RESOURCE MANUAL

FOR

COMPLIANCE TEST PARAMETERS

OF

DIAGNOSTIC X-RAY SYSTEMS

Reprinted

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Diagnostic Devices Branch

Division of Enforcement I

Office of Compliance

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PREFACE

This manual was originally prepared by the X-Ray Products Branch, Division of Compliance, Office of Radiological Health for the convenience and use by personnel of the Food and Drug Administration and contract states who perform compliance surveys of diagnostic x-ray systems.

The manual provides information on each of the performance requirements that are evaluated under the "Routine Compliance Testing for Diagnostic X-Ray Systems" program. The purpose of this manual is to aid the investigator in gaining a fuller understanding of the basic philosophy and rationale of the test parameters such that the task will be less repetitive in nature and the investigative approach more intuitive.

The descriptions are limited to those test parameters that require a measurement of variability, thus excluding functional tests or observations that are performed concomitant with the full survey. The discussions of the test parameters are of a general nature, but occasionally provide specific emphasis on areas that are sometimes troublesome to the investigator or have resulted in false noncompliances due, in part, to a misunderstanding of the test objective. The manual is not a compilation of OC policy guides or interpretations, nor is it a step-by-step procedure manual or survey checklist. It is simply an instructional tool for the investigator's own edification.

Information on specific test procedures, policy guides, and interpretations can be obtained from the Diagnostic Devices, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850   (301-594-4591).

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BEAM QUALITY (1020.30(m)), 21 CFR Subchapter J.

I. Objective of Requirement:

To ensure within acceptable limits that an x-ray machine has sufficient filtration in the beam to produce an HVL appropriate for the designed operating kVp.

II. Performance Standard:

A. Requirement:

   The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in the chart below. "Specified dental systems" refers to any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; "Other x-ray systems" refers to all other x-ray systems subject to this requirement.

X-ray tube voltage (kilovolt peak)		Minimum *HVL (mm* of Al)	
Designed operating range	Measured operating potential	Specified dental systems	Other X-ray systems
Below 50	30	1.5	0.3
	40	1.5	0.4
	49	1.5	0.5
50 to 70	50	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

If it is necessary to determine such a half-value layer for a tube potential not listed in the table, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that the minimum filtration needed to achieve the beam quality requirements is in the useful beam during each exposure.

Note: In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlock with the kilovoltage selector. This will prevent x-ray emission if the minimum required filtration is not in place.

B. Applicability:

Applies to any diagnostic radiographic or fluoroscopic x-ray machine.

III. Special Measurement Requirements Incorporated in the Performance Standard:

For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

IV. Discussion:

A. X-ray machines produce a continuous spectrum of x-rays with energies ranging from near zero up to some maximum value, determined by the selected tube potential (Fig. 1). Note that the largest number of x-rays occurs at an energy much lower than the maximum. The energy at which this occurs is known as the "effective energy" of the x-ray beam. This means that the beam's physical properties are comparable to monoenergetic x-rays of that energy. A good estimate of the effective energy of an x-ray beam is approximately 1/3 of the maximum energy.
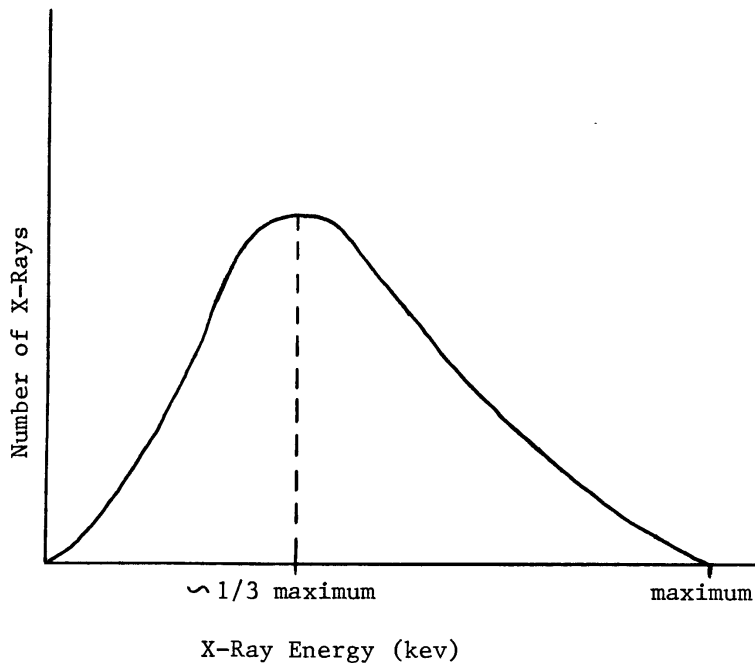
X-Ray Energy (keV)

Figure 1.

This spectral distribution is not ideal for diagnostic radiology for two reasons. First, the lower energy x-rays, not having sufficient energy to pass into or through the patient, do not contribute any diagnostic information on the film or image receptor, but do result in unnecessary skin exposure since the x-rays are energetic enough to penetrate the skin.

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Second, when the radiographer looks at the x-ray image, he is seeing the contrast between various constituents in the body (i.e. bone and muscle). The contrast between these constituents varies greatly, depending on the x-ray energy producing the image. For example, at one energy, the contrast between two types of soft tissue is maximum, while at another energy it is much less. The same can be said for the contrast between other bodily tissues including bone, muscle, fluid, and air-filled organs. Thus, the type of diagnostic information needed dictates the x-ray energy required. Using an x-ray beam with wide spectral energy, as in Figure 1, for a particular procedure would not yield as good an image as an x-ray beam "tuned" to a more narrow and appropriate energy range. Fortunately, there is a simple method to handle both problems simultaneously, by the use of filtration. By placing material in the path of the x-ray beam, the lower energy x-rays are eliminated, while the effective energy is increased (see Figure 2).
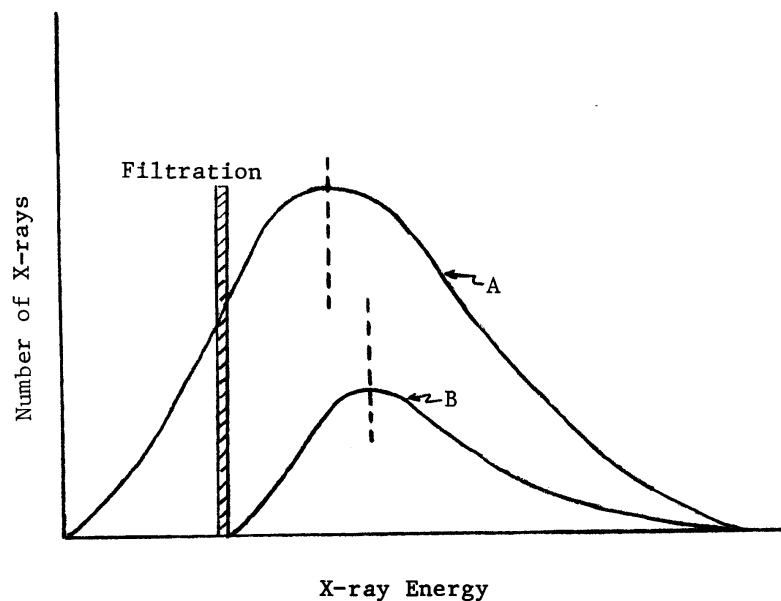

Figure 2.

In the figure, curve A is an x-ray spectrum without added filtration, and curve B is the same spectrum with the beam filtered. Note that the filtration has cut out a significant percentage of low energy x-rays and that the lowest energy is now some value well above zero. Note also that the spectrum peak has been shifted towards the higher energies such that the effective energy is greater than before. By continuing to add more filtration, the effective energy could theoretically be made to approach the maximum kVp with elimination of all but the most energetic x-rays. However, as can be seen in the figure, the filtration reduces the total number of x-rays and continuing to add filtration will finally result in too few to produce a useful image. Therefore, the amount of filtration placed in the beam is a compromise among the three effects (i.e., low energy x-ray elimination, increased effective energy and reduction in number of x-rays).

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B. The simplest way to assure that enough filtration is provided would be to require a certain

minimum amount to be in the x-ray beam. However, this approach is unsatisfactory for two reasons. First, the filtration is usually designed as an integral part of the tube housing assembly and beam-limiting device, making it difficult or impossible to measure the amount of filtration present without some disassembly. Second, since the amount and type of filtration in an x-ray machine is a matter of design rather than performance, a requirement for minimum filtration would not be in keeping with the intent of the federal regulations which are strictly performance specifications. Thus a requirement is needed that is performance oriented but still assures that enough filtration is provided. This is accomplished through the concept of "beam quality". As the effective energy of an x-ray beam is increased (i.e., reducing the number of low energy x-rays by adding filtration), the penetrability is also increased. Penetrability refers to the range of x-ray beams in matter; higher energy x-ray beams are able to penetrate matter farther than low-energy beams. The penetrability, or penetrating power, of an x-ray beam is called the "x-ray quality". X-ray beams with high penetrability are termed high quality, or "hard" beams, while those with low penetrability are of low quality and are called "soft" beams. In radiology, the quality of x-rays is characterized numerically by half-value layer (HVL). The HVL of an x-ray beam is the thickness of absorbing material necessary to reduce the x-ray intensity to one-half its original value. By measuring the HVL instead of filtration, it does not matter what or how much material is used as a filter, as long as a sufficient beam quality is obtained. The advantage of using HVL is that it is a performance characteristic of the x-ray machine and allows the manufacturer freedom of design for any type of filtration as long as the x-ray beam quality is of the specified HVL. One additional advantage is that the HVL can be measured quickly using non-invasive techniques, as will be described in paragraph D.

