Sections 1020.31(a) - 1020.31(k)

SECTION 1020.31(a) - CONTROL AND INDICATION OF TECHNIQUE FACTORS

Remote Exposure Switch

QUESTION: May we be permitted to install a wall-mounted, remote exposure switch? The purpose of this switch would be to permit the operator to be further removed from the x-ray switch than normally would be permitted by the use of a retractable cord.

The remote, wall-mounted, exposure switch option is provided in a separate box, the front panel of which contains the exposure switch and two lights. One light indicates when power is on to the entire control; the second light indicates an exposure.

The installation instructions governing this option will clearly indicate that the location must be such that the x-ray controls shall be in clear view of the operator at that location.

ANSWER: The remote exposure switch would be permissible provided the control indicates the technique factors to be used before an exposure begins (1020.31(a)(1)), and there exists a signal audible to the operator that indicates that the exposure has terminated (1020.31(i)). The technique factors must be visible and identifiable from the operator position before exposure begins.

Axial Transverse Tomography and Exposure Requirements

QUESTION: Does the axial transverse tomography unit have to meet the requirement of 21 CFR 1020.31(a)(2), that is, "means" shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor?"

ANSWER: The requirement of 21 CFR 1020.31(a)(2) is applicable to the axial transverse tomography unit.

Exposure Termination Switch Selection for Tomographic Attachment

QUESTION: Traditionally, a tomographic attachment for a general purpose table and tube carrier consists of a mechanical interconnecting arm; a drive system; and electrical switches, one of which initiates exposure and another of which terminates the exposure. Thus, it becomes an exposure timing device. However, its accuracy may be suspect because of mechanical friction or accuracy of attachment by the user.

If the exposure termination switch is deleted, the exposure timing function would revert to the x-ray control, to be set by the user. We judge, then, that the tomographic attachment would no longer be a designated component.

Do you concur?

ANSWER: Yes, we concur.

Tomographic Exposure Control Serves as a Back-Up

QUESTION: Prior to August 1, 1974, we cataloged a tomographic kit to be added to our radiographic table. However, since it controlled exposure time and was thus subject to the standard, it was discontinued since it could not be considered completely in compliance with the standard. The tomographic attachment is being redesigned but will not be capable of retrofitting to old tables. We believe that we could furnish an old style tomographic attachment if our instructions specify that the console timer must be set to terminate the exposure before the exposure switch in the tomograph would terminate it, thus making the tomographic exposure control merely serve as a back-up. Would this be a satisfactory approach?

ANSWER: Only tomographic attachments manufactured after August 1, 1974, and which control the exposure time, are required (under the Performance Standards for Diagnostic X-Ray Equipment) to be certified. If you give specific instructions for setting the console timer to terminate the exposure, your tomographic timer attachment would not require certification. These instructions should specify time settings for all techniques for which the tomographic attachment is intended. Also, the operator should be warned that the tomographic switch is intended strictly as a backup to the radiographic timer and should not be used to terminate the exposure.

SECTION 1020.31(b) - REPRODUCIBILITY

Controls That Contain Automatic Line Voltage Compensator (21 CFR 1020.31(b)(2))

REVISED LANGUAGE REF:BRH:DOC:MA 261

The Center considers controls that contain an automatic line voltage compensator which automatically adjusts one or more technique factors to compensate the output for line voltage changes to be automatic exposure controls by the nature of their design. As such, measurements for compliance of these devices with the exposure reproducibility requirements of the standard will be made with a minimum of 12 pulses to be consistent with the intent of paragraph 1020.31(b)(2).

Tomography Requirements for Reproducibility and Linearity

QUESTION: Are exposures made during tomography subject to the reproducibility and linearity requirements of 21 CFR 1020.31(b) and (c)?

ANSWER: We consider the timer to be any mechanism that controls the actual x-ray "on" time. Thus, the provisions of 21 CFR 1020.31(b) and (c) are applicable during the tomographic mode of operation.

Measuring Compliance and Line-Voltage Regulation

QUESTION: In Section 1020.31(b)(2), "Measuring Compliance and Line-Voltage Regulation," does this apply only to the time of measurement? Will plus or minus 1 percent line-voltage regulation have to be provided for all users?

ANSWER: The plus or minus 1 percent line-voltage regulation to which you refer is a test condition only. This means if the line voltage regulation (expressed as a percent) for one measurement departs from the mean value of line-voltage regulation for all 10 measurements (expressed as a percent) by more than 1 percent, the test is not valid. It carries no implication concerning any line that must be provided with an x-ray machine.

