year with the high heat capacity tubes is unknown, however the number of angiographic systems installed each year can provide an upper limit for this estimate of the number of systems to which this requirement will apply.

The added cost of a system provided with the means to use added filtration will depend on the method used to implement this feature. This can be as simple as providing a means for manual addition of filtration at the user's discretion or provision of an automatic or semi-automatic system. Such systems could be designed to insert additional filtration when this option is selected or to automatically insert filtration based on the system technique factors as determined by the automatic exposure rate control system. The optimum or preferred design for such

systems would assure that the system technique factors are automatically adjusted to optimize imaging performance for the selected imaging task.

The added material and manufacturing costs per system required to provide this feature will depend on the method chosen by the manufacturer. These costs are estimated to range from a few dollars per system for the totally manual means to several hundred dollars for the more complex systems. As an upper limit estimate, it is assumed that every one of the 650 angiographic systems installed annually will be equipped with an automatic system costing an additional $1,000. This results in an upper limit of $650,000 for the annual cost for this additional feature.

Cost to Regulatory Agencies: The cost to regulatory agencies is that associated with the implementation and enforcement of this regulation. These costs should be minimal as the minimum HVL requirement is currently evaluated in the field as part of the compliance testing program for radiographic and fluoroscopic x-ray systems. Minor revisions in the test protocols and action levels will be required. For the option of adding additional x-ray filtration, the initial enforcement can be a simple review of the manufacturer's initial report and visual inspection during system inspections after the date this regulation takes effect. This is estimated to require an initial effort by FDA of about 0.1 FTE and no significant increase of inspectional effort on an annual basis.

Benefits: The use of x-ray filtration to increase the quality or homogeneity of an x-ray beam through selective absorption of the low-energy photons has been a recommended practice for a long time. As mentioned above, the values of beam quality in the Standard are based on NCRP Report No. 33, which was originally published in 1968. The addition of either beam-hardening or K-edge x-ray filters can provide a significant reduction in the exposure, particularly skin exposure, to the patient.

Alternatives: Several alternatives to the proposed change were considered and rejected.

- No change to the HVL requirement –This alternative was rejected because it would not provide the improvements in beam quality necessary to assure reduced patient radiation exposures from modern x-ray systems with improved generators and increased x-ray tube output capabilities.

- Applying the requirement for additional, optional filtration to all fluoroscopic x-ray systems- This alternative was rejected as inappropriate because it likely would have an adverse impact on clinical performance of systems with lower capacity x-ray tubes.

Manufacturers' costs		
Nonrecurring costs	Redesign of systems to comply with minimum HVL requirement. Estimated 20 manuf. x 10 models per manuf. x $20K per model = $4,000,000	$4,000,000
Nonrecurring costs	Redesign of systems with high heat load to permit additional filtration. Estimated 10 manuf. x 10 models per manuf. x $50K per model = $5,000,000	$5,000,000
Annual costs to manufacturers based on per system production costs	650 systems per year x $1,000 cost per system = $650,000	$650,000
Regulatory agency cost		
Nonrecurring FTE cost	0.1 FTE x $117K = $11,700	$11,700
Other nonrecurring costs	None	
Annual FTE cost	None	
Other annual cost	None	

5. Change in the Requirement for Fluoroscopic X-ray Field Limitation and Alignment

Requirement: This amendment will result in improved x-ray field limitation for fluoroscopic x-ray systems. Under the current requirements, worst-case values of geometrical efficiency of 50 percent to 70 percent are possible under typical geometrical and operating conditions of fluoroscopic systems. Geometrical efficiency is defined as the ratio of the visible area of the image receptor divided by the area of the x-ray field. Thus, geometrical efficiencies of 50 percent to 70 percent mean approximately 50 percent to 30 percent of the radiation incident on the patient is not used to form an image and therefore results in unnecessary exposure. The proposal will require geometrical efficiencies of 80 percent or more for all fluoroscopy systems. Although the field limitation requirements for fluoroscopic equipment in the current Standard are based on the presence of an x-ray image intensifier that is inherently circular, additional requirements are also appropriate for newer imaging systems that do not use an x-ray image intensifier tube as the fluoroscopic image receptor. These image receptors are inherently rectangular. For these rectangular image receptors, the proposal is to apply the current requirements of the standard for x-ray field limitation which were developed for general-purpose radiographic systems that use rectangular image receptors. These requirements will result in worst-case values of geometrical efficiency of greater than 75 percent for systems with rectangular image receptors under typical geometrical and operating conditions of fluoroscopic systems.