C. Although any material may be used for filtration, aluminum is the most common because it is lightweight, inexpensive, easy to machine, and has desirable absorption properties for diagnostic x-ray energies. Thus the HVL requirement is specified in terms of millimeters of aluminum equivalence. Furthermore, since aluminum can vary in impurity content, the federal performance standard defines the type of aluminum upon which the requirements are based. Note that the table in paragraph II specifies the minimum HVL for a given Designed Operating Range kilovoltage. The values in the table were obtained from the National Council on Radiation Protection and Measurements (NCRP) Report No. 33, issued February 1, 1968. The NCRP is a nonprofit corporation chartered by Congress in 1964 to study the effects of radiation and make recommendations as to its safe use. A number of these recommendations have subsequently become state and federal regulations including the table of half-value layers. The values were determined empirically and, within each kVp operating range, are fairly linear with respect to kVp. For example, at 90 kVp the required HVL is 2.5 mm Al. The filtration in a machine meeting this requirement will have an HVL of 2.5 mm Al at 90 kVp and (with the same filtration) an HVL of 3.5 mm Al at 130 kVp. Again, for kVp values not found in the table, simple linear interpolation or extrapolation can be used to compute the required HVL.

D. Testing for HVL is performed by making successive exposures with increasing thicknesses of aluminum sheets interposed in the beam. A plot on semilog paper (absorption is exponential) is made with the exposure reading on the y-axis versus the aluminum thickness on the x-axis (see Figure 3).
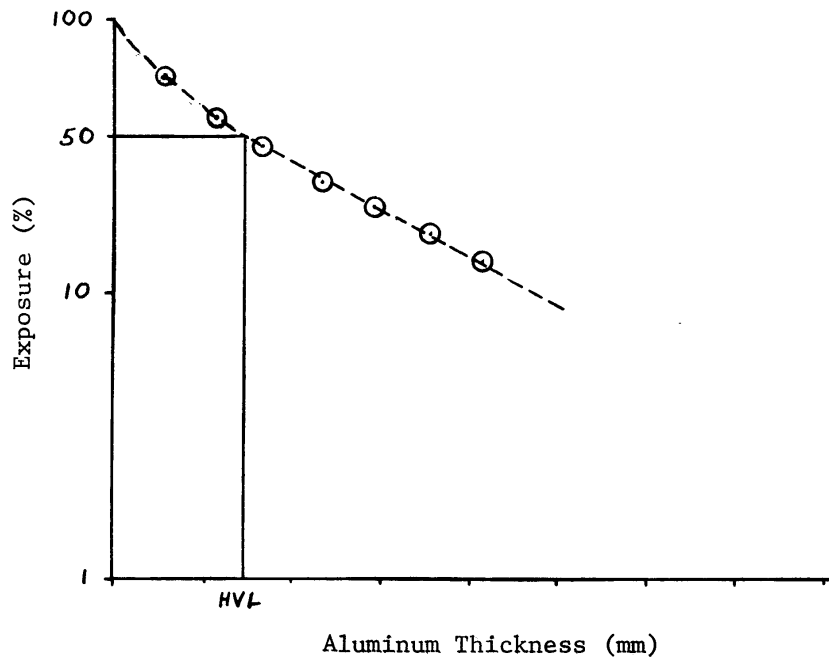

Figure 3.

The HVL can be determined by finding the 50% value of the initial exposure on the y-axis and then across to the curve and down to the x-axis for the equivalent aluminum thickness.

V. Summary Guidelines:

A. For systems that provide adjustable filtration, testing will be done with the minimum filtration that will still allow an exposure at the selected kVp.

B. The system being tested must be reproducible.

C. For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

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I. Objective of Requirement:

To ensure that unintentional high fluoroscopic entrance exposure rates are not produced.

II. Performance Standard:

A. Requirement for fluoroscopic equipment manufactured before May 19, 1995:

(1) Fluoroscopic equipment which is provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute (10 R/min) at the point where the center of the useful beam enters the patient, except: (i) during recording of fluoroscopic images, or (ii) when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 R/min at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activating the high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal, audible to the fluoroscopist, shall indicate that the high level control is being employed.

(2) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 R/min at the point where the center of the useful beam enters the patient except: (i) during recording of fluoroscopic images, or (ii) when an optional high level control is activated. Special means of activating the high level controls shall only be operable when continuous manual activation is provided by the operator. A continuous signal, audible to the fluoroscopist, shall indicate that the high level control is being employed.

B. Applicability:

Applies to any fluoroscopic x-ray machine manufactured before May 19, 1995, operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of 1020.30(h)(3).

III. Special Measurement Requirements Incorporated in the Performance Standard:

Compliance shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.

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

(3) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

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

IV. Discussion:

A. Fluoroscopy is continuous x-ray exposure at low mA techniques for the purpose of dynamic or "live time" diagnosis. Fluoroscopic examinations can be lengthy, increasing the potential for a high radiation dose to the patient. For this reason, it is imperative that the exposure rate output be as low as possible. As the exposure rate is lowered, however, the image brightness decreases until eventually it is too dim for diagnostic use. Hence, a compromise exposure rate is obtained that yields a useable image while not resulting in excessive exposure to the patient. The National Council on Radiation Protection and Measurements has determined that most fluoroscopy can be carried out with exposure rates of less than 5 R/min (NCRP Report No. 33). There may be an occasional need to go above this level for unusually obese patients or imaging of particularly dense anatomical regions. The exposure rate limits of the standard are based on the NCRP findings. For purposes of the standard, the exposure rate is called "Entrance Exposure Rate" (EER) and is measured at a specific point according to the type of system involved. The word "entrance" refers to the point where the x-ray beam enters the patient. For above table source systems, C-arm fluoroscopes, and lateral fluoroscopes, a standard body thickness of 30 centimeters is assumed, and the measurement point is established accordingly.

B. Fluoroscopic systems provide several optional means of operation, which necessitates different entrance exposure rates depending on the mode of operation. The simplest systems are manual only. Selection of kVp, mA, and time is at the discretion of the fluoroscopist via manual adjustments. More sophisticated systems can be automatic, meaning that a sensor samples the radiation output and automatically changes the kVp, mA, or both to maintain a constant exposure rate. These systems are said to have Automatic Brightness Control (ABC) or Automatic Exposure Rate Control (AERC). Often, systems are designed to provide both manual and automatic modes of operation. In addition to these modes, some fluoroscopic systems have a high-level control (HLC). This is a boosting circuit which when activated by the fluoroscopist increases the exposure rate significantly. It is used when the normal mode exposure rate is not sufficient to produce a good quality image (i.e. examining a particularly dense region of the body). Both types of systems (both manual and automatic modes available in one machine) can have HLC in either mode or both.

C. The rationale for establishment of the EER limits in the standard was not straightforward. To a large extent, both the manufacturers and fluoroscopists influenced the final published limits (see Tables 1 and 2).

TABLE 1

<u>Manual</u> <u>Only</u> <u>Systems</u>

    Without a High-Level Control (HLC)   5 R/min

    With a High-Level Control (HLC)   5 R/min*

<u>Automatic</u> <u>Only</u> <u>Systems</u>

    Without a High-Level Control (HLC)   10 R/min

    With a High-Level Control (HLC)   5 R/min*

*Unlimited when the HLC is activated.

TABLE 2

<u>Dual</u> (<u>both</u> <u>manual</u> <u>and</u> <u>automatic</u> <u>modes)</u> <u>Systems</u>

    Manual Mode Selected:

        Without a High-Level Control (HLC)   10 R/min

        With a High-Level Control (HLC)   5 R/min*

    Automatic Mode Selected:

        Without a High-Level Control (HLC)   10 R/min

        With a High-Level Control (HLC)   5 R/min*

    *Unlimited when the HLC is activated.

D. As the radiological community generally agrees that most fluoroscopic examinations can be performed at 5 R/min or less, this became the established upper limit for manual systems and systems with high-level control (not activated). For those procedures that sometimes require a higher EER, it was felt that this could be obtained by activating the high-level control. Initial attempts to establish an upper EER limit for the HLC mode proved unproductive. At the time, fluoroscopic systems operating in HLC were producing EER's from 5 R/min to 25 R/min, depending largely on what the purchaser wanted. Whereas some fluoroscopists were satisfied with the images at lower EER's, others wanted brighter images produced by higher EER's such that no single upper limit value seemed to satisfy all. The argument that use of HLC represented a special instance, and for a short period of time only, where the fluoroscopist wanted to zero in on a pathology and needed a brightness acceptable to him, had merit from a medical stand point where the benefits could be shown to outweigh the risks.