Linearity Requirement for Two or More Diagnostic Source Assemblies (21 CFR 1020.31(c))

REF:BRH:DOC:MA 3553

A manufacturer has asked for clarification as to how the linearity requirement applies to an x-ray system with a single x-ray control used to control the operation of two or more diagnostic source assemblies. This becomes important when the operating range of the two or more diagnostic source assemblies is significantly different since the linearity requirement is applicable over an x-ray tube potential range of 40 percent to 100 percent of the rated peak tube potential.

The National Center for Devices and Radiological Health advises that if two or more diagnostic source assemblies are operated from the same control, each combination of tube housing and control will be considered as a separate system for the purpose of determining applicability of the linearity requirement. Therefore, linearity is applicable over the range of 40 to 100 percent of the maximum peak tube potential rating of each such combination.

Applicability to X-Ray Systems or Individual Components

QUESTION: Does the linearity requirement of Section 1020.31(c) apply to the x-ray system rather than individual components? If so, is the maximum milliampere-second product selection or the maximum current setting used in determining the linearity requirements of the system in a compliance test restricted to the maximum value as stated by the manufacturer's rating of the limiting component; i.e., an x-ray tube rated at 1200 milliamperes maximum and used in conjunction with a 2000 millampere maximum generator would only be tested for compliance at a maximum of 1200 milliamperes?

ANSWER: Yes, the requirement does apply to the x-ray system, and the maximum milliampere-second product or maximum current setting of the system is limited by the manufacturer's rating of the limiting component. The limits of operation of the system must be consistent with the information supplied to the purchaser.

SECTION 1020.31(d) FIELD LIMITATION AND ALIGNMENT FOR MOBILE AND STATIONARY GENERAL PURPOSE X-RAY SYSTEMS

Portable and Mobile X-Ray Units

QUESTION: We manufacture a small portable x-ray unit that is designed to be used with various image receptor sizes in combination with certain SID's. It is provided with a fixed collimator in combination with field adaptor plates (for 8" x 10", 10" x 12", 14" x 17" at 30" SID and 14" x 17" at 72" SID). It is therefore a fixed aperture beam limiting device. Since this is a portable unit, it should be distinguished from a mobile unit as mentioned in Section 1020.31(h)(2). We therefore consider that it is appropriate to apply the provisions of Section 1020.31(f)(4). Is this interpretation correct?

ANSWER: In terms of the beam limiting device requirements, no distinction is made between a portable and mobile x-ray unit. Therefore, all the requirements of Section 1020.31(d) would apply to this unit. One of the requirements is that the unit be provided with a means of stepless adjustment of the x-ray field. Therefore, the beam limiting device you describe would not be appropriate, as it would not meet this requirement of the standard.

Light Intensity Arranged to Provide Less Than 160 Lux at Times

QUESTION: Would it be permissible to arrange the switching on our light localizer such that there are two switches performing the following functions:

(1) When switch No. 1 is activated, the light intensity is equal to about 100 lux; and

(2) when both switches No. 1 and No. 2 are activated, the light intensity is equal to about 160 lux, but is timed so that after 30 seconds, the intensity decreases to about 100 lux?

This system is proposed for a condenser discharge mobile x-ray unit.

ANSWER: This arrangement would not be permissible. The standard requires that whenever the light localizer is activated the intensity must be equal to or greater than 160 lux.

FOOD AND DRUG ADMINISTRATION
COMPLIANCE POLICY GUIDES

GUIDE 7133.08 *

CHAPTER 33 - RADIOLOGICAL HEALTH

SUBJECT: Override of Positive Beam Limitation - 21 CFR 1020.31(e)(2)(v)

BACKGROUND:

On November 21, 1973, the Bureau of Radiological Health issued an advisory opinion which stated that Positive Beam Limitation (PBL) can be overriden only at Source to Image Receptor Distances (SID's) for which PBL is provided, and operation of the override switch must still prevent x-ray production at any SID where PBL is not provided. However, questions have been raised as to whether this policy should apply when an override switch is provided only for system failure. Because PBL system failures often involve the SID sensing mechanism, it is reasonable for an overide switch for PBL system failure to totally disconnect the PBL logic system, providing totally manual collimator operation at all SID's, including those where PBL does not exist. This opinion is contrary to the Bureau's advisory opinion of November 21, 1973. In addition, after studying the designs of numerous PBL system manufacturers, the Bureau has discovered that service switches are sometimes provided to override the PBL function during repair of the PBL system. However, not all of these service switches have been captured key switches as described in Section 1020.31(e)(2)(v).