Those Affected: These amendments would apply to all fluoroscopic x-ray systems.

Cost to Manufacturers: For fluoroscopic systems using rectangular image receptors, the requirements proposed are the same as the current requirements for general-purpose radiographic systems**.** Since collimators are available to meet these requirements and since all of the new fluoroscopic systems with rectangular image receptors that have been cleared for marketing to date by FDA have been designed to provide this type of beam limitation, the proposed requirement for beam limitation for fluoroscopic systems with rectangular collimation will not add significant new costs for modification of existing designs.

For circular image receptors, the increase in the required efficiency for image receptors with diameters less than or equal to 34 cm will most likely cause changes in the manner in which existing designs of collimators are adjusted in order to meet the new requirements. This change will require only minor changes to the manufacturer's assembly and testing procedures. In a few cases, some redesign may be required.

Only the requirement for an increase in the efficiency of beam limitation for circular image receptors will add significant additional costs for the manufacturer. For fluoroscopy systems using circular image receptors the intent of the amendment is to promote the incorporation of continuously adjustable, circular collimators and/or circular apertures along with adjustable rectangular collimators.

For circular image receptors the new requirements could be met through the use of less complex, currently available, rectangular collimators which are adjusted to provide "under-framing" of the x-ray beam. Obviously, the cost to the manufacturer will depend on their approach to meeting

the requirement. If the approach is to use the currently available, rectangular collimators and under-frame, the cost will be minimal as it would only involve a re-calibration of the existing collimator and a change to installation and testing procedures. It should be noted that the requirements in the current IEC international standard require that the length and width of the x-ray field be less than the diameter of the maximum visible area of the image intensifier. Manufacturers meeting this requirement would most probably meet the proposed amendment without any changes on their fluoroscopic systems.

For systems with image-receptor area of diameter greater than 34 cm, either a similar change in system adjustment procedures or a redesign of the collimation systems will be required. If a redesign is required, additional design and production change costs must be recovered over the life of the product design. This redesign may be required for systems with large circular image receptors that do not currently utilize collimation to produce a near-circular x-ray field.

For manufacturers implementing design changes to their collimators such as to provide nearly circular x-ray fields to comply with the new requirement, this addition to the regulations will cause recurring and non-recurring costs to the manufacturer. The non-recurring costs are the one-time costs associated with any changes to system design required and the development of new test protocols. This cost will occur regardless of the number of systems eventually produced. The recurring cost is the cost for parts and production associated with each system after the non-recurring costs are absorbed.

The cost of this requirement cannot be estimated precisely as it will depend on the choices made by manufacturers regarding readjustment versus redesign. In addition, specific information on the collimator designs provided by each manufacturer that would permit estimation of whether readjustment is feasible are not currently available. An upper bound on this cost can be estimated using the larger of the following estimates.

Cost to readjust current designs It is estimated that each of 20 fluoroscopic system manufacturers will develop modified procedures for collimator adjustment and that each manufacturer has five different collimator models requiring such adjustment procedures. It is further estimated that for each model the manufacturer will incur a cost of $20,000 to implement the new procedures in manufacturing and assembly. This would result in a non-recurring cost to manufacturers of a total of $2,000,000 for development of revised adjustment procedures.

Cost to redesign collimators If manufacturers choose to redesign all of their collimators to provide variable circular collimation, an upper bound to this cost is also estimated by considering 20 manufacturers with five different collimator models requiring redesign. The total redesign cost for each model are expected to be less than $50,000 per model, resulting in an upper bound on the cost to redesign of $5,000,000.