Furthermore, beyond a certain EER (approximately 25 R/min), the image begins to "wash out". Therefore, an upper limit is ostensibly established by the performance limitation of the

equipment. Because of the arguments presented in support of allowing flexibility in setting the EER for high-level control at the discretion of the user, it was agreed to not establish an upper limit, realizing of course, that an upper limit would be achieved by the electronic limitations of the machine. Along with this decision, however, was the feeling that the fluoroscopist should be constantly reminded during the entire time that the HLC is activated since high exposure rates would be in use. Therefore, the standard was written to require a continuous audible signal and continuous manual activation by the operator during use.

E. Table 1 shows an EER limit for automatic systems that is different than that for manual systems. Automatic fluoroscopic systems are designed to maintain the desired image at the lowest EER possible during the entire examination. This means that in dynamic studies involving imaging of different density regions of the body, the EER will fluctuate up and down and will not be constant. This is not the case for manual systems, where once the fluoroscopic techniques are set, a constant EER is produced, regardless of imaging requirements. Early in the development of the standard, manufacturers and fluoroscopists agreed that the limit of 5 R/min imposed on automatic systems would be unrealistic. Since automatic systems operate at the lowest possible EER, it is less than 5 R/min most of the time. Occasionally, certain complicated procedures of high density techniques require an EER that "spikes" higher than 5 R/min to maintain a proper image throughout the examination. Thus, it was argued that by limiting the EER to 5 R/min for automatic systems, the greater flexibility would be lost and the system would be no more than a sophisticated manual system. This argument was accepted, and a compromise EER limit of 10 R/min was established for automatic systems without HLC. For systems with HLC, the consensus was that the EER be limited to 5 R/min, since the capability for obtaining a higher EER was available through use of the HLC.

F. An exception to the 5 R/min EER applies to dual mode equipment. In Table 2, note that the EER for the manual mode without HLC is 10 R/min, whereas it is 5 R/min for manual only equipment.

Manufacturers of dual mode equipment argued that since the electronics controlling the EER limit was the same for both modes, it would be much more complicated and expensive to design the circuitry to deliver a different EER in each mode. Thus, it was agreed to raise the 5 R/min EER limit to 10 R/min for the manual mode without HLC to match the automatic mode without HLC.

V. Summary Guidelines:

A. Measurement of EER is usually performed in conjunction with measurement of "primary protective barrier" transmission in accordance with 1020.32(a)(2). Care should be taken to assure proper measurement geometry for the type of system being tested.

B. Some systems provide the control buttons for HLC, but it is not connected at the user's request. Such systems must be tested for HLC operation before measuring EER since the limits are different for systems with HLC compared to those without HLC.

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C. For dual mode equipment, the EER must be measured in both the automatic and manual mode.

D. Many systems, both automatic and manual, do not yield their maximum EER at maximum tube potential or tube current; therefore, during the test, the kVp and mA should be varied to obtain the highest EER for comparison to the limits of the standard.

E. For some image-intensified systems with automatic exposure rate control, but with only direct mirror viewing (i.e., no television monitor), room light can leak into the system and cause the AERC to suppress the kVp and mA. Therefore, when testing these systems the room light should be as low as possible.

ENTRANCE EXPOSURE RATE (1020.32(e)), 21 CFR Subchapter J

I. Objective of Requirement:

To ensure that unintentional high fluoroscopic entrance exposure rates are not produced.

II. Performance Standard:

A. Requirement for fluoroscopic equipment manufactured after May 19, 1995:

(1) Fluoroscopic equipment which is provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute (10 R/min) at the point where the center of the useful beam enters the patient, except: (i) during recording of fluoroscopic images from the image intensifier while in pulsed mode operation, or (ii) when an optional high level control (HLC) is provided. When an optional high level control is provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 R/min at the point where the center of the useful beam enters the patient, when the high level control is activated. Special means of activating the high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal, audible to the fluoroscopist, shall indicate that the high level control is being employed.

(2) Fluoroscopic equipment operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 R/min at the point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of technique factors may be provided.

B. Applicability:

Applies to any fluoroscopic x-ray machine manufactured after May 19, 1995, operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of 1020.30(h)(3).

III. Special Measurement Requirements Incorporated in the Performance Standard:

Compliance shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.

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

(3) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

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

IV. Discussion:

The Diagnostic Federal Performance Standard was amended on May 19, 1994, in an attempt to limit the misuse of the HLC during routine fluoroscopic procedures. The amendments removed the two tier EER system set the EER to 10 R/min. Because the old requirement limited the EER to 5 R/min in those modes provided with HLC, the user often initiated the HLC to increase brightness. Such activation increased the EER from 5 R/min to 10, 20, or 30 R/min when perhaps 8 or 9 R/min would have been sufficient. Because of the way the electronics were set up, higher exposures than necessary were being used and the EER limits were being circumvented in compliance with the standard. The amendments attempted to eliminate this loop hole and provide a range where the majority of fluoroscopic procedures could operate without excessive exposures. In addition because of reports of some radiation burns, the amendments put a limit on the maximum EER while in high level mode of operation. It did not however, put a limit on record mode EER. The amendments also limited any manual only type system to 5R/min or lower. If the unit could operate above this level then it must also have AERC.

FIELD LIMITATION AND ALIGNMENT (1020.31(e), (f), (g), 1020.32(b)), 21 CFR Subchapter J

I. Objective of Requirement:

To ensure within acceptable limits that the x-ray field is of appropriate size and aligned with the image receptor.

II. Performance Standard:

A. Stationary General Purpose Systems:

1. Requirement:

Means shall be provided to align the center of the x-ray field with respect to the center of the image receptor within 2 percent of the source-image receptor distance (SID).

Means shall be provided for positive beam limitation (PBL) which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within 5 seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than 5 seconds, or is manual, will prevent production of x-rays until such adjustment is completed. At SID's at which the device is not intended to operate, the device shall prevent the production of x-rays.

The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign be no greater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than 5 by 5 centimeters. Return to PBL shall occur upon a change in image receptor size or SID.

2. Applicability:

Applies to stationary general purpose radiographic systems except when spot-film devices.

B. Equipment Using Intraoral Image Receptors:

1. Requirement:

Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

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

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

2. Applicability:

Applies to radiographic equipment designed for use with an intraoral image receptor.

C. X-ray Systems Designed for One Image Receptor Size:

1. Requirement:

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

2. Applicability:

Applies to radiographic equipment designed for one image receptor size at a fixed SID.

D. Mammography:

1. Requirement:

Radiographic systems designed for mammography shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.

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2. Applicability:

Applies to mammography equipment manufactured before September 30, 1999.

For mammography equipment manufactured after September 30, 1999, the x-ray field may not extend beyond any edge of the image receptor by more than 2 percent of the SID.

E. Other X-ray Systems:

    1. Requirement:

Radiographic systems not specifically covered in paragraphs A, B, C, and D and systems designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

    2. Applicability:

Applies to radiographic systems not covered in the previous paragraphs and are also designed for use with extraoral image receptors.

F. Spot-Film Devices:

    1. Requirement:

Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the film is greater than the selected portion of the film. If the field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option. The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

2. Applicability:

Applies to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system.

G. Nonimage-intensified Fluoroscopic Systems:

1. Requirement:

The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size at the greatest SID shall be equal to or less than 5 by 5 centimeters.

2. Applicability:

Applies to fluoroscopic x-ray systems that do not have an image intensifier.

H. Image-intensified Fluoroscopic Systems:

1. Requirement:

For image-intensified fluoroscopic equipment other than radiation therapy simulation systems, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. For rectangular x-ray fields used with circular image receptors, the error alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 by 5 centimeters or less.

2. Applicability:

Applies to fluoroscopic systems that use an image intensifier except for radiation therapy simulation systems.

III. Special Measurement Requirements Incorporated in the Performance Standard:

A. Stationary General Purpose Systems:

Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical use (such as SID's of 36, 40, 48, and 72 inches and nominal image receptor dimensions of 5, 7, 8, 9, 10, 11, 12, 14, and 72 inches) or at any other specific dimensions at which the beam limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

B. Equipment Using Intraoral Image Receptors:

None

C. X-ray Systems Designed for One Image Receptor Size:

None

D. Mammography:

None

E. Other X-ray Systems:

Compliance will be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

F. Spot-film Devices:

For spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

G. Nonimage-intensified Fluoroscopic Systems:

For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

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H. Image-Intensified Fluoroscopic Systems:

For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

IV. Discussion:

A. Equally important to assuring that the x-ray beam passes through the region of the patient's body of clinical interest, is that the x-ray beam also aligns with the image receptor. As discussed in the "requirement" sections of paragraph II, there are a variety of diagnostic x-ray systems, each with its own alignment criteria. However, the net result is an attempt to assure that the x-ray beam not only strikes the image receptor, but is also (within allowable tolerances) contained within it.