POLICY:

The Bureau believes that in the event of PBL system failure, it is important to keep the x-ray system operational until it can be repaired. Therefore, it is consistent with the intent of the Regulations for any override swith provided only for use by the serviceman or for any override key provided for PBL system failure, to allow totally manual collimator operation at all SID's including those where PBL is not provided. Any service switch which has a capability of overriding the PBL and which is readily available to the operator, must be a captured key switch as described in Section 1020.31(e)(2)(v). Any service switch that is normally inaccessible to the operator does not require a key.

The Regulations also provide for an additional override capability to perform special procedures. If such an override capability is provided, it shall only override the PBL function at those SID's where PBL is provided. A captured key switch is required for all override switches that are readily accessible to the operator.

*This FDA Compliance Policy Guide is applicable to units manufactured before December 1, 1983. After December 1, 1983, refer to November 5, 1982 (21 CFR 1020, 77N-00661) Federal Register Amendments to 21 CFR 1020.31.

Numerical Indication of Source to Image Receptor Distance (SID) (21 CFR 1020.31(e)(1)(i))

REVISED LANGUAGE REF:BRH:DOC:MA 353

This is intended to clarify the FDA position regarding the numerical indication of SID on stationary general purpose systems as required by 21 CFR 1020.31(e)(1)(i). This regulation states that "means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent, and to indicate the SID to within 2 percent."

Assemblers contend that this requirement is met on certified, PBL-equipped systems by (1) user instructions specifying the position of each microswitch and the corresponding SID to the permanently-mounted image receptor, and (2) installation of an "exposure ready" light on the beam limiting device. This light is only illuminated when the microswitch is activated. The microswitches are frequently used to provide discrete SID's to the wall-mounted image receptor, and are occasionally used to provide discrete SID's to the under-table image receptor. Most stationary general purpose radiographic systems, however, permit exposures to the image receptor(s) at SID's for which PBL is not provided, through use of an override switch.

It is the FDA position that all stationary general purpose radiographic systems must be equipped with means to provide numerical indication of any and all SID's (inches and/or centimeters) at which the system is designed to operate when the useful beam is perpendicular to the plane of the image receptor. This requirement may be satisfied by means of a retractable tape measure on the tube housing assembly, a tape measure mounted on the tubestand track parallel to the beam axis, or by other means which provide the required numerical indication at all operational SID's. A statement in the user instructions relating microswitch locations to SID's is not acceptable.

Requirement When the Bucky Cassette Holder is Not Vertical

QUESTION: What type of field limitation is required for combination bucky and cassette holder that can be used in a vertical position or tilted down for use in a horizontal position? It can be used for chest, head and extremities. The height of the bucky from the floor on the stand is variable in either the vertical, tilted, or horizontal position. The height of the x-ray source is also variable. There is no reasonably simple way to automatically determine the SID within the tolerances specified when the bucky is in the horizontal or tilted position. Is the intent of the law met by use of the key in PBL systems for horizontal or tilted bucky cassette work? (See Section 1020.31(e)(6)). In other words, does 1020.31 (e)(6) allow bypassing positive beam limitation when the bucky cassette holder is not vertical?

ANSWER: The permanently mounted vertical cassette holder, which can be used in the vertical and horizontal positions when used as a part of a stationary general purpose x-ray system, requires positive beam limitation (PBL) as described in Section 1020.31(e)(2).

Section 1020.31(e)(6) allows a manufacturer to design into his system an optional provision to "override" PBL with a key, but this device is only for servicing the system or is to be used in the event of system failure.

Section 1020.31(e)(3) allows a manufacturer to bypass PBL. This "bypass" mode can automatically take place in a positive beam limitation system without the use of a key or any other manually actuated device only when radiography is conducted which does not use the cassette tray or vertically mounted cassette holder; when either the beam axis or the cassette angulation is not within 3 degrees of horizontal or vertical during any part of the exposure; or during tomographic or stereoscopic radiography.

Tiltable Wall Bucky Stand Requirements

QUESTION: Tiltable Wall Bucky Stand - This unit incorporates a bucky and, therefore, we agree that positive beam limitation is required for normal use except when tilted beyond 3 degrees from the vertical position. This unit, however, has the capability of being tilted to horizontal position near the floor level. When in this position, two support legs are brought into position so as to provide firm support when a patient sits on the bucky.

We are unable to provide positive beam limitation in this position because the floor to film distance is different than the floor to film distance of the x-ray table normally found in such rooms. For example, if the floor to film distance of the image receptor in the table bucky is 30", the vertical SID sensor in the overhead ceiling tube crane is set to sense vertical travel from that point. The tilting bucky in the horizontal position can vary from a low of 20" to about 70" above the floor.

We submit that film exposures made in the horizontal mode on a tilting bucky or cassette holder are special procedures that cannot be performed in the positive mode and that, therefore, positive beam limitation is not mandatory.

