FOOD AND DRUG ADMINISTRATION
COMPLIANCE POLICY GUIDES

GUIDE 7133.09

CHAPTER 33 - RADIOLOGICAL HEALTH

SUBJECT: Automatic Adjustment of the X-ray Field Size to the Selected Spot-Film Size - 21 CFR 1020.31(g)(1)

BACKGROUND:

Section 1020.31(g)(1) of the Diagnostic X-ray Standard addresses field limitation and alignment for spot-film devices. It requires that the manufacturer provide means for the adjustment of the x-ray field size to the size of that portion of the film which the user selects on the spot-film selector. It is further required that the x-ray equipment perform this adjustment automatically, except when the x-ray field size is smaller than that of the selected portion of the film.

This policy guide has been prepared to clarify the requirements of the standard for this latter condition, that is, when the x-ray field size being used during fluoroscopy is smaller than the selected size of the spot film.

POLICY:

If the size of the x-ray field at the film is smaller than the selected spot film size, it is the intent of the standard to require that fluorscopic/-spot-film systems be designed to permit the fluoroscopist to maintain this smaller x-ray field size when taking a spot film. Such designs will minimize exposure to the patient because the automatic enlargement of the x-ray field size to cover the size of the film portion selected would result in a field size larger than desired by the fluoroscopist and unnecessary radiation exposure to the patient. For this reason, manufacturers should interpret Section 1020.31(g)(1) as prohibiting the manufacture of a fluoroscopic/spot-film system which does not permit the fluoroscopist to maintain the x-ray field size when taking a spot film if the size of the x-ray field at the film is smaller than the selected spot-film size.

There may be occasions, however, when the fluoroscopist may desire to increase the x-ray field size from a size smaller than the selected format to the selected format size. The following systems are examples that would allow such flexibility but would not conflict with the intent of Section 1020.31(g)(1).

1. A system that provides the fluoroscopist a manual adjustment to the selected spot film size, or

2. A system that provides a switch, button, or similar device, which must be activated prior to each spot-film exposure whenever the full selected spot film size is desired, or

3. A system that provides the fluoroscopist a choice of two modes of operation. In one mode, the beam limiting device would adjust automatically to the selected spot-film size while in the other mode the beam limiting device would not automatically adjust to the selected spot-film size when the size of the x-ray field at the film is smaller than the selected spot-film size. This mode selection should be changeable at any time by the fluoroscopist, but should remain in the selected mode until changed. (This is the only acceptable design for those x-ray systems using the same x-ray tube for spot film and other radiographic procedures. For thses systems, the requirements applicable to PBL systems (21 CFR 1020.31(e) should be met when automatic spot film sizing is selected. When the other mode is selected, the requirements applicable to spot-film devices (21 CFR 1020.31(g)) should be met).

Field Limitation and Alignment for Spot-Film Devices (21 CFR 1020.31(g))

REF:BRH:DOC:MA 347

Background

21 CFR 1020.31(g) requires that spot-film devices have automatic field sizing capability and, whenever automatic sizing is employed, must meet the field limitation alignment criteria specified in this section.

Most overtable spot-film devices are designed to provide size sensing for a limited number of cassette sizes and to prevent spot-film radiography for unacceptable cassette sizes. Recently, several manufacturers expressed concern about compliance when metric sized cassettes were accidently inserted or when English sizes were inserted into devices designed only for metric sizes. This concern is based on the fact that many metric and English sizes are nearly the same and that the sensing systems will be unable to identify the differences, thereby resulting in possible incorrect size sensing.

Opinion

Compliance of overtable spot-film devices with the requirements of 21 CFR 1020.31(g) will be based on the manufacturer's design for metric or English cassette sizing sensing. If the spot-film device has been specifically designed and manufactured to accept either English sized cassettes or metric sized cassettes, but not both, compliance determination will be based on the measurement system (English or metric) for which the product was designed and manufactured.

The National Center for Devices and Radiological Health expects manufacturers of overtable spot-film devices to prominently label the spot film device for either English or metric sized cassettes to reduce the possibility of system misuse or malfunction.