B. The benefits of confining the x-ray beam within the image receptor are twofold. First, any part of the beam that "spills" over the image receptor is useless and only contributes to increased patient exposure. Eliminating this excess helps to lower the radiation dose received by the patient. Second, collimating the beam reduces scatter radiation resulting in a radiograph of improved clarity. Usually the radiographer will choose an image receptor that is just large enough to cover the area of clinical interest, and while the x-ray field can be no larger than the image receptor, it normally should not be smaller either since loss of diagnostic information or key landmarks may occur from unexpected "cone cutting" or collimation. Sometimes it is desirable to be able to collimate the x-ray field smaller than the image receptor for exceptional clarity. Thus the provisions of the standard for certain systems allow further reduction of the x-ray field at the discretion of the radiographer.

C. Since each x-ray system is unique in its performance, the x-ray field/image receptor alignment problems are also unique. Accordingly, the requirements in the standard are tailored to each individual system type. Because stationary general-purpose systems use a variety of image receptor sizes at varying SID's, it cannot be guaranteed that proper collimation will always be obtained if left to the discretion of the operator. Hence, a positive means for assuring collimation is required. This requirement is met by positive beam limitation (PBL). PBL provides collimation by either automatically adjusting the size of the x-ray beam to the size of the image receptor (automatic PBL) or by preventing the exposure until the size of the x-ray beam is adjusted manually to the size of the image receptor (semiautomatic PBL). Additionally, PBL must allow for reduction of the x-ray field to a size smaller than the image receptor, since it is sometimes desirable or necessary to reduce the field for improved image quality. Under certain conditions, it is agreed that PBL is either not practical or possible.

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For example, some radiographic procedures require that the image receptor (film cassette) be placed directly in contact with the patient (extremities imaging) and not in the sensing tray. When this occurs, there is no way for the system to sense the cassette size, thus PBL is impossible to achieve. Under these circumstances, the standard allows for the "bypass" of PBL. Bypass means that the system can automatically disengage the PBL. However, the standard requires that the system return to PBL operation automatically when PBL conditions are once again established. Other conditions of bypass are given in 1020.31 (g)(2)(i-v).

D. Since the specific x-ray field/image receptor alignment requirements of each type of system are explained in paragraph II of this part, it is suggested that they be studied individually for a better understanding of the unique provisions. While reviewing the requirements, it should be noted that two distinct methods of achieving alignment are written into the standard, and depending on the system, one or the other applies. The first method is a misalignment requirement where the misalignment of the respective edges of the x-ray field and image receptor cannot exceed a certain percentage of the SID. The second method is a "size and centers" requirement, which provides for the x-ray field to be the same size as the image receptor and the centers of each to be aligned. Each method assures congruence of the x-ray field and image receptor within certain tolerances as related to the SID.

V. Summary Guidelines:

A. Since each type of system has unique requirements for x-ray field/image receptor alignment, care must be used when testing the system to assure that the appropriate measurements are made.

B. For those systems that require size comparison of the x-ray field and image receptor, the centers alignment must also be determined.

C. For PBL systems, the alignment should be checked at more than one image receptor size and SID to determine if the system is functioning throughout the PBL range.

D. For spot-film devices and both image-intensified and nonimage-intensified fluoroscopic systems manufactured after February 25, 1978, indication of perpendicularity of the x-ray beam axis with the image receptor is required. Testing of alignment is to be performed with the x-ray beam axis indicated to be perpendicular to the plane of the image receptor.

E. If using light field measurements to determine x-ray field/image receptor alignment, correction factors for the difference in light field/ x-ray field size and alignment must be computed and applied in the final compliance determination.

F. When using x-ray film for determining x-ray field/image receptor alignment, care must be exercised in discerning the x-ray field edge at the cathode side since the penumbra at this edge can be quite large and the edge not clearly defined.

ILLUMINANCE (1020.31(d)(2)(ii)) 21 CFR Subchapter J

I. Objective of Requirement:

To ensure that the light localizer provides enough light to define the x-ray field and is easily seen under ambient lighting conditions.

II. Performance Standard:

A. Requirement:

When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux (15 foot-candles) at 100 centimeters or at the maximum SID, whichever is less.

B. Applicability:

Applies to any diagnostic radiographic x-ray system employing a light localizer for visual definition of the x-ray field.

III. Special Measurement Requirements Incorporated in the Performance Standard:

The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

IV. Discussion:

A. The most common method for visually defining the x-ray field of radiographic x-ray systems is by use of a light localizer. The light localizer is part of the beam limiting device (BLD) and consists of a light source and mirrors or prisms which direct the light out of the BLD as if it emanated from the target (see Figure 1). In some systems, the mirror mechanism and light source are fixed such that the x-ray beam actually passes through the mirror. In this instance, the mirror is considered to be part of the inherent filtration. In others, the mirror is hinged so that during an x-ray exposure it retracts out of the path of the beam.
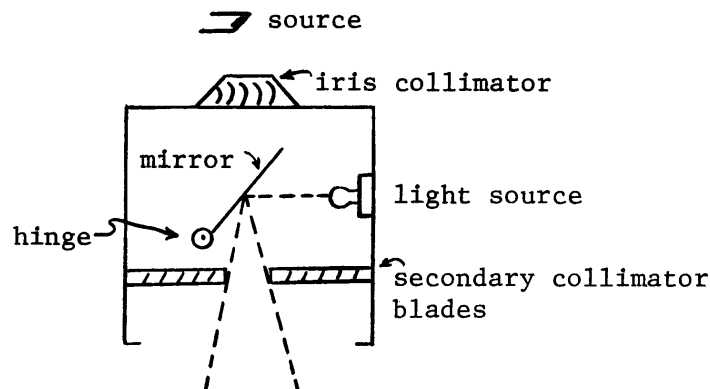

Figure 1.

B. Since the radiographer often relies solely on the light localizer to position the patient, it is extremely important that there is enough light produced to see the light field clearly even on low contrast surfaces such as dark clothing. Additionally, the light field must be of sufficient illumination to be seen easily in ambient room lighting. The requirement of 160 lux at 100 centimeters or maximum SID represents a reasonable compromise to achieve the above performance characteristics while still allowing for practical design by the manufacturer when considering size of the light source and heat capacity.

C. It is important that the light field be uniform over the entire illuminated area including the edges to facilitate proper patient positioning. For this reason, it is more realistic to test for illumination at several different points of the field rather than at just one, such as the center, where oftentimes the illuminance is greatest. Thus, the standard provides for testing of four points, one in each quadrant, with calculation of the average illumination.

V. Summary Guidelines:

A. When testing for illuminance, four measuring points are to be used, one in each quadrant of the light field.

B. The ambient room light illuminance must be subtracted from the light field illuminance at each measurement point. Avoid moving the detector between measurements of the light field illuminance and ambient room light illuminance.

C. When placing the detector in the light field, avoid any dark bands such as those caused by cross-hair images.

LINEARITY (1020.31(c)), 21 CFR Subchapter J

I. Objective of Requirement:

To ensure within acceptable limits that an x-ray machine can deliver a one-to-one proportionate exposure when increasing or decreasing the tube current (mA).

II. Performance Standard:

A. Requirement:

The average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. That is:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of two consecutive tube current settings.

B. Applicability:

For radiographic controls manufactured before May 1994, that have independent tube current settings or if manufactured after May 1994 have independent tube current selection or mAs selectable techniques. The x-ray unit must be operated on a power supply as specified in accordance with the requirements of 1020.30(h)(3) for any fixed x-ray tube potential (kVp) within the range of 40 to 100 percent of the maximum rated kVp.

III. Special Measurement Requirements Incorporated in the Performance Standard:

Determination of compliance will be based on 10 exposures at each of two consecutive x-ray tube current settings made within one hour. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within +/- 1 of the mean value for all measurements at these technique factors. Where tube current selection is continuous, X0.5 and X2 shall be obtained at current settings differing by no greater than a factor of 2.

