

PART F

MEDICAL DIAGNOSTIC AND INTERVENTIONAL X-RAY AND IMAGING SYSTEMS

Sec. F.1 - Purpose and Scope. This Part establishes requirements, for which a registrant [licensee] is responsible, for use of diagnostic and interventional x-ray equipment and imaging systems by, or under the supervision of, an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of Parts A, B, D, G J, I, X, and Z of these regulations.

Sec. F.2 - Definitions. As used in this Part, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Air kerma" means kerma in air (see definition of Kerma).

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

"Alert value" means a dose index (e.g., of CTDI_{vol}(mGy) or DLP(mGy-cm)) that is set by the registrant [licensee] to trigger an alert to the CT operator prior to scanning within an ongoing examination. The Alert value represents a universal dose index value well above the registrant [licensee]'s established range for the examination that warrants more stringent review and consideration before proceeding.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy^{1/} affording the same attenuation, under specified conditions, as the material in question.^{*/}

"Articulated joint" means a joint between two separate sections of a tabletop which joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.^{*/}

"Attenuation block" means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.^{*/}

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.^{*/}

"Automatic exposure rate control (AERC)" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.^{*/}

^{1/} The nominal chemical composition of type 1100 aluminum is 99.00 percent minimum aluminum, 0.12 percent copper.

^{*/}Based on Current FDA standards.

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.^{*/}

"Bone densitometry" means a noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

"Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.^{*/}

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

"Cantilevered tabletop" means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.^{*/}

"Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of the image receptor during a radiographic exposure.

"Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n - 1} \right]^{1/2}$$

where:

s = Estimated standard deviation of the population.

\bar{x} = Mean value of observations in sample;

x_i = i_{th} observation in sample;

n = Number of observations sampled.^{*/}

"Computed radiography (CR; also see DR)" means a digital x-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house

^{*/} Based on Current FDA standards.

the phosphor, or it may be integrated into a digital radiography system.

"Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.^{*/}

"Computed tomography dose index" (CTDI) means the average absorbed dose, along the z-axis, from a series of contiguous irradiations. It is measured from one axial CT scan (one rotation of the x-ray tube), and is calculated by dividing the integrated absorbed dose by the nominal total beam collimation. The scattering media for CTDI consist of two (16 and 32 cm in diameter) polymethylmethacrylate (PMMA, e.g., acrylic or Lucite) cylinders of 14 cm length. The equation is:

$$CTDI = \frac{1}{NT} \int_{-\infty}^{\infty} D(z) dz ,$$

Where: $D(z)$ = the radiation dose profile along the z-axis,

N = the number of tomographic sections imaged in a single axial scan. This is equal to the number of data channels used in a particular scan. The value of N may be less than or equal to the maximum number of data channels available on the system, and

T = the width of the tomographic section along the z-axis imaged by one data channel. In multiple-detector-row (multislice) CT scanners, several detector elements may be grouped together to form one data channel. In single-detector-row (single-slice) CT, the z-axis collimation (T) is the nominal scan width.

" $CTDI_{100}$ " means the accumulated multiple scan dose at the center of a 100-mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The $CTDI_{100}$, requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of $CTDI_{100}$, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available "pencil" ionization chamber. $CTDI_{100}$ is acquired using a 100-mm long, 3-cc active volume CT "pencil" ionization chamber and one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table. The equation is:

$$CTDI_{100} = \frac{1}{NT} \int_{-50mm}^{50mm} D(z) dz$$

" $CTDI_{vol}$ " see "Volume Computed Tomography Dose Index ($CTDI_{vol}$) "

" $CTDI_w$ " see "Weighted Computed Tomography Dose Index ($CTDI_w$) "

"Cone Beam Computed Tomography (CBCT)" is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays, and a cone-shaped x-ray beam (instead of

^{*/} Based on Current FDA standards.

fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, keypads, touchscreens, and other hardware necessary for manually setting the technique factors.

"Cradle" means:

- (1) A removable device which supports and may restrain a patient above an x-ray table;
or
- (2) A device;
 - (i) Whose patient support structure is interposed between the patient and the image receptor during normal use;
 - (ii) Which is equipped with means for patient restraint; and
 - (iii) Which is capable of rotation about its long (longitudinal) axis.^{*/}

"CT" (See "Computed tomography").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in F.2.^{*/}

"CT gantry" means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components within a computed tomography system.^{*/}

"CT number" means the number used to represent the x-ray attenuation associated with each

$$\overline{\text{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

elemental area of the CT image:

where:

- | | | |
|---------|---|---|
| k | = | A constant, a normal value of 1,000 when the Hounsfield scale of CT number is used; |
| μ_x | = | Linear attenuation coefficient of the material of interest; |
| μ_w | = | Linear attenuation coefficient of water. |

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

^{*/} Based on Current FDA standards.