This opinion does not apply to undertable spot-film devices (overtable x-ray tube), because they are generally part of the positive beam limitation system which must provide proper sizing or exposure prevention for any size cassette, English or metric sized.

SUBJECT: Minimum X-ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size

BACKGROUND:

The minimum field requirement for spot-film devices is stated in 21 CFR 1020.31(g)(3): "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 minimum field requirement for image-intensified fluoroscopy is given in 21 CFR 1020.32(b)(2)(iv). That regulation allows for a minimum field size of 125 square centimeters or less for devices not equipped with stepless adjustment collimation.

FDA believes that it is not appropriate to have different minimum field size requirements for fluoroscopic and spot-film modes of operation of fixed SID fluoroscopic systems, and plans to revise 21 CFR 1020.31(g)(3) to make it compare with 21 CFR 1020.32(b)(2)(iv).

POLICY:

Fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field during fluoroscopy must provide a minimum x-ray field size of 125 square centimeters or less during fluoroscopy and spot-film radiography. For those systems, the Food and Drug Administration will not enforce the 5 by 5 centimeter minimum field size for spot-film collimation.

Spot-Film Pushbutton Size Selector

QUESTION: Will NCDRH consider the following to be acceptable? Our spot film system allows use of several different size film cassettes. A cassette size sensing tray is used which requires the user to center the cassette in the tray in one direction, and clamps are used to center it in the other direction. The beam limiter automatically adjusts to the proper field size for a 1 on 1 film. A pushbutton selector is used to select the desired program of 1 on 1, 2 on 1, 3 on 1, 4 on 1, and 6 on 1. Since various size cassettes can be used, different pushbuttons must be operated for different size cassettes for each program. For example, there is a different pushbutton cassette for a 2 on 1 on a 9.5 x 9.5 cassette than for a 2 on 1 on a 10 x 12 cassette. It is necessary for the operator to select the pushbutton corresponding to the cassette size being used for the beam limiter to adjust the x-ray field size to match the image receptor size as required by Section 1020.31(g). If the button for a 2 on 1 on a 10 x 12 cassette were operated with a 9.5 x 9.5 cassette in the tray, the x-ray field should exceed the image receptor. However, we feel this would be an operator error similar to putting the wrong size film in the cassette.

ANSWER: The proposed solution would not meet the requirements of 21 CFR 1020.31(g). As is stated in Section 1020.31(g)(1), "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 field which has been selected on the spot film selector. Such adjustments shall be automatically accomplished . . ." Since your proposed solution would require a selection on the part of the operator and would not be accomplished automatically, it would not meet the intent of this paragraph.

SECTION 1020.31(i) - BEAM-ON INDICATORS

mA or mAs Meters as Visual Indicators

QUESTION: Is it correct to interpret that a milliammeter or a milliampere-second meter is an appropriate kind of visual indicator as required by this paragraph (1020.31(i))?

ANSWER: A milliammeter or milliampere-second meter which deflects upon initiation of an exposure would be an appropriate kind of visual indicator and would meet the intent of this paragraph.

SECTION 1020.31(j) - MULTIPLE TUBES

Indicator Location for Spot-Film Tubes

QUESTION: Is the tube under the table used for spot-films considered a radiographic tube and, if so, where should the indicator be placed to show that it was selected for an exposure as required by Section 1020.31(j)?

ANSWER: Section 1020.31(j) is intended for the situation where two or more radiographic tubes are controlled by one exposure switch. The fluoroscopic tube used for making a spot film has a separate exposure switch for spot filming and, consequently, Section 1020.31(j) would not apply.

SECTION 1020.31(k) - STANDBY RADIATION FROM CAPACITOR ENERGY STORAGE EQUIPMENT

BRH:DOC:MA 355

The standby radiation requirement of the Performance Standards for Diagnostic X-ray Equipment was written with the worst case assumption that the unit was continually on standby (i.e., charged up) and the user was in close proximity to the unit. The 2 mR per hour at 5 cm limit ensures that the 40-hour week occupational exposure of 100 mR protection guideline is not exceeded.