IV.   Discussion:

A. Tube current in an x-ray tube is the flow of electrons from the cathode (filament) to the anode (target). Each electron has the potential to produce an x-ray when striking the target. By increasing the tube current, or number of electrons, the number of x-rays will increase. Theoretically, if the tube current is doubled, the number of x-rays will double, and the x-ray emission spectrum will be changed in amplitude but not in shape, as shown in the figure.
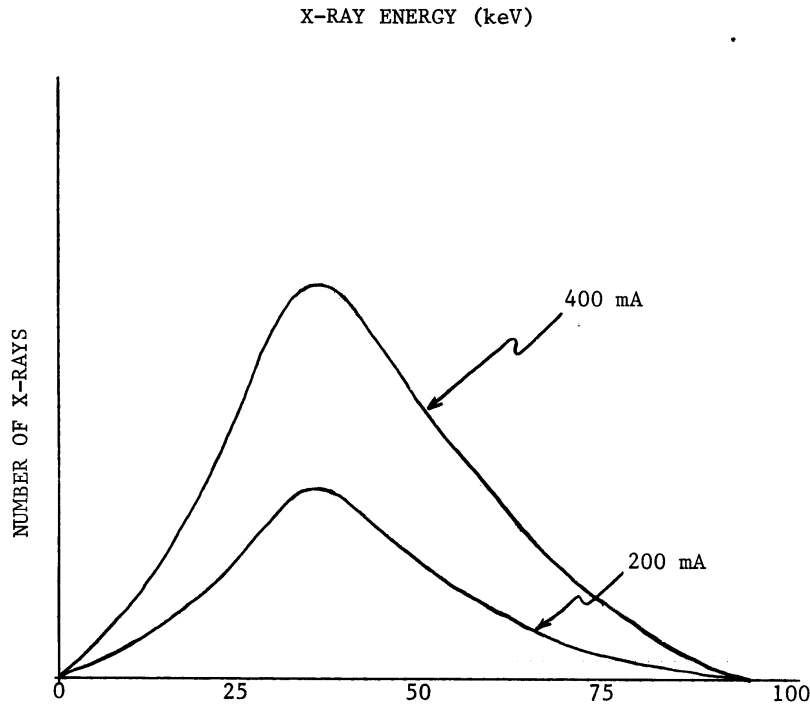
X-RAY ENERGY (keV)

This "linear" response is important to the radiographer in that he can adjust the quantity of x-rays required to produce the radiograph in a predictable manner while maintaining the same effective x-ray energy for appropriate image contrast.

B. Electrical design limitations make it impossible to have a perfectly linear x-ray machine. However, current state-of-the-art designs do result in machines exhibiting extremely good linearity. Sometimes, by reason of design or component malfunction, the linearity capability is degraded and the exposure output is erratic with changes in the tube current. This condition is unacceptable in diagnostic radiology because the unpredictability of x-ray output can result in retakes, and less than optimum radiographs.

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For this reason, the federal performance standard addresses linearity and imposes a maximum limit of variation when changing from one mA setting to another. It is important to note that since the x-ray tube current and high voltage are supplied from a step-up transformer, a change in one affects the other according to the transformer law. This law basically states that tube current and tube potential are inversely proportional to each other. Thus when the tube current is increased, the high voltage drops. This decrease in high voltage results in lower energy x-rays being produced such that more of them are absorbed in the target, glass envelope, filters and other components of the tube housing. Hence, the x-ray output is altered to the extent that it is no longer linear with changes in tube current unless the high voltage is adjusted to the same value at each mA setting. Most x-ray systems employ a compensating circuit that automatically adjusts the kVp to the original selected value whenever the mA is changed. Some older systems, however, do not have these circuits and must be compensated manually to assure optimum linearity. Systems requiring manual compensation can be recognized by the kVp selector. The control typically contains a kVp meter and major and minor kVp knobs for increasing or decreasing the kVp through a continuous range. Thus any deviation in kVp can be compensated back to the originally selected value by adjusting the major and/or minor kVp knobs. It is extremely important to perform this compensation because small changes in kVp can result in very large changes in exposure. For example, whereas a 5% change in mA results in only a 5% change in exposure, a 5% change in kVp results in an approximately 15% change!

C. As discussed in the preceding paragraph, design limitations preclude perfect linearity so that some variation is almost always present. The amount of this variation becomes more drastic the further apart the mA values are from each other. In actual practice, however, the radiographer, in seeking to adjust the tube current to an appropriate value for imaging, will rarely jump from one extreme to another but, rather, select consecutive settings to obtain the proper exposure. Hence it is more realistic to test x-ray systems under actual use conditions. Therefore, the federal performance standard provides that testing for linearity will be done for consecutive tube current settings. Because some systems do not provide discrete mA stations but continuous selection only, the standard (following the same philosophy for actual use) requires testing these systems at mA settings not varying from each other by more than a factor of 2.

D. Ideally, the filament of an x-ray tube should be infinitely small so that the cross section of the electron stream will be as small as possible. This would result in a small focal spot that is extremely desirable in diagnostic radiography. Unfortunately, the tremendous heat buildup in the filament and the target during x-ray production, and the number of available electrons required to be released from the filament limit the minimum size. Most general-purpose diagnostic x-ray systems actually have two filaments of different sizes. At low mA settings a small filament is used since it gives a small focal spot but is still able to deliver the desired tube

current while withstanding the heat stress. At larger mA settings the x-ray system switches to a large filament in order to compensate for the increased load. Sometimes, due to geometric effects and other physical phenomena, the exposure output can be nonlinear when the adjacent mA settings selected involve two different filaments (or focal spots). Appropriately designed systems, however, eliminate this problem. Thus, there is no reason for the x-ray machine to be unable to maintain linearity within the limits specified in the standard. The only qualifications made were in the amendments of May 1995. Because very small focal spots may be used on some special type equipment for high resolution, the regulations prohibit the testing between focal spot sizes of less than 0.45 mm and those greater than 0.45 mm. No qualification is made when selecting consecutive mA settings involving different focal spot sizes within the same range specified above, and the test for linearity is valid for those conditions as well.

E. All x-ray machines allow for certain technique selections, the most common being kVp, mA, and time. Usually, the more general in purpose, the more independent technique selections are available. For those systems with limited technique selection, the common design is to combine mA and time into one selector (mAs), to provide phototiming only, or to fix the mA. These systems cannot be tested for linearity since other electrical parameters are integrated with mA and cannot be separated such that the test evaluates changes in tube current only, to which the requirement in the standard applies. No attempt should be made to evaluate performance of these type systems with respect to the limits of the linearity requirement.

V. Summary Guidelines:

A. Testing is performed only on radiographic systems that provide a choice of x-ray tube current settings.

B. A change in tube current may cause a shift in kVp. The kVp must be adjusted back to the original setting if manual compensation is available.

C. Testing is performed between any two consecutive settings for discrete stations, or between two settings not differing by more than a factor of 2 for continuous selection.

D. Exposure values should be approximately doubled when the tube current is doubled or halved when the tube current is halved.

MINIMUM SOURCE-SKIN DISTANCE (SSD) (1020.31(i), 1020.32(g)), 21 CFR Subchapter J

I. Objective of Requirement:

To reduce the skin exposure to the patient as much as possible while still assuring that sufficient x-ray output is obtainable to perform the diagnostic procedure.

II. Performance Standard:

A. Requirement:

1. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:
(i) eighteen centimeters if operable above 50 kilovolts peak, or
(ii) ten centimeters if not operable above 50 kilovolts peak.

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

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

B. Applicability:

Applies to mobile and intraoral (dental) radiographic x-ray systems, and fluoroscopic systems.

III. Special Measurement Requirements Incorporated in the Performance Standard:

None

IV. Discussion:

A. No less important to the diagnostic information obtained from an x-ray examination is minimum exposure to the patient and operator. In fact, the federal performance standard for diagnostic x-ray systems is directed specifically towards the latter.

Many design features provide for both patient and operator protection such as proper collimation and tube housing shielding. Other design features provide for reduction of patient exposure only. The minimum "source-to-skin distance" (SSD) is such a feature.

B. Obviously, by simply moving the x-ray source further from the patient the exposure is decreased by virtue of the inverse square law. However, to obtain a desired radiographic image, the amount of radiation striking the image receptor must be the same no matter at what distance the source is positioned. Therefore, as the source is moved further away from the patient (and, of course, the image receptor) the mAs must be increased accordingly to maintain a constant exposure. How then does increasing the source-to-skin distance reduce patient exposure? Figure I illustrates this "skin sparing" effect of increasing the SSD.
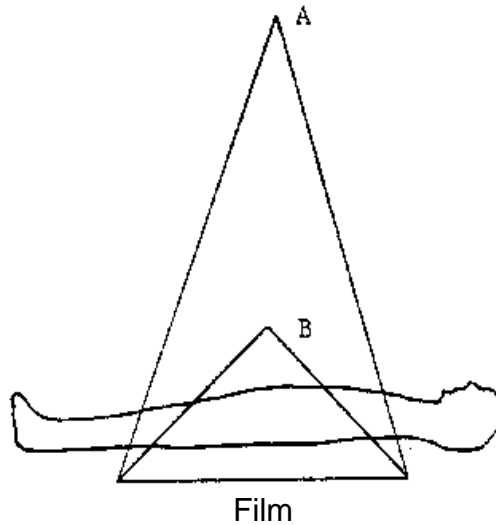

Film

Figure I

Points A and B represent the x-ray source at two different distances from the patient. Note that in order to maintain the same exposure at the film, the mAs for the source at point A has to be increased (either more mA, more time, or both) to compensate for the inverse square law loss as discussed previously. Hence, in the figure, the cross sectional exposure of each beam is the same. Note that where the beam enters the patient, the exposure from the source at B is spread over a smaller area than the source at A, thus the exposure per unit area (i.e., mR/cm2) is greater at the shorter SSD. Conversely, by moving the source further away, the radiation is spread over a larger area, lowering the per unit exposure and reducing the biological insult to the skin.