If fluoroscopic system collimators are redesigned to meet the requirements for improved radiation efficiency, these redesigned collimators may increase the cost of the collimator due to increased complexity of parts or production. An upper limit for these recurring costs may be estimated by assuming that all of the stationary fluoroscopic systems installed each year are provided with redesigned collimators, increasing the cost per system by $2,000 over current

costs. It is likely that manufacturers will not redesign all collimators and choose to satisfy the proposed requirements by readjustment of some collimators. It is not possible to predict for which systems this will occur. It is more likely that redesign will occur for the systems with larger size image receptors. Stationary fluoroscopic systems are more likely to be equipped with the larger image receptors, while mobile fluoroscopic systems typically have the smaller image receptors. For the purpose of this estimate, it is assumed that all new stationary fluoroscopic systems are provided with a redesigned collimator. From the FDA records on new system installations, there are about 2,500 stationary fluoroscopic systems installed each year, resulting in an annual cost of $5,000,000 from the added cost associated with redesigned collimators.

Cost to Regulatory Agencies: The cost of this requirement to the FDA will be that associated with the implementation and enforcement of this regulation. These costs should be relatively minor as the field limitation requirement is currently evaluated during compliance testing by the agency. However, some revisions in the test protocol and action levels will be required to test to the new requirement. In addition, there will also be costs associated with training inspectors to test to the new requirement. It is estimated that these activities will require a one time effort of about 0.4 FTE by the FDA.

Benefits: A fundamental principle of radiation safety in x-ray system design is to limit the area of the x-ray field (the cross-sectional area of the x-ray beam) to be no larger than necessary to adequately cover and expose the image receptor active area. This limits the amount of radiation that impinges on the patient but is not used to form the image. A reduction in unnecessary patient exposure is the basis for all of the x-ray field limitation and alignment requirements in the performance standard. Any radiation falling outside the visible area of the image receptor provides no useful diagnostic or visualization information and therefore represents unnecessary patient exposure. As mentioned above, the current requirements allow a worst-case value of geometrical efficiency of 50 percent under typical geometrical and operating conditions on fluoroscopic systems. This value of geometrical efficiency means approximately 50 percent of the radiation incident on the patient is not used to form an image. The proposal will require geometrical efficiencies of 80 percent or more for all x-ray fluoroscopy systems. For this worst-case condition, the proposal results in a reduction of unnecessary radiation in the order of 60 percent. Thus, considering worst-case values not as dramatic as 50 percent, the proposal can result in the reduction of unnecessary radiation of anywhere from 60 percent to 0 percent depending on the initial geometrical efficiency associated with the fluoroscopic system.

Alternatives: Several alternatives to the proposed change were considered and rejected.

- No change to the field limitation requirement – This alternative was rejected because it would not provide the improvements in field limitation necessary to decrease the amount of unnecessary radiation incident on the patient under current requirements.

- Implementing a more stringent requirement to require that the x-ray field area never exceed the area of the image receptor – This option would provide increased radiation protection but would be technically very difficult to accomplish as it would require significantly more stringent and costly design tolerances. Such a requirement would likely be met by adjusting the

x-ray field to be smaller that the image receptor. This could adversely impact the amount of clinical information available in the images.

Manufacturers' costs		
Nonrecurring costs	(1) Development of procedures to readjust collimators. 20 manuf. x 5 models per manuf. x $20,000 per model = $2,000,000 **(or)** (2) Redesign of collimators. 20 manuf. x 5 models per manuf. x $50,000 per model = $5,000,000	$5,000,000 **(larger of the options)**
Annual costs to manufacturers based on per system production costs	2,500 stationary systems per year x $2,000 increased cost per system = $5,000,000	$5,000,000
Regulatory agency cost		
Nonrecurring FTE cost	0.4 FTE x $117K = $46,800	$46,800
Other nonrecurring costs	None	
Annual FTE cost	None	
Other annual cost	None	

6. Change to limits on maximum entrance air kerma:

Requirement: The current requirement in the Standard establishing a maximum limit on air kerma rate (AKR) and describing the exception to this limit during the recording of images will be modified to extend the limit to apply to the recording of images using an analog recording device such as a video tape recorder regardless of whether the x-ray exposure is pulsed or not. The current reference to a pulsed mode of operation will be removed. The exception to the limit on maximum AKR will continue to apply to the recording of images from the fluoroscopic image receptor except for recording using an analog video recorder and without reference to whether or not the x-ray exposure is pulsed.

Those Affected: Any manufacturer providing an analog video image recording feature or a fluoroscopic facility desiring to add such a capacity. The proposed requirement will not prevent use of such a recording means but will require that the maximum AKR be limited.