In many capacitor discharge x-ray systems, radiation may be emitted under the following situations:

(1) the kilovoltage is too high for the radiological procedure and this kilovoltage is lowered by discharging through the x-ray tube either automatically or manually ("discharge pushbutton");

(2) the radiological procedure is completed and the unit is manually discharged ("discharge pushbutton") through the x-ray tube before or after deactivating the input power; or

(3) the radiological procedure is completed and the unit automatically discharges through the x-ray tube upon deactivating the input power.

These circumstances do not involve the exposure switch or timer and, therefore, are regarded as standby radiation according to the regulations.

The worst case assumptions of the standby requirements are not appropriate for the discharge situations described above. First, the assumption cannot be made that the unit is continually being discharged, and secondly, the user will not be in close proximity to the radiation source during discharge, certainly not at 5 cm. An exposure rate limit of 2 mR per hour at 5 cm is unduly restrictive for these situations.

In view of these considerations, the Center will use a radiation level of 100 mR in one hour at 1 meter from the x-ray source as the prescribed level for the following discharge situations on capacitor energy storage equipment:

(1) the kilovoltage is lowered by discharging through the x-ray tube either automatically or manually ("discharge pushbutton");

(2) the unit is manually discharged ("discharge pushbutton") through the x-ray tube before or after deactivating the input power; or

(3) the unit is automatically discharged through the x-ray tube upon deactivating the input power.

Compliance shall be determined by measurements of the maximum exposure per discharge multiplied by the total number of discharges in one hour (duty cycle). These measurements may be averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Sections 1020.32(c) - 1020.32(e)

SECTION 1020.32(c) - ACTIVATION OF TUBE IN FLUOROSCOPIC MODE

Delays Between the Time the X-Ray Exposure Switch is Activated and Initiation of the First Exposure

QUESTION: Our proposed method of making a single photospot camera exposure by momentary actuation of the "RECORD" foot switch through limited time latching will be acceptable only if "SEQUENCE" operation is selected (single shot switch indicating shot position). We assume the statement, "but means may be provided to permit completion of any single exposure of the series in process," also applies to the first exposure in a sequence. Does the paragraph imply that the latching action can commence only after exposure begins? If so, it would be very difficult to get one exposure only with the system in the "SEQUENCE" or "SERIAL" mode. This certainly would be a loss in convenience to many operators and could result in extra unwanted exposures if they do not switch to "SINGLE SHOT" each time.

Completion of the exposure cycle after momentary actuation of "RECORD" in the single shot mode is also an advantage to the operator in that the interruption of fluoro can be maintained at a minimum with earliest possible resumption of fluoro after exposure completion.

Can we interpret Section 1020.32(c) to permit including the preparation cycle (approximately 1/2 second) as well as the exposure cycle to complete any single exposure whether in a "SINGLE" or "SERIAL" mode?

ANSWER: Yes, Section 1020.32(c) allows for the completion of the exposure in process which includes any "latching action" or delay between the time the x-ray exposure switch is activated and initiation of the first exposure.

SECTION 1020.32(d) - ENTRANCE EXPOSURE RATE LIMITS

Fluoroscopic High-Level Control Operation

REVISED LANGUAGE REF:BRH:DOC:MA 1189

This is intended to clarify what the Center considers acceptable arrangements of equipment to comply with Section 1020.32(d)(1) of the standard. The acceptable options will be discussed in turn. It is assumed in this discussion that automatic brightness control has been provided.

Option No. 1: Equipment with no optional high level control provided. Operation in both the manual and automatic modes must be such that the exposure rate at the tabletop does not exceed 10 roentgens per minute.

Option No. 2: An optional high level control is provided.

Situation A

The optional high level control functions in both the manual and automatic modes of operation. In this case, the exposure rate limit at the tabletop is 5 roentgens per minute without activation of the high level control. When the high level control is activated, the exposure rate at the tabletop is not limited.

Situation B

The optional high level control applies to only one mode of operation, either manual or automatic. In this case, the mode of operation to which the high level control applies is limited to an exposure rate at the tabletop of 5 roentgens per minute when the high level control is not activated. When it is activated, there is no limit on the exposure rate at the tabletop. The mode of operation to which the high level control does not apply is limited to to an exposure rate at the tabletop of 10 roentgens per minute.