C. Although the objective of greater SSD's is to obtain the "skin sparing" effect, two additional advantages are realized. First, the "unsharpness" of the image is reduced due to a smaller penumbra at the larger SSD (Figure 2).
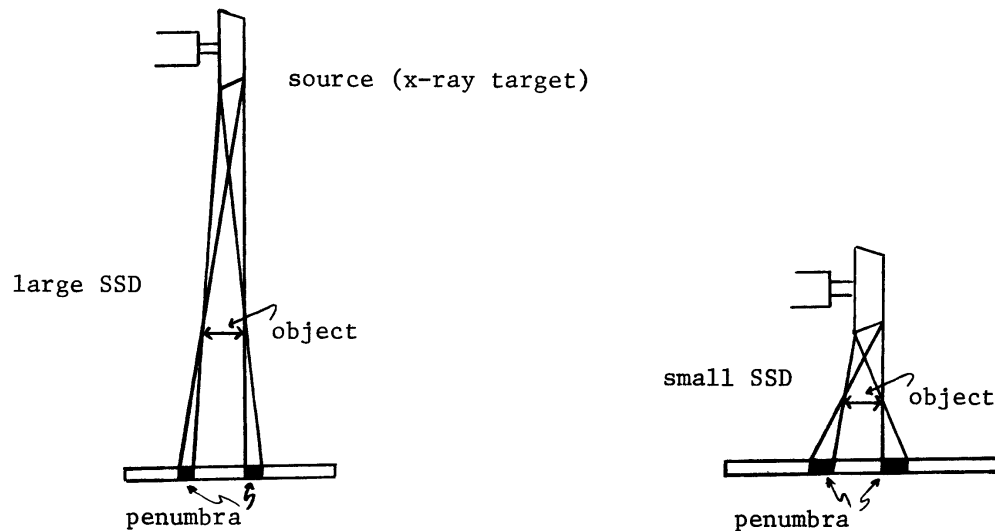

Figure 2.

Second, the magnification of the image at the image receptor is reduced which is desirable for most diagnostic procedures since the radiographer wants to see pathology of actual size for proper comparison to other internal structures. Along with the advantages of greater SSD's, however, is the disadvantage of reduced exposure due to the inverse square degradation. To compensate, the mA and/or time must be increased. If the heat loading capacity of the machine limits the mA, then the time is increased, which means a greater possibility of patient motion resulting in unsharpness. Therefore, the establishment of minimum source-to-skin distances represents a compromise of all factors discussed in these paragraphs. Notice that the standard does not specify a minimum SSD for stationary general-purpose systems. As a rule, these type systems are of such a design that an adequate SSD is obtained, and it was agreed at the outset that imposing a minimum SSD requirement on stationary general-purpose systems was unnecessary.

D. Determining the minimum SSD is not so simple as measuring the distance between the source and the point where the x-ray beam enters the patient (e.g., the end of the beam-limiting device for mobile and dental systems). The source, being contained

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within the tube housing assembly, is inaccessible, thus the measurement of SSD is somewhat indirect by use of triangulation as shown in Figure 3.
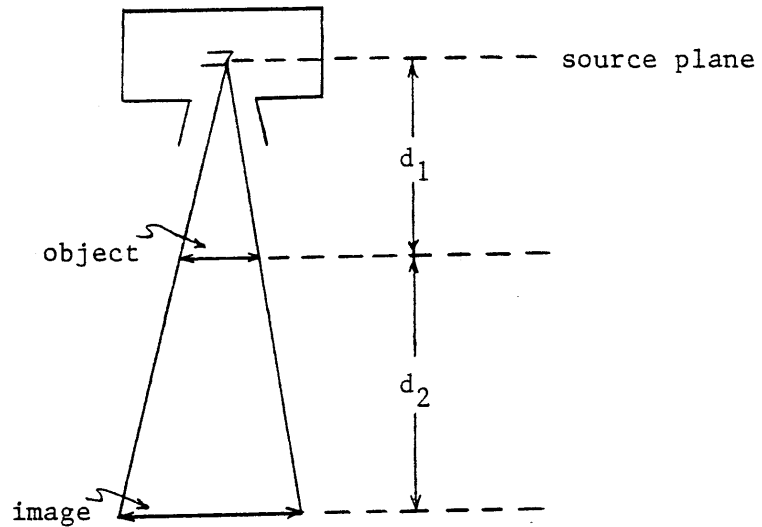

Figure 3.

The test setup involves placing an object of known dimension in the path of the beam, which produces an image of measurable dimensions at some known distance (d_2) from the object. By use of the similar triangles equation, the unknown distance (d_1) can be calculated as follows:

$$\frac{d_1}{\text{Object dimension}} = \frac{d_1 + d_2}{\text{Image dimension}}$$

or

$$d_1 = \frac{d_2 \times \text{Object dimension}}{\text{Image dimension - Object dimension}}$$

Once the distance d_1 is obtained, the minimum SSD can be determined, as all other measurements can be made directly (i.e. distance from object to tip of BLD).

IV.   Summary Guidelines:

A. The type of system to be tested dictates the measurement geometry. Care must be exercised to use the appropriate test setup.

B. As can be seen in Figure 3, the "object" must be positioned in the beam such that it is fully covered by the beam, and the image receptor is large enough to contain the image produced.

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PRIMARY PROTECTIVE BARRIER TRANSMISSION (1020.32(a)), 21 CFR Subchapter J

I. Objective of Requirement:

To ensure that the radiation passing through the primary protective barrier does not exceed a level deemed occupationally acceptable.

II. Performance Standard:

A. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in 1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to 1020.32(h)(1)(i), precautions concerning the importance of remote control operation.

B. Applies to any fluoroscopic x-ray machine operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of 1020.30(h)(3).

III. Special Measurement Requirements Incorporated in the Performance Standard:

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

IV. Discussion:

A. All fluoroscopic systems consist of an x-ray source and a receptor of some type for imaging. This receptor is often an image intensifier and sometimes includes an attached spot-film apparatus. Two basic systems exist; those with the x-ray

source below the table with the imaging system above, and the others with the x-ray source above the table and the imaging system beneath. The imaging system serves two purposes. One is to provide the imaging function, while the other is to act as a barrier to the useful beam. Thus the imaging system is considered to be a "primary protective barrier" (PPB) as defined in 1020.30 (b), and for fluoroscopic systems is designed to intercept the entire useful beam.

B. Fluoroscopists typically work close to the patient during the fluoroscopic exam, often with part of their body adjacent to or in contact with the imaging system or table. Therefore, if any part of the useful beam extends beyond the edges of the PPB, the fluoroscopist could be exposed directly to the beam. Additionally, any radiation transmitted through the barrier via poorly fitted joints or improperly shielded spots can also put the fluoroscopist at risk. The performance standard requires that the primary protective barrier intercepts the entire useful beam and that the transmitted radiation through the barrier not exceed 2 mR/hr per each R/min of entrance exposure rate and measured as illustrated in Figures 1 and 2.
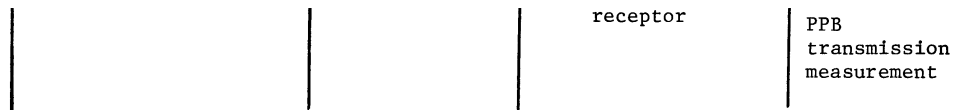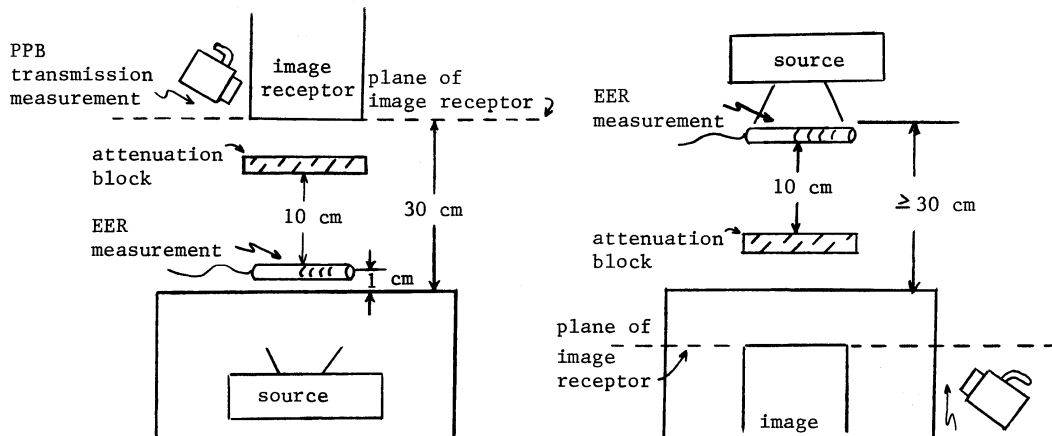

Figure 1.
(source below table)

Figure 2.
(source above table)

The attenuation block simulates a patient of average size for purposes of duplicating the same scattering geometry as obtained during actual fluoroscopic examinations. Note that the maximum allowable transmission limit in the Standard is not one constant value, but depends on the entrance exposure rate. Therefore, the PPB transmission must be measured while also measuring the EER as illustrated in the figures. The value of 2 mR/hr for each R/min of EER has been established as an occupationally acceptable level and the requirement can be met quite easily through appropriate design and assembly.