We are unable to provide positive beam limitation where both the x-ray source assembly and image receptor are adjustable so that the SID can be varied by either component independently, unless the two are more or less permanently, mechanically linked. This cannot be done with a ceiling mounted tube crane.

The requirement of positive beam limitation in such cases would force us, and we believe the industry, to eliminate this capability from new equipment and deprive the user of a valuable diagnostic tool.

Our request is that positive beam limitation not be required when:

1. The SID can be varied, independently, by the diagnostic source assembly and the image receptor; and

2. the diagnostic source assembly and image receptor are not mechanically linked.

ANSWER: We believe that with the addition of a second sensor to sense vertical travel of the table bucky with respect to the floor, positive beam limitation could be provided for this equipment. It is not clear to us why positive beam limitation would interfere with exposures made in the horizontal mode.

PBL and Use of a Film Changer

QUESTION: From 21 CFR 1020.31(e)(3) and (6) we conclude that positive beam limitation may be bypassed or overridden when the x-ray system is used to expose x-ray films in a filmchanger and that the filmchanger is not required to actuate the PBL system. We respectfully request your confirmation that our conclusion is in conformity with the Center's intentions. We, furthermore, request your ruling on whether an arrangement by which the collimator was automatically adjusted to the field size of the film changer operation (PBL), would be:

(a) a requirement, (b) optional, (c) not desirable

ANSWER: Your interpretation is correct. Positive beam limitation may be bypassed when a film changer is used. Since return to the positive beam limitation is automatic when the bypass mode is used, it is better to use a bypass mode rather than override. Although not required when a film changer is used, the National Center for Devices and Radiological Health does encourage the use of positive beam limitation as an optional function.

SID and Requirements of Collimators, X-Ray Tube Housing Assemblies, and Tube Stands

QUESTION: SID indication and perpendicularity of x-ray beam to image receptor are performance standard requirements. Your guide of standards applicable to major components indicates SID indication is a requirement of collimators and x-ray tube housing assemblies, and that perpendicularity indication is required for x-ray tube housing assemblies. Cannot these requirements be satisfied by either the x-ray tube housing assemblies or the beam limiting device or, for that matter, the tube stand, which is not a certified component?

ANSWER: Yes. These requirements can be satisfied by any of the components specified. The essential elements are that these be indicated in the assembled unit.

Crosstable Radiography and Non-Permanently Mounted Cassette Holder

QUESTION: In some instances, we have a cassette clamped to the side of an x-ray table for cross-table radiography. The means of attachment are usually suction cups or clamps with thumb screws. We have interpreted this arrangement as not being a permanently mounted cassette holder and, therefore, positive beam limitation may be bypassed for radiography in this mode.

ANSWER: Your interpretation is correct. Positive beam limitation is not applicable in this instance.

Permanently Mounted Cassette Holders

QUESTION: If a doctor has a certified stationary, general purpose unit with a vertical cassette holder that is used at 72 inches only and only for chest work, is PBL required with the vertical cassette holder?

ANSWER: If the stationary general purpose unit is equipped with PBL, the permanently mounted vertical cassette holder must be compatible with the PBL system. PBL must be provided with this vertical cassette holder.

Fixed Aperture Beam Limiting Device Identification Used to Reduce the PBL Field Size

QUESTION: How should removable, fixed aperture beam limiting devices used at variable source-to-image receptor distances be marked? These beam limiting devices (cones) are designed to fit on a positive beam limiting device to reduce the field to sizes significantly smaller than the cassette size.

ANSWER: The certified beam limiting device should be marked to indicate the image receptor size and the maximum SID for which the device is designed.

January 16, 1984 Ref:MA:NCDRH:OC:XPB:378

TO: MANUFACTURERS AND ASSEMBLERS OF DIAGNOSTIC X-RAY EQUIPMENT

SUBJECT: Automatic Sizing Requirements of 21 CFR 1020.31(e)(5) Effective December 1, 1983

We are writing this letter to the x-ray industry to state the position of the National Center for Devices and Radiological Health on the subject of automatic field-size adjustment requirements associated with operator-initiated undersizing of x-ray fields.

The revision of 21 CFR 1020.31(e)(2), "Positive Beam Limitation (PBL)" was published in FR 50215, November 5, 1982, and became effective December 1, 1983. Concurrent with the revision of 1020.31(e)(2), paragraphs 1020.31(e)(3) through 1020.31(e)(6) were added.

The principal intent of PBL operation is to match the size of the x-ray field to that of the image receptor. In addition, PBL systems are required to "track" changes in SID and automatically adjust the x-ray field size (or prevent exposure) to assure that it does not exceed the maximum x-ray field size permitted by 21 CFR 1020.31(e)(2).