All of the configurations of equipment described above meet the intent of the standard, and would be found acceptable when compliance with the standard is determined.

Entrance Exposure Rate for Lateral-Type Fluoroscopes (21 CFR 1020.32(d))

REF:BRH:DOC:MA 335

Background

Lateral fluoroscopes are generally subsystems of biplane fluoroscopic x-ray systems. Typically, they consist of a lateral image intensifier, lateral source assembly, and a ceiling crane with centering interlocks. Recent FDA field tests of these systems have indicated high lateral entrance exposure rates. The Performance Standard for Diagnostic X-ray Equipment specifies compliance measurement geometries for undertable equipment, overtable source systems, and C-arm fluoroscopes. However, no specific guidance is stated for lateral fluoroscopes.

The following opinion describes the entrance exposure rate measurement geometry which will be used by the Center for measuring compliance of the lateral fluoroscopes with the provisions of 21 CFR 1020.32(d).

Opinion

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

Momentarily Exceeding the 5R/minute Limit

QUESTION: Our system would use a radiation flux detector calibrated to limit the entrance exposure rate to 5 R/min by limiting the maximum peak tube potential for the four values of mA which could be selected. However, the fluoroscopic entrance exposure rate could exceed the 5 R/min limit momentarily (less than two seconds) if the operator changes to a higher mA setting while x-rays are produced. This occurs during the time that the peak tube potential is driven down to a value sufficient to limit the entrance exposure rate to 5 R/min. The alternative would be to terminate production of x-rays during this time and that could lead to a loss of important diagnostic information. The audible signal is set so that anytime the entrance exposure rate exceeds 5 R/min the signal is activated. Would such a system be acceptable?

ANSWER: The system you have described would be acceptable, with one exception. The audible signal must sound whenever the high level control is activated, regardless of whether the entrance exposure rate exceeds 5 R/min.

Measurement Point for Entrance Exposure Rate

QUESTION: For a remote control system with a top that can be raised, must the 5 R/min or 10 R/min limit be measured at a point nearest the x-ray source or at a point most used on equipment? If 5 R/min is chosen with high level control, could measurement be made at normal use point (farthest from x-ray source) if raising the tabletop locked out x-ray until high level mode was chosen?

ANSWER: The 5 R/min limit should be set at the shortest source to skin distance.

March 24, 1986 Ref:MA:OC:DRP:387

TO: MANUFACTURERS AND ASSEMBLERS OF DIAGNOSTIC X-RAY EQUIPMENT AND FIELD COMPLIANCE TESTING PERSONNEL

SUBJECT: MEASUREMENT OF ENTRANCE EXPOSURE RATE FOR C-ARM FLUOROSCOPIC X-RAY SYSTEMS - 21 CFR 1020.32(d)(3)(iii)

C-arm fluoroscopic x-ray systems may be employed in various configurations; with the source above the x-ray table and the image intensifier below the table, with the source below the table and the image intensifier above, with the source and image intensifier opposite one another in lateral alignment across the table, and in some configurations where no table is used. Because the entrance exposure rate (EER) measurement methodology differs among under-table, over-table, lateral, and C-arm fluoroscopic x-ray systems, there has been a great deal of confusion about EER measurement for stationary C-arm type x-ray systems which may be used in any of these configurations. Inquiries are frequently received from users, manufacturers, and field inspection personnel asking how to measure EER on such systems. The confusion appears to stem from the fact that 21 CFR 1020.32(d)(3)(iii) refers to "C-arm type" fluoroscopes, without describing the system as stationary or mobile, or having fixed or variable SID.

The following clarifies the Food and Drug Administration's intent concerning applicability of the EER limits in 21 CFR 1020.32(d)(1) and (2) to any C-arm fluoroscope. Compliance of all C-arm fluoroscopes with the EER limits shall be determined as directed by 21 CFR 1020.32(d)(3)(iii), which states: "In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly."