Cost to Manufacturers: Information is not available to permit an estimate of the cost of this amendment, although one can argue that the costs will not be significant. At the most, the requirement will require that systems be adjusted to meet the maximum EAKR limit if provided with a high level control and an analog image recording device. Fluoroscopic systems are normally equipped with a means to adjust the radiation output rate in each mode of operation in order to meet existing limits and to properly limit the radiation output to acceptable levels. Establishment of new adjustment procedures to limit maximum AKR could be required for any system equipped with an analog recording device. Such changes to an adjustment procedure are not expected to result in significant costs.

Costs to Regulatory Agencies: This requirement is not expected to add significant costs for the FDA associated with administration and enforcement of the Standard. The compliance test procedures already test for compliance with maximum AKR and can be readily modified to include a check of any analog recording mode.

Benefits: This amendment will assure that the radiation output of fluoroscopic systems equipped with analog video recording devices is maintained or limited to the same radiation output as required for real-time, non-recorded fluoroscopy. This will prevent the practice of using an analog video-recording device to establish a recording mode and thereby avoiding the limitation on maximum entrance exposure rate applicable to real-time fluoroscopy without recording under the current Standard. The practice of adding an analog video recording device and increasing the radiation output for the system, as a less expensive alternative to replacing a degraded imaging system, has been reported. Such a practice results in patient radiation exposures larger than necessary during routine fluoroscopy. There is no information available on the extent of this practice or the number of installations of this type which the proposed requirement would be expected to prevent, so the magnitude of the radiation reduction cannot be estimated.

Alternatives: Two alternatives were considered regarding this amendment and rejected.

- No change to the current requirement – This alternative would not address the concern about the practice of using the installation of an analog video recording device as a means to avoid the limitation on entrance exposure rate and the resulting increased patient radiation exposure that can result from this practice. This alternative was rejected as not providing the level of radiation protection appropriate to prevent unnecessary patient exposure.

- Establishment of maximum air kerma rate limits for all fluoroscopic recording modes – This alternative, although considered to be desirable, was not possible because there is not a current consensus as to the appropriate exposure level required for all recording modes. The level of radiation exposure rate during recording of fluoroscopic images directly impacts the quality of the image. There is not a current consensus as to how to appropriately characterize fluoroscopic image quality or to determine the minimum acceptable quality for recorded images for the various recording modes, and therefore the required exposure level.

Manufacturers' costs	No significant costs expected	
Nonrecurring costs		
Annual costs to manufacturers based on per system production costs		
Regulatory agency cost	No significant costs expected	
Nonrecurring FTE cost		
Other nonrecurring costs		
Annual FTE cost		
Other annual cost		

7. Requirement for Minimum Source–Skin Distance for Small "C-Arm" Fluoroscopic Systems

Requirement: The proposed changes would label C-Arm fluoroscopic systems with source-image receptor distance (SID) of less than 45 centimeters as a special type of system designed only for extremity use. The amendment would also require that the minimum source-skin distance (MSSD) for these systems be at least one half of that required for the larger format C-Arm systems. This amendment will recognize in the Standard the performance previously permitted for these types of systems through the granting of several variances from the Standard.

Those Affected: The proposed amendment will affect C-Arm systems with SID less than 45 centimeters. The purpose of having a MSSD equipment performance requirement is to protect the patient and provide for skin dose sparing; that is, to limit the dose that may be delivered to the skin as a result of the patient's being too near the x-ray source. The proposed amendment affects manufacturers of small C-Arm systems whose SIDs are less than 45 cm and that do not currently meet the proposed requirement for MSSD.

Cost to Manufacturers: The proposed amendment will impact manufacturers of small C-arm systems whose current design does not meet the parameters for MSSD and SID established by the amendment. There are some current models of C-arm systems with SIDs slightly larger than 45 cm (in the range of 45 to 48 cm) that would require redesign to take advantage of the smaller MSSD allowed for systems with SIDs less than 45 cm. This redesign would involve changes to the support structure for the x-ray source and the image receptor to change the SID and possibly adjustments to the beam-limiting device to assure appropriate x-ray field size at the image receptor for the new ID. These changes would result in one-time costs associated with implementing the new designs and would not add significantly to the cost of materials or production for individual systems meeting the new designs.