The stimulus for the Center to amend the x-ray standard was provided by the need for undersizing. Many users of stationary general purpose x-ray systems requested that PBL systems be capable of retaining a reduced (coned down) x-ray field size smaller than the image receptor size while they made a series of exposures. Under the previous rule, this series could not be performed in normal PBL mode, because replacing one image receptor with another, regardless of size, caused the field size to automatically return to the full image receptor size upon insertion of the image receptor.

The new paragraph 21 CFR 1020.31(e)(5) permits (but does not require) retention of a reduced x-ray field size during a series of exposures to the same size image receptors. The insertion of the same size image receptor during such a series would not require automatic adjustment of the x-ray field to the size of the image receptor as was required by the previous rule. Since we expect the source-to-image receptor distance (SID) to remain unchanged during the series, section 21 CFR 1020.31(e)(5) requires automatic adjustment of the x-ray field size to the size of the image receptor if the SID is changed during the series. We intended this requirement to apply to those PBL systems which are designed to permit retention of a reduced x-ray field size during a series of exposures to the same size image receptors.

When we amended 21 CFR 1020.31(e)(2)(iii), now 21 CFR 1020.31(e)(5), we did not intend to make any existing PBL design noncompliant with the automatic sizing requirements. Both the previous rule and the new paragraph 21 CFR 1020.31(e)(5) require automatic adjustment of an operator-initiated undersized x-ray field to the size of the image receptor when the image receptor size is changed. The new paragraph 21 CFR 1020.31(e)(5) now allows PBL systems which permit the operator to reduce the x-ray field size and retain the reduced field size during series of exposures to the same size

image receptors when the SID remains unchanged. We did not, however, intend that all PBL systems must be designed to provide the series option just described. We intended, rather, that PBL systems be available which would meet either the automatic sizing requirements of the previous rule, or the series option of new paragraph 21 CFR 1020.31(e)(5).

SECTION 1020.31(f) - FIELD LIMITATION ON RADIOGRAPHIC X-RAY EQUIPMENT OTHER THAN GENERAL PURPOSE RADIOGRAPHIC SYSTEMS

Field Limitation and Alignment for CT Equipment (21 CFR 1020.31(f)(4))

REVISED BRH:DOC:MA 344

Background

CT diagnostic procedures were determined to be special purpose in nature. Thus, Section 1020.31(f)(4), instead of Sections 1020.31(d) and (e), was prescribed as the appropriate performance criteria for CT equipment. The image receptor size is the active area of the detector as restricted or defined by the beam-limiting device between the patient and the detector.

The following policy statement describes the clarification and interpretation necessary to ensure compliance with the provisions of Section 1020.31(f)(4).

Policy

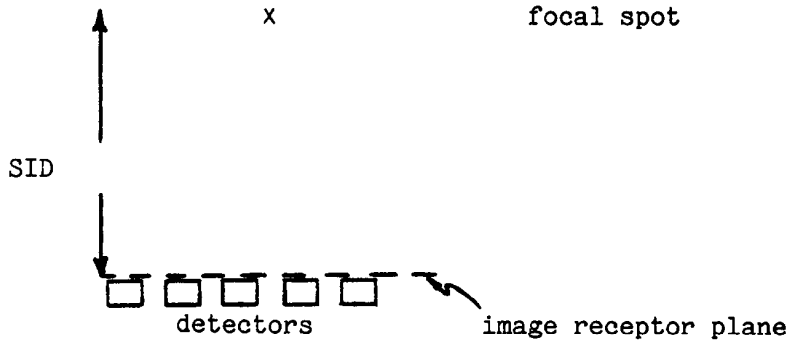
Image Receptor Size

In determining compliance with the standard, it is necessary to obtain the dimensions of an individual detector along directions perpendicular and parallel to the slice plane. The active area of the detector is defined as that portion over which incident x-ray photons produce an electronic signal for image production. The active area of the detector is dependent on a) the beam-limiting device between the patient and detector, b) the focal spot size, and c) the physical structure of the detector itself. The length of each detector perpendicular or parallel to the slice plane should be determined from this active area.