All C-arm fluoroscopes (stationary and mobile) must meet the EER limits in 21 CFR 1020.32 (d)(1) and (2) 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly. NOTE: Fluoroscopic radiation therapy simulation systems are exempt from the entrance exposure rate requirements.

SECTION 1020.32(e) - INDICATION OF POTENTIAL AND CURRENT

Automatic Exposure Controls (AEC's) Acceptable Tube Current Indications

QUESTION: In systems with automatic exposure control where peak tube current is held constant, will a label of specified tube current meet the requirement of Section 1020.32(3)(e)? In our system, it is the average current which changes automatically by varying current pulse width and frequency of pulse (to correspond to frame rate) in a grid controlled tube.

ANSWER: In the passage cited, current is interpreted to mean average current. Therefore, a milliameter must be provided to meet the requirement.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-177:410

FDA 86-8258	Computed Tomography Techniques and Quality Assurance Programs in the Mid-1980's (PB 86-182508/AS, $11.95).
FDA 86-8259	Guide for Preparing Initial Reports and Model Change Reports on Lasers and Products Containing Lasers (September 1985) (PB 86-192689/AS, $9.95).
FDA 86-8260	Compliance Guide for Laser Products (September 1985) (PB 86-192697/AS, $9.95).
FDA 86-8261	The Selection of Patients for X-Ray Examinations: Presurgical Chest X-Ray Screening Examinations (April 1986) (PB 86-205424/AS, $9.95).
FDA 86-8262	Laser Light Show Safety. Who's Responsible? (booklet).
FDA 86-8263	The Selection of Patients for X-Ray Examination: Skull X-Ray Examination for Trauma (GPO 017-015-00233-1, $1.75) (PB 87-107892/AS, $9.95).
FDA 86-8264	Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Compliance Survey Instruments (June 1986) (PB 87-107900/AS, $9.95).
FDA 86-8265	The Selection of Patients for X-Ray Examinations: Presurgical Chest X-Ray Screening Examinations (pamphlet).
FDA 86-8266	Joint CDRH and State Quality Assurance Surveys in Nuclear Medicine: Phase 2 - Radiopharmaceuticals (PB 87-113031, $13.95).
FDA 86-8267	The Selection of Patients for X-Ray Examinations: Skull X-Ray Examination for Trauma (flyer).
FDA 86-8268	Workshop Manual for Computer-Interfaced Scintillation Camera Quality Assurance (PB 87-113817, $13.95).
FDA 87-8269	CSU-FDA-NCI Collaborative Radiological Health Laboratory Annual Report 1985: Health Effects of Prenatal and Postnatal Whole-Body Exposure to Ionizing Radiation in the Beagle Dog (PB 87-109773/AS, $13.95).
FDA 87-8270	The Darker Side of Indoor Tanning (poster).
FDA 87-8271	Developmental and Teratogenic Effects of 2450 MHz Microwaves in Mice (PB 87-200598/AS, $13.95).
FDA 87-8272	The Darker Side of Indoor Tanning (flyer).
FDA 88-8033	Center for Devices and Radiological Health Publications Index (August 1988) (PB 89-120372/AS, $28.95).
FDA 88-8035	Regulations for the Administration and Enforcement of The Radiation Control for Health and Safety of 1968 (April 1988) (PB 88-208657/AS, $19.95).
FDA 88-8127	Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) (PB 89-131890/AS, $13.95).
FDA 88-8140	Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) (May 1988) (PB 89-131908/AS, $13.95).
FDA 88-8234	Quality Control Guide for Sunlamp Products (March 1988) (PB 88-192729/AS, $12.95).
FDA 88-8264	Guide for Establishing and Maintaining A Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (March 1988) (PB 88-192711/AS, $12.95).
FDA 88-8273	The Selection of Patients for X-Ray Examinations: Dental Radiographic Examinations (GPO 017-015-00236-5, $2.00) (PB 88-136791, $12.95).
FDA 88-8274	The Selection of Patients for X-Ray Examinations: Dental Radiographic Examinations (flyer).
FDA 89-8008	Imports: Radiation-Producing Electronic Products (November 1988) (brochure).

U.S. DEPARTMENT OF
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Food and Drug Administration
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Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment

FDA 89-8221