An upper limit on the redesign costs can be estimated by assuming that the approximately three current manufacturers of small C-arm systems each must redesign their current models and that this redesign effort and change to production will have one-time costs of $50,000 per model, resulting in an estimate of $150,000 in total manufacturer costs.

Cost to Regulatory Agencies: This amendment is not expected to result in any significant costs to FDA as it will only result in a different system design and description by the manufacturer in the initial reports submitted by manufacturers, not a substantial increase in the information submitted in the reports or the effort required by FDA to review this information. Slight modifications may be required in the description of the compliance testing procedures to instruct inspectors on how to review the new designs during compliance testing. These additional efforts are expected to require at most 0.2 FTE of FDA resources.

Benefits: The primary benefit of these amendments is the elimination of the need for manufacturers to request a variance and the costs associated with that process. Clarification of how the standard applies will eliminate confusion or doubt about the requirements for systems with small SID. The amendment will recognize in the performance Standard the same performance that has been heretofore permitted under variances granted to manufacturers of systems with smaller MSSD than required by the Standard. Systems manufactured under these

variances were determined to provide equivalent radiation safety as the Standard. The proposed amendments will make it clear to manufacturers the conditions under which systems with smaller MSSD will be allowed and remove any uncertainty in development of new products and the added expense associated with requesting and justifying a variance.

Alternatives: Two alternatives were considered and rejected.

- No change to the current requirement - This would require the continued submission and review of variance requests for systems that do not conform to the current requirements. This alternative was rejected as inappropriate as it would continue the unnecessary costs to manufacturers and the agency associated with the submission and processing of requests for variance from the current Standard.

- Prohibition of systems with SIDs that do not conform to the current standard - This alternative would prohibit systems that have clinical utility and can be used safely with appropriate controls.

Manufacturers' costs		
Nonrecurring costs	Three manuf. x $50,000 redesign cost per manuf. = $150,000	$150,000
Annual costs to manufacturers based on per system production costs	No significant costs anticipated	
Regulatory agency cost		
Nonrecurring FTE cost	0.2 FTE x $117K = $23,400	$23,400
Other nonrecurring costs	No significant costs expected	
Annual FTE cost	No significant costs expected	
Other annual cost	No significant costs expected	

8. Requirements for Display of Fluoroscopic Irradiation Time, Air Kerma Rate and Cumulative Air Kerma

Requirement: These amendments would require that all newly manufactured fluoroscopic equipment display to the fluoroscopist at the fluoroscopist's working position values of the total irradiation time, entrance air kerma rate, and cumulative air kerma during use of the equipment for a procedure. Additionally, there is a requirement that an audible signal sound every five minutes during the exposure. The current requirement for a re-settable exposure timer with a five minute maximum interval would be removed.

Those Affected: These amendments are proposed to apply to all fluoroscopic systems manufactured after the effective date and will therefore impact all manufacturers. FDA will also be impacted by the need to modify the compliance testing program.

Cost to Manufacturers: These amendments will require both modification of the design of fluoroscopic systems and the provision of additional features on systems that will increase the cost for each systems produced. The cost anticipated to provide the display of total irradiation time and an audible signal are expected to be modest on a per systems basis, and these estimates will be included in the costs estimated for display of values of the entrance air kerma.

There are several approaches that manufacturers might take in developing systems that will meet the proposed requirements. There is currently available at least one add-on accessory system that, with minor modification, could be used to provide the information required by this proposed amendment. Such a system is available for about $6,000 currently as a low volume specialty item from a third-party supplier. Thus, it is estimated that the additional cost per system resulting from these requirements will be less than $4,000 per system if such systems are produced in volume. Using the annual installation estimate of 4,200 fluoroscopic systems per year results in an annual cost of $16,800,000 for the added materials and production costs for these systems.

There will also be non-recurring costs to manufacturers to develop the required redesign of fluoroscopic systems to meet these new requirements. An upper limit to these costs can be estimated by assuming that each of the approximately 20 different manufacturers of fluoroscopic x-ray systems experiences a redesign cost of $500,000 for all of their system models. This leads to an upper bound in the non-recurring costs of $10,000,000 for these requirements.

Cost to Regulatory Agencies: The costs for FDA associated with these requirements will be the one-time costs associated with developing modifications to the compliance test procedures to evaluate the entrance air kerma display feature, to develop new initial report review criteria, to revise initial report guidance for manufacturers and to train FDA inspectors in the new compliance testing procedures. These efforts are estimated to require about 4.0 FTE to accomplish.