Image Receptor Plane and SID

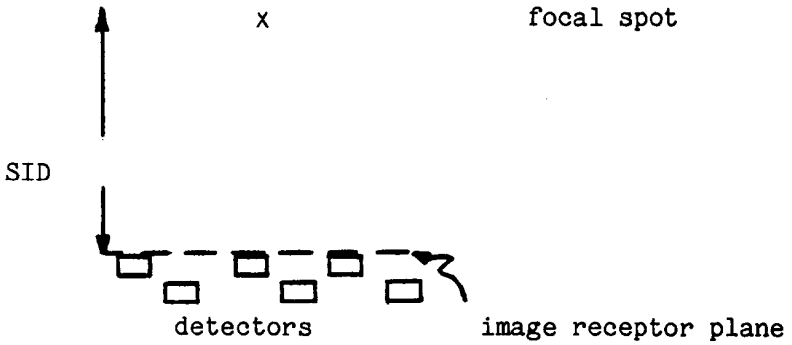
Since 21 CFR 1020.31(f)(4) prescribes criteria for matching the x-ray field to the image receptor (detectors) at a specific plane in space, it is necessary to define this plane for CT equipment. This plane is defined by the input surface of the detectors. Consider CT systems with detector arrays as shown in the following diagrams (i.e., view looking down on slice plane, detector array and focal spot).

Case I



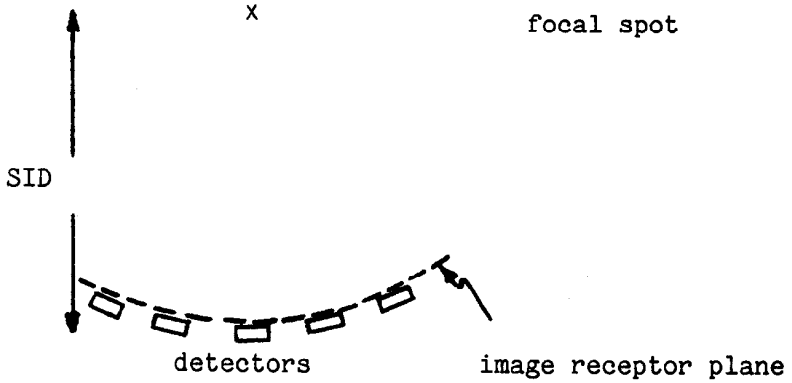
For this case, compliance with the standard is checked at the plane defined by the input surfaces of the detectors.

Case II



For this case, compliance with the standard is checked at the plane defined by the input surfaces of the detectors at the front of the array.

Case III



For this case, compliance with the standard is checked at the "plane" defined by the input surfaces of the detectors.

In all cases, the source-image receptor distance (SID) is defined as the distance along the central ray through the x-ray field from the focal spot to the image receptor (detectors) plane.

Multiple Detector Arrays

Since CT systems use an array of at least two detectors to produce electronic signals for image production, a determination must be made as to whether individual collimation is needed for each detector. Individual detector collimation shall be provided whenever the edges of the active areas on the image receptor (detectors) plane of adjacent detectors are separated by 2 or more percent of the SID. This determination shall be made along directions both perpendicular and parallel to the slice plane.

Field Limitation in a Direction Parallel to the Slice Plane

Small increases in the length of the x-ray field in a direction parallel to the slice plane do not result in increased dose to the patient for some systems.

These systems are characterized as follows:

a) a detector array for image production that does not require individual collimation for each detector in this direction, and

b) a detector array for image production that necessitates an x-ray field in this direction at the center of the gantry aperture larger than typical patient sizes.

As long as the CT system meets the above criteria, the length of the image receptor can be determined by the active areas of all detectors whether they are used for image production or normalization and calibration. Also, if the detector array shifts by a small amount relative to the x-ray field during the scan, the length of the image receptor can be determined by the active area of the detectors plus the shift.

360-Degree Detector Arrays

Compliance with the field limitation requirement in a direction parallel to the slice plane is automatically ensured for some systems. These systems are characterized as follows:

a) a detector array for image production that does not require individual collimation for each detector in this direction, and

b) a detector array for image production that forms a complete circle around the patient.

Manufacturers of systems meeting these conditions need not describe their testing program to ensure compliance with the field limitation requirement in this direction.

Applicability of the Beam Size Requirement for Dental Panoramic-Type Units

REF:BRH:DOC:MA 3552

In response to recent questions by manufacturers concerning the applicability of the beam size requirement to dental panoramic-type units, the following opinion is issued by the National Center for Devices and Radiological Health, FDA:

(a) This opinion applies to dental panoramic-type units that employ the laminographic technique in which the x-ray source is moved in one direction and the film in the opposite direction about the object to be radiographed. In addition, the x-ray beam is limited to a narrow slit and the cassette holder contains a shield in front of the film in which a slit allows for the entrance of the x-rays.

(b) For dental panoramic units as described in (a), the image receptor size shall be considered as that area of the film which is being exposed. This area is considered to be equal to the size of the slot in the cassette holder. Consequently, for those dental panoramic type units that are designed with a fixed SID and one image receptor size, the size of the x-ray beam at the front plane of the cassette holder must be limited to the dimensions of the slot in the cassette holder. For those dental panoramic type units in which the SID is variable, the x-ray beam dimensions at the front plane of the cassette holder shall not exceed the dimensions of the slit by more than 2 percent of the SID.