C. Two additional qualifications for measuring compliance are contained in the provisions of the standard. First, the requirement specifies that the measurement for PPB transmission be averaged over 100 square centimeters with no linear dimension greater than 20 centimeters. Care must be exercised to use an instrument with appropriate dimensions of the sensitive area of the detector or with the necessary correction factors available to calculate the actual exposure rate. Second, some image intensifiers emit radiation during operation due to the type of electronic components employed. The PPB transmission limit of 2 mR/hr for each R/min of entrance exposure rate includes this image intensifier emission.

V. Summary Guidelines:

A. The type of system to be tested dictates the measurement geometry. Care must be exercised to use the appropriate test setup.

B. Since radiation detection instruments exhibit a finite response time, scanning of the primary protective barrier must be slow enough to allow the instrument to react. Particular attention should be paid to suspect areas such as joints and bolts.

C. The absolute allowable transmission rate is dependent on the entrance exposure rate. Thus, the EER must be measured simultaneously with measurement of the primary protective barrier transmission.

D. For undertable source systems, in which there is no spot-film device, the primary protective barrier is the image intensifier housing. In these cases, measurement of barrier transmission will be significantly biased by radiation scattered from the attenuation block. Therefore, while scanning with a radiation detection instrument or quantitatively measuring with an ion chamber, a lead sheet should be positioned parallel to the tabletop at the plane of the image intensifier input phosphor and positioned to shield the chamber from all radiation except that transmitted through the primary barrier.

E. If using an integrating instrument rather than a rate meter to determine the primary protective barrier transmission, any useful reading should be at least 0.05 mR or greater.

I. Objective of Requirement:

To ensure within acceptable limits that for a given set of technique factors, an x-ray machine can deliver the same exposure each time.

II. Performance Standard:

A. Requirement:

The estimated coefficient of variation of radiation exposures shall be no greater than 0.05 for any specific combination of technique factors. "Coefficient of Variation" is defined as the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{S}{\overline{X}} = \frac{1}{\overline{X}}(\sum_{i=1}^{n}(X_i - \overline{X})^2 / (n-1))^{1/2}$$

where

S = estimated standard deviation of the population

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

X_i = ith observation sampled

n = number of observations sampled

B. Applicability:

Applies to any radiographic x-ray machine operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of 1020.30(h)(3).

III. Special Measurement Requirements Incorporated in the Performance Standard:

Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978 shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test settings after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the

mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

IV.   Discussion:

A. The production of a diagnostic radiograph of acceptable quality depends on many factors. Film composition, processing techniques, and x-ray machine performance are just a few that affect the final image produced on the radiographic film. Of these, machine performance plays a most important role, because a small change in radiographic technique factors such as kVp or mA can greatly affect the image. Thus, for a given set of technique factor settings, it is desirable that the exposure be the same each time because the radiographer is depending on a certain radiographic outcome from the techniques he is using. Any unexpected deviation could result in less than optimum diagnostic information or possibly a need to retake the radiograph.

B. The ultimate x-ray output is dependent on many electronic circuits and components functioning together to provide the desired kVp, mA, and time. Because of small transients existing in any circuit operation, along with other influential factors such as target and filament heating effects, the exposure is hardly ever the same for each initiation, but tends to fluctuate within a certain range. This fluctuation is tolerable as long as the variation does not cause a discernable difference in image quality. However, if the machine is not designed carefully or malfunctions, the fluctuation in exposure can be so drastic as to produce radiographs of unexpected and poor or unusable quality. Hence the reproducibility requirement, while allowing for a small fluctuation, limits it to a reasonable and obtainable range to assure consistency in image quality.

C. In actual day-to-day use the x-ray machine technique factors are constantly being changed from one value to another for different imaging procedures. The machine should, however, be able to maintain reproducibility under these conditions because the radiographer is expecting to get the same exposure for proper image quality each time he adjusts the technique factors back to the original values. Thus it is more realistic to test for reproducibility by varying the technique factors to alternate settings and return to the original settings between each exposure. Although the performance standard initially did not require varying the technique factors between exposures, it was later amended to be more in line with the philosophy of testing under actual use conditions as discussed above. Therefore, x-ray machines manufactured after September 5, 1978 must meet the reproducibility standard with the additional requirement of varying the technique factors between exposures imposed.

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D. As discussed in paragraph III of this part, field emission equipment or systems employing phototimers are to be tested at exposure times not less than 12 pulses and 100 milliseconds respectively. These limits were established as the minimum exposure time at which most common x-ray machines could still be expected to meet the reproducibility requirements within reasonable design and expense. Although the more sophisticated x-ray machines using "forced commutation" circuitry are capable of meeting the requirements at the shorter times, it was deemed impractical to force every manufacturer to adopt this more expensive design since most phototimed diagnostic procedures are in excess of 100 milliseconds.

V. Summary Guidelines:

A. The reproducibility test is valid only for systems operated on an adequate power supply. An exposure value that differs drastically from all the others is suspect and may have been produced during a substantial voltage drop caused by a transient in the power supply.

B. Systems manufactured after September 5, 1978 are to be tested by adjusting the technique factor controls to alternate settings and resetting them to the test setting between each exposure measurement.

C. Field emission systems and systems using phototiming are to be tested with enough attenuation material in the beam to produce an exposure interval of 12 pulses or greater for field emission systems and 100 milliseconds or greater for systems using phototiming.

STANDBY RADIATION (1020.31(l)), 21 CFR Subchapter J

I. Objective of Requirement:

To ensure that the radiation emitted from capacitor energy storage equipment does not exceed a level deemed occupationally acceptable when the exposure switch is not activated or when the system is discharged through the tube.

II. Performance Standard:

A. Requirement:

Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.03 milliroentgens in one minute at 5 centimeters from any accessible surface of the diagnostic source assembly.

Radiation discharged through the x-ray tube will not exceed 100 mR in 1 hour at 100 cm from the x-ray source.

B. Applicability:

Applies to any capacitor energy storage diagnostic x-ray system.

II. Special Measurement Requirements Incorporated in the Performance Standard:

The measurement shall be made with the beam-limiting device fully open. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The response time of the (radiation measuring) instrument system shall be no less than 3 seconds and no greater than 20 seconds.

IV. Discussion:

A. The capacitor discharge principle is employed in a radiographic system so that the machine can be operated from a normal low-current wall outlet, eliminating the need for special wiring at the various locations where use is intended. Such operation is possible because a charge sufficient to produce a reasonable x-ray exposure in a short time is stored in capacitors prior to exposure. The charge is accumulated over a much longer time period, eliminating the sudden surge during exposure required by conventional equipment.

B. When "charging" the system, the control circuits energize the high-voltage supply, which charges the capacitors. When the preset voltage is reached, the kV-sensing circuit causes the high-voltage supply to be de-energized. The capacitor voltage appears across the tube at all times, but the tube has an electronic grid that suppresses the conduction of electrons from the filament to the target until an exposure is initiated. Making an exposure is a two-stage process using an exposure switch that is either a two position button, or two separate buttons

to initiate the stages. The first stage heats the tube filament and rotates the anode, while the second stage removes the grid bias and allows the electrons to flow from filament to target for x-ray production. After the capacitors have discharged to a value as determined by the preselected techniques, the grid bias is reapplied and the x-ray exposure is terminated.

C. Whenever the capacitors are charged to a sufficient voltage, a small current flows in the tube ("leakage"). This occurs because the electric field strength at the grid is sufficient to cause electrons to be pulled from its surface and strike the target producing x-rays. This small current is not affected by either the grid bias voltage or the filament temperature, and is capable of producing exposure rates in excess of 40 mR/hour at distances up to a meter away. Furthermore, the exposure continues as long as a charge remains on the capacitors (either pre-exposure or post exposure which does not always fully discharge the capacitors). This radiation, known as "dark current" or "standby radiation", is useless for diagnostic purposes, and represents an unnecessary risk to anyone near the machine. The problem is especially acute for mobile systems that are usually wheeled out of the x-ray room upon completion of the radiographic procedure and left unattended in the halls or other pedestrian avenues. Thus, the federal performance standard was developed to limit standby radiation to an acceptable level.