The review of manufacturers initial reports and additions to the compliance testing procedures to evaluate the new features required by these amendments will also require additional FDA staff

time on an ongoing basis. It is estimated that this will require no more than about 2 FTE per year on a continuing basis.

Benefits: The benefits of the requirements are anticipated to be a better, more informed use of fluoroscopic x-ray systems by physicians who are equipped with the additional information provided by these new features during a fluoroscopic procedure. The additional information will enable the physician to be better aware of the level of radiation exposure to which the patient has been subjected and will allow informed decisions to be made regarding the technique factors and modes of operation used during a procedure. These factors are expected to lead to a reduction in patient radiation exposures and greatly reduce the probability of the occasional serious radiation-induced skin injury that currently occur. It is difficult to estimate the magnitude of this potential dose reduction or injuries that will be avoided as a result of these features.

Alternatives: Several alternatives were considered to these requirements and rejected.

- No change to the current requirement – This alternative would not address the need that has been recognized to provide users of fluoroscopic x-ray systems with additional information and assistance to reduce radiation exposure and to avoid radiation injuries. As many fluoroscopic procedures now require extended period of exposure, it has become widely recognized that users need tools that will enable them to be aware of the amount and extent of fluoroscopic exposure during the procedure so that appropriate clinical decisions can be made.

- Rely on a voluntary international standard – A voluntary international standard is currently under development for x-ray systems designed for interventional radiology. FDA has actively participated in the development of this standard. However, this international standard is not yet finalized, will not apply to all fluoroscopic x-ray systems and will not provide assurance that all fluoroscopic x-ray systems sold in the U.S. have the radiation safety features thought to be necessary and incorporated in the voluntary standard and in these proposed amendments.

- Require display of information related to "dose-area product" rather than air kerma – This approach to the type of information to be displayed was considered and rejected. The entrance air kerma rate and cumulative air kerma were judged to be more relevant to the need to provide immediate information to the user that is related to the potential for skin injuries, to thresholds for fetal mental retardation when patients may be pregnant, and to the risk for radiation-induced cancer morbidity and mortality.

Manufacturers' costs		
Nonrecurring costs	20 manuf. x $500,000 per manuf. = $10,000,000	$10,000,000
Annual costs to manufacturers based on per system production costs	$4,000 per system x 4,200 systems per year = $16,800,000	$16,800,000
Regulatory agency cost		
Nonrecurring FTE cost	4.0 FTE x $117K = $468K	$468,000
Other nonrecurring costs		
Annual FTE cost	2.0 FTE x $117K = $234K	$234,000
Other annual cost		

9. Amendment to Require "Last-Image Hold" Capability on All Fluoroscopic Systems

Requirement: This amendment will require that all fluoroscopic x-ray systems be provided with means to temporarily display the image acquired at the end of each fluoroscopic exposure sequence.

Those Affected: This amendment would apply to all manufacturers of fluoroscopic x-ray equipment.

The amendment will affect all manufacturers of fluoroscopic equipment who do not now provide the capability for last image hold (LIH) on all equipment models. A review of the World Wide Web sites of eleven major manufacturers of fluoroscopic systems was made to determine the proportion of currently marketed fluoroscopic x-ray systems that provide the LIH capability as a feature or as an option. Of the eleven manufacturers, only one of the smaller firms does not describe a LIH feature as being available. Of the total of 70 models of currently marketed fluoroscopic systems from these eleven manufacturers, the web sites describe 64 of these as having LIH available as a standard feature or as an option. The other manufacturers of fluoroscopic systems not included in this review of web sites market only a very small fraction of the systems sold. It is recognized that to a very large extent most of the high-end fluoroscopic equipment now being offered has this capability or has it available as an option. On the other hand, low-end fluoroscopic devices, such as small portable C-Arms do not always have such capability. As a result, these will be the most affected by this requirement.

Cost to Manufacturers: The cost of this amendment will occur to manufacturers that do not currently provide LIH capability on their systems. These costs will consist of the non-recurring costs to redesign systems and production to provide this feature on all systems. There will also be recurring, per system costs associated with the added expense of components and production to provide LIH for each system that currently does not provide this feature.