Special Purpose X-ray Systems Utilizing a Light Localizer (21 CFR 1020.31(f)(4))

REVISED LANGUAGE REF:BRH:DOC:MA 263

Background

The use of light localizers for other than general purpose systems falls into one of two categories. The first category contains those systems where the light field is used for both alignment and definition of the perimeter of the x-ray field. The second contains those systems where the light field is used only for alignment, e.g., light field cross-hairs for centers alignment of the x-ray field and image receptor.

Initially, questions were raised by manufacturers concerning requirements applicable to light localizers used in systems designed specifically for podiatric radiology. Recently, the same questions were raised about other than general purpose systems. The following policy statement is applicable to all special purpose systems utilizing a light localizer.

Policy

This opinion is applicable to special purpose systems. If a light field device is used as an alignment device and the light field is intended to visually define the perimeter of the x-ray field, then the illumination intensity requirement of 1020.31(d)(2)(ii) and the light field edge contrast requirement of 1020.31(d)(2)(iii), as applicable to mobile systems, are applicable.

If the light field device is only a centering light and is not intended to visually define the perimeter of the x-ray field, then no specific illumination intensity or light field contrast requirements apply. The light intensity must be sufficient, however, to permit proper alignment in a normally illuminated room.

Cephalometric Beam Limiting Devices
(21 CFR 1020.31(f))

REF:BRH:DOC:MA 3584

Background

The following opinion is issued by the National Center for Devices and Radiological Health, FDA, in response to questions that have arisen concerning the manufacture and assembly of cephalometric attachments designed and manufactured for use with convential intraoral dental x-ray equipment.

Cephalometric system attachments generally contain two certifiable components: a beam limiting device and a cassette holder. In the past, practitioners have used either one or both in their cephalometric x-ray systems. Since many purchasers of these cephalometric attachments already own an x-ray system, many unique situations develop when a practitioner elects to add to or upgrade his cephalometric capability.

As indicated in 1020.31(f)(4) of the Code of Federal Regulations, Title 21, "radiographic systems . . . designed for use with extraoral image receptors . . . shall be provided with means to . . ." limit and align the x-ray field to within 2 percent of the SID. If the x-ray system is to be used only for cephalometric examinations and has a fixed SID and one image receptor size, 1020.31 (f)(2) would apply and would require beam limitation to a size no greater than the image receptor.

Opinion

When a certified cephalometric beam limiting device (BLD) is added to any existing x-ray system (certified or uncertified), means must be provided to limit and align the x-ray field to the image receptor as specified in 1020.31(f)(2) or (4), whichever is applicable. Therefore, a complete cephalometric system may have to be installed if the means for alignment is dependent on other apparatus or certified components being installed such as head positioners, cassette holders, etc. If the equipment is designed to be operated at one SID and one image receptor size, 1020.31(f)(2) is applicable; otherwise 1020.31(f)(4) is applicable.

Before a certified cephalometric BLD may be installed on any certified x-ray system, it must be determined that the certified BLD is compatible with the certified tube housing assembly to which it is to be attached. If no compatible certified BLD is available, a noncompatible certified BLD may be installed in those cases where noncompatibility is due to an uncertified component in the x-ray system or to a component not requiring certification and purchased before August 1, 1974.

When a certified cassette holder (with or without head positioner) for cephalometric procedures is added to an x-ray system containing a certified BLD, the cassette holder must be compatible with the certified BLD. It is unlikey that the cassette holder will be compatible directly with the existing intraoral BLD.

If the certified cassette holder is not directly compatible with the existing BLD, this installation can be undertaken only by installing the proper certified BLD compatible with the cassette holder, the tube housing assembly, and the existing BLD if it is retained in the x-ray system. Means to align and limit the x-ray field as specified in 1020.31(f)(2) or 1020.31(f)(4), whichever is applicable, must be provided.

When a certified cassette holder for cephalometric procedures is added to an x-ray system with an uncertified BLD, a noncompatible certified cassette holder may be installed only when no compatible certified cassette holder exists. There is no Federal requirement that a certified BLD or any other apparatus for proper beam alignment and limitation be installed when a noncompatible certified cassette holder is installed in an x-ray system containing an uncertified BLD.

The preceding discussion is also applicable to those situations where a partial cephalometric system is already present and the practitioner wishes to upgrade his existing uncertified system.