D. Since the x-ray tube is completely contained within a protective housing, the only point where standby radiation (as well as the useful beam) emerges is through the beam-limiting device. With the BLD fully closed and blocking the exit port, the standby radiation would be sufficiently attenuated; however, there is no guarantee, nor is it practical, that the BLD will be completely closed at all times except during an exposure. Additionally, some BLD's when fully closed still have a small opening where the collimator blades do not completely overlap. Therefore, the intent of the standard is for the system to provide a more positive means to limit standby radiation than just by use of the BLD itself. To assure that positive means are provided, the standard requires the systems to meet the limits specified with the beam-limiting device <u>fully open</u>.

E. The most common method for positive shielding of standby radiation is by use of an electrically operated spring-loaded shutter (Figure 1) mounted between the tube housing and the beam limiting device. The shutter is electrically wired to the exposure switch and is activated during stage one of the exposure initiation (paragraph B). During this stage, along with the filament being heated and the anode rotated, the shutter is also retracted. When power is removed from the shutter mechanism, the spring forces the shutter into a closed or "safe" position.
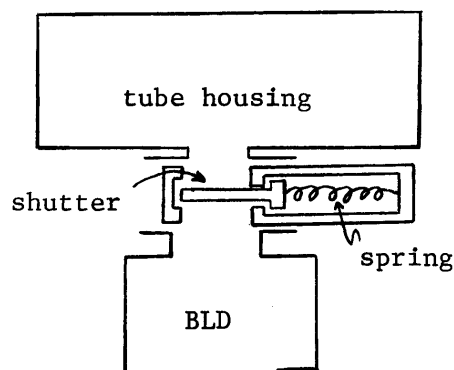
Figure 1.

F. As discussed in paragraph C, a capacitor will slowly "leak" the charge until eventually no charge remains. It is undesirable, to allow the capacitor to remain charged for a long period of time without making an exposure or otherwise reducing the charge because of possible electrical damage to the system and potential shock hazard to uninformed service personnel. To eliminate these problems, most systems have a discharge button which when activated empties the charge from the capacitor. When the discharge button is pressed, radiation emission through the BLD occurs. The exposure rate is much less than the useful beam because the filament is not heated and the shutter is closed, but the exposure rate is still much higher than that from the standby radiation. However it is not the intent of the standard to consider this discharge radiation as standby radiation since it is agreed that operator attendance is necessary for activation of the discharge button, thereby insuring emission only under controlled conditions. Because radiation emitted during the discharge mode cannot be considered as "useful beam", it is considered as leakage radiation and is subject to the limits specified in 1020.30(k).

V. Summary Guidelines:

A. Testing for standby radiation will be done with the beam-limiting device fully open, and the capacitors fully charged.

B. Compliance shall be determined by measurements averaged over an area of 100 cm^2 with no linear dimension greater than 20 cm.

C. If testing with a rate meter, the response time must be no less than 3 seconds nor greater than 20 seconds. The slower response time allows for averaging of the needle deflection and less sensitivity to transient "spikes" in the radiation output.

D. If testing with an integrating instrument, a measurement time of approximately 2 minutes is recommended. Because of this long measuring time, it may be necessary to periodically recharge the capacitors by manually activating the "charge" switch when the tube potential drops by more than 5 kV.

E. The system discharges by the activation a "discharge" switch or deactivation of input power, the test for will be conducted similar to the leakage requirements at 100 cm from the x-ray source. The limit will be determined by the maximum exposure per discharge times the number of discharges in one hour (duty cycle).

VISUAL DEFINITION (1020.31 (d)(2)), 21 CFR Subchapter J.

I.   Objective of Requirement:

        To ensure within acceptable limits that the visual definition of the x-ray field is congruent with the field.

II.   Performance Standard:

   A.   Requirement:

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

   B.   Applicability:

        Applies to any mobile or stationary general-purpose radiographic x-ray system or any special purpose or mammographic system that uses a light field to define the perimeter of the x-ray field.

III. Special Measurement Requirements Incorporated in the Performance Standard:

        None

IV.   Discussion:

   A.   Before initiating an x-ray exposure for diagnosis, it is necessary to assure that the x-ray beam will pass through that region of the patient's body that is of clinical interest. Early x-ray practices in aligning the x-ray beam axis to the image receptor were a matter of visual inspection and sometimes trial and error. This was inefficient and represented a potential for unnecessary x-ray exposure to the patient. Present day systems have remedied this problem by providing mechanical and/or electrical means for visually defining the x-ray field with relatively high precision.

   B.   The most popular method for visually defining the x-ray field of radiographic x-ray systems is by use of a light localizer. The light localizer is part of the beam-limiting device and consists of a light source and mirrors or prisms that direct the light out of the BLD as if it emanated from the target (see Fig. 1). In some systems, the mirror mechanism and light source are fixed such that the x-ray beam actually passes through

the mirror, making it part of the inherent filtration. In others, the mirror is hinged so that during an x-ray exposure it retracts out of the path of the beam.
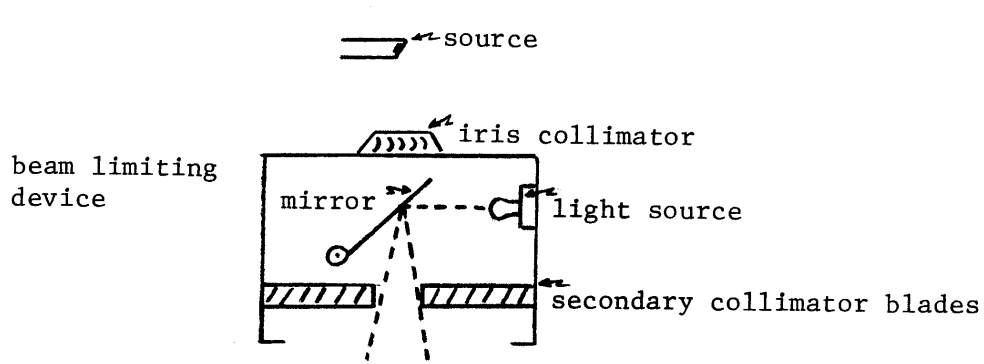

Figure 1.

The system is designed such that the x-ray field will be congruent with the light field, thus allowing the radiographer to position the patient and align the x-ray beam axis precisely by using the light localizer prior to the exposure.

C. Although the objective of the design is to assure exact congruence of the light field and x-ray field, several factors such as production tolerances and improper assembly or adjustment often cause the respective fields to be dissimilar in size and/or misaligned. The federal performance standard allows for a finite amount of misalignment between the light field and x-ray field. Figure 2 illustrates the common types of misalignments typical of x-ray systems.
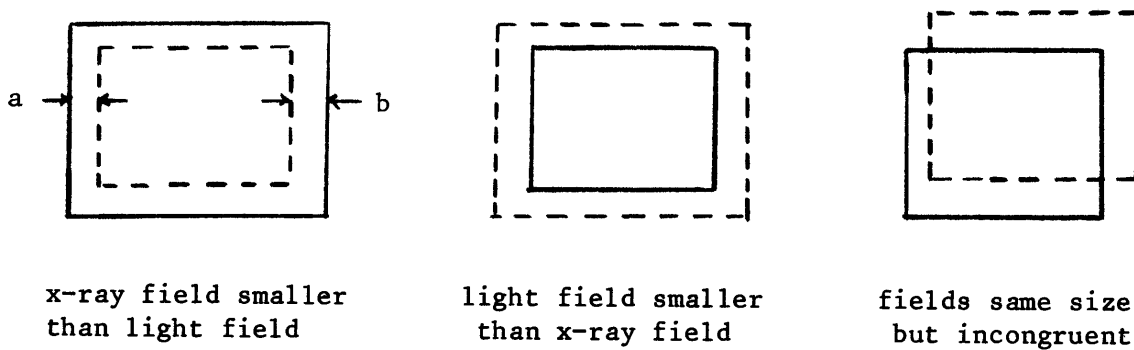

x-ray field smaller
than light field

light field smaller
than x-ray field

fields same size
but incongruent

Figure 2.

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The total misalignment along one direction is the sum of the misalignments at each edge (e.g., a+b in the first illustration of figure 2). This misalignment cannot exceed 2 percent of the source-to-image distance (SID).

V. Summary Guidelines

A. When testing for light field/x-ray field congruence, since an image of the light field itself does not actually show up on the image receptor, the edges must be marked with radio-opaque strips to indicate the perimeter.

B. During testing, an image receptor must be used that is substantially larger than the light field/x-ray field. This is to assure that all four edges of both the light field and x-ray field will be imaged even if grossly misaligned.

C. Sometimes the room lights may be too bright to see the edges of the light field clearly. When testing under these conditions, the room lights should be dimmed or extinguished until the perimeter of the light field is marked.

D. It is the manufacturer's responsibility to assure that the tolerances on the x-ray field to light field alignment should be sufficient to assure that the x-ray field to image receptor alignment conditions can be met.