An upper limit to the non-recurring costs can be estimated by assuming that no more than 10 manufacturers will be required to develop new designs for LIH and that each of these redesign efforts will cost $100,000 per manufacturer, resulting in an upper bound for this cost of $1,000,000.

The proportion of fluoroscopic systems currently marketed that are provided with a LIH capability is not known; however this is an increasingly common feature. The majority of systems currently marketed are thought to be provided with this feature. An upper limit on the annual costs to provide this feature on systems that otherwise would not be equipped with LIH can be made by assuming that one-half of the systems installed annually (about 2,100 systems) do not currently have LIH and would require that this feature be added. This is very likely a significant overestimation of the number of systems that will require the addition of LIH, and will therefore provide an upper limit on the cost of this feature. It is estimated that the additional component and production costs per system for this feature will be less than $2,000 per system. Thus, the addition of this feature would result in an additional cost of no more than $4,200,000 annually.

Cost to Regulatory Agencies: The cost of this requirement for the FDA is expected to be minimal. The review of initial reports will be modified to include review for this feature and the enforcement can be simply the addition of a check for the presence of the last-image hold capability on fluoroscopic systems manufactured after the date this regulation takes effect. It is estimated that these efforts will require a one-time effort of 0.2 FTE to modify procedures.

Benefits: The primary benefit of this capability is the reduction of total x-ray exposure to a patient (and scatter to the user) during an examination or procedure that uses fluoroscopy.

Experience with fluoroscopic systems indicates that often the user needs to examine a static image for a period of time to study what is being presented and/or to decide what should be the next step in the ongoing procedure. Without last-image hold, the patient must be irradiated for the entire time these analyses are being performed. With last-image hold, no radiation is being delivered to the patient during these periods of review and analysis, and the analysis can be performed more thoroughly without fear of overexposure. Minor benefits are less wear on the x-ray tube and less power consumption.

Alternatives: Two alternatives were considered to these requirements and rejected.

- No change – This alternative was rejected as not providing the reduction in radiation exposure that will be possible through the proposed requirement. The advances in computer technology make the provision of the LIH feature very affordable and a common feature on many current systems.

- Applying the proposed requirement only to certain types of fluoroscopic systems, such as systems designed for interventional procedures – This alternative was rejected because the dose reduction potential of this requirement was considered appropriate for all types of fluoroscopic systems and to be feasible at minimal cost.

Manufacturers' costs		
Nonrecurring costs	Redesign by 10 manuf. at $100,000 per manuf. = $1,000,000	$1,000,000
Annual costs to manufacturers based on per system production costs	2,100 systems annually x $2,000 per system = $4,200,000	$4,200,000
Regulatory agency cost		
Nonrecurring FTE cost	0.2 FTE x $117K = $23.4K	$23,400
Other nonrecurring costs		
Annual FTE cost	Minimal	
Other annual cost		

Summary of costs

The table below summarizes the total non-recurring and recurring costs that are estimated to result from the proposed amendments. The total non-recurring costs for manufacturers and FDA are estimated to be less than about $26,150,000 and $602,600 respectively. These non-recurring costs for manufacturers will be recovered in the increased prices of fluoroscopic x-ray systems and will likely be spread over the life of the produced models. Assumption of a period of 10 years for manufacturers to recover these costs, which are primarily due to redesign, will result in an additional annual cost for fluoroscopic x-ray systems of about $3,723,000 to recover these one-time costs. Combining this annual estimate with the maximum estimate of annual recurring costs for manufacturers of about $26,650,000 gives an upper limit estimate of $30,457,000 for the annual cost to manufacturers of these proposed amendments.

Estimate of total costs

Section	Non-recurring costs to Manufacturers ($ millions)	Non-recurring costs to FDA ($ thousands)	Annual costs to Manufacturers ($ millions)	Annual costs to FDA ($ thousands)
1.	none	5.9	none	none
2.	none	23.4	none	none
3.	1.0	none	0.084	11.7
4.	9.0	11.7	0.650	none
5.	5.0	46.8	5.0	none
6.	none	none	none	none
7.	0.150	23.4	none	none
8.	10.0	468.0	16.8	234.0
9.	1.0	23.4	4.2	none
Total	26.150	602.6	26.734	245.7