Intraoral Dental Equipment Used for Extraoral Radiography (21 CFR 1020.31(f)(4))

REVISED REF:BRH:DOC:MA 4105

The Bureau recognizes that the use of radiographic equipment designed for intraoral image receptors for extraoral radiographic procedures is an established practice in dentistry (i.e., cephalometry and other radiography of the skull). Some manufacturers of this equipment acknowledge this practice in their user's information and, in some cases, document the recommended technique factors required for specific procedures. A possible conflict between the design of this equipment and the Performance Standards for Diagnostic X-ray Equipment concerns compliance with 21 CFR 1020.31(f)(4), X-Ray Field Alignment and Limitation. Therefore, the following guidance is provided for intraoral systems:

(a) If the system is equipped with an extraoral image receptor support structure, means for x-ray field alignment and limitation must comply with Section 1020.31(f)(4).

(b) If the condition in Guidance (a) is not applicable and if the system's user information includes extraoral technique factors or promotes such an application, the system must provide, as an option, means for x-ray field alignment and limitation compliant with Section 1020.31(f)(4).

(c) If the system is in no way purported for extraoral applications, the system is subject to Section 1020.31(f)(1), and is not subject to Section 1020.31(f)(4).

Clearly, the use of systems designed for intraoral image receptors for extraoral procedures is beyond the control of the manufacturer, but the manufacturer could anticipate the user's needs for this application by devising the necessary alignment equipment. For this reason, manufacturers are encouraged to provide optional means for alignment and limitation of the x-ray field with extraoral image receptors. Manufacturers of systems described in items (a) and (b), above, must supplement their respective initial reports to document their intention to comply with this guidance relative to Section 1020.31(f)(4).

Removable Fixed Aperture Beam Limiting Device Identification

QUESTION: How should a removable fixed aperture beam limiting device be marked to comply with Section 1020.31(f)(4)(ii) when it is to be used with a specified image receptor size over a specified SID range?

ANSWER: The beam limiting device should be marked to indicate the image receptor size and the maximum SID for which the device is designed.

Other Than General Purpose and Stereoscopic Radiography

QUESTION: Our urological x-ray tables have provision for moving the x-ray tube into two additional positions for stereoscopic radiography. This is a straight line motion with no tube tilt. To cover the entire film area the collimator is opened to allow full exposure of a 14" x 17" film with the x-ray tube 1-3/8" off-center each way.

In Section 1020.31(e)(3) permission is granted to bypass positive beam limitation in stationary general purpose equipment during stereoscopic radiography. However, since this equipment is not for general purpose use, it is subject to Section 1020.31(f)(4), which does not mention this exclusion for stereoscopic radiography. Is it the intention of the regulations to make the same exemption for stereoscopic radiography on special purpose equipment as on general purpose equipment?

ANSWER: Since the provisions to which this equipment must comply do not require positive beam limitation, but require only a means to limit the field to the size of the image receptor, it would appear that there is no technical problem in accomplishing the technique desired. One method of accomplishing proper beam limitation would be with a beam limiting device having a series of fixed apertures. It would be necessary for the apertures intended for stereoscopic use to be offset so that the field corresponded to the image receptor. Also, if the machine were equipped with a variable aperture beam limiting device, it would be in compliance with this paragraph.

Axial Transverse Tomography and X-Ray Beam Limitation

QUESTION: What requirements of the Performance Standards for Diagnostic X-Ray Equipment do axial transverse tomographs have to meet, with respect to x-ray beam limitation?

ANSWER: As we understand the description of this unit, the x-ray beam is always at an angle of 20 degrees from the vertical, is never perpendicular to the image receptor, and the unit is used only for tomography. In addition, it is designed for only two source-to-image receptor distances (SID) with two cassette sizes available for use at one of these SID's and only one cassette size for the other SID. In consideration of these limitations, we interpret that this unit is not a "general purpose radiographic x-ray system." Consequently, regarding x-ray field limitation and alignment, your unit must comply with Section 1020.31(f)(4). Since the film also rotates on an axis perpendicular to and through the center of its surface, we would interpret the image receptor dimensions as a square with sides equal to the longest film dimension.

A Fixed SID and One Anatomical Part Use Requirement for Beam Limitation

QUESTION: If a doctor works with one anatomical part (i.e., chest) at a fixed SID (72 inches), can we install a cassette that will rotate 90 degrees to allow the single size image receptor (14" x 17") to be used in both orientations without PBL?

ANSWER: Yes. This is an other-than-general-purpose system and uses a single size image receptor. The provisions of Section 1020.31(f)(2) may be met without PBL. A fixed aperture or cone that can be rotated 90 degrees with the cassette with adequate means for alignment or a manual collimator with a light field would be acceptable.