"Detector" (See "Radiation detector")

"Diagnostic reference level" (DRL) is an investigational level used to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.^{*/}

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human [or animal] body for the purpose of diagnosis or visualization.^{*/}

"Digital radiography (DR)" means an x-ray imaging method (or radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.

"Direct digital radiography (DDR; also see CR and DR)" means an x-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an x-ray image. Some DDR systems use a scintillator to convert x-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert x-rays directly to charge, which is stored on the thin-film transistor.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

"Direct supervision" means a qualified practitioner must exercise general supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the licensed practitioner must be present in the room when the procedure is being performed.

"Dose" means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D , is the quotient of de by dm , where de is the mean energy imparted to matter of mass dm ; thus $D=de/dm$, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).^{*/}

"Dose area product (DAP) (aka kerma-area product (KAP))" means the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm², so it does not change with distance from the x-ray tube.

"Dose length product (DLP)" means the indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the formula:

$$DLP \text{ (mGy-cm)} = CTDI_{vol} \text{ (mGy)} \times \text{scan length (cm)}$$

"Dose profile" means the dose as a function of position along a line.^{*/}

^{*/} Based on Current FDA standards.

"Effective dose (E)" means the sum of the tissue-weighted equivalent doses for the radiosensitive tissues and organs of the body. It is given by the expression $E = \sum_T (w_T H_T)$, in which H_T is the equivalent dose in tissue or organ T and w_T is the tissue weighting factor for tissue or organ T. The unit of E and H_T is joule per kilogram ($J \cdot kg^{-1}$), with the special name sievert (Sv).

"Equipment" (See "X-ray equipment") means x-ray equipment.^{*/}

"Exposure (X)" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus $X = dQ/dm$, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.^{*/}

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.^{*/}

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.^{*/}

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

"Fluoroscopically-Guided Interventional (FGI) Procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.^{*/}

"Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.^{*/}

"General supervision" means the procedure is performed under the overall direction and control of the qualified practitioner but who is not required to be physically present during the performance of the procedure.

^{*/} Based on Current FDA standards.

"Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.^{*/}

"Hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

"HVL" (See "Half-value layer").

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.^{*/}

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.^{*/}

"Irradiation" means the exposure of matter to ionizing radiation.

"Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.^{*/}

"Kerma" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K = dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."^{*/}

"Kerma-area product (KAP) " (See "dose area product")

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kW_s" means kilowatt second.

^{*/} Based on Current FDA standards.

"Last-image hold (LIH) radiograph" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.^{*/}

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

- (1) The useful beam; and
- (2) Radiation produced when the exposure switch or timer is not activated.^{*/}

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

- (1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;
- (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and
- (3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.^{*/}

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.^{*/}

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where:

$$\begin{array}{ll} V_n & = \text{No-load line potential; and} \\ V_l & = \text{Load line potential.}^{*/} \end{array}$$

"mA" means milliamperes.

^{*/} Based on Current FDA standards.

"mAs" means milliamperere second.

"Medical event" means one or more of the following criteria have occurred:

- a. Unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rad);
- b. Unintended dose other than skin dose in a single procedure greater than:
 - i. 5 times the facility's established protocol, and > 0.5 Gy (50 rad) to any organ, or
 - ii. 5 times the facility's established protocol, and > 0.05 Sv (5 rem) effective dose;
- c. Wrong patient or wrong site for entire procedure when the resultant dose is:
 - i. Dose > 0.5 Gy (50 rad) to any organ or,
 - ii. Effective dose ≥ 0.05 Sv (5 rem).

"Mobile x-ray equipment" (See "X-ray equipment").

"Mode of operation" means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.^{*/}

"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.^{*/}

"Noise" in CT means the standard deviation of the fluctuations in CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

\overline{CS} = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated [S]standard deviation of the CT numbers of picture elements in a specified area of the CT image.^{*/}

^{*/} Based on Current FDA standards.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.^{*/}

"Notification value" means a protocol-specific dose index (e.g. CTDI_{vol}(mGy) or of DLP(mGy-cm)) that is set by the registrant [licensee] to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

"Picture element" means an elemental area of a tomogram.^{*/}

"PBL" See "Positive beam limitation."

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.^{*/}

"Personal supervision" means a qualified practitioner must exercise General Supervision and be present in the room or adjacent control area during the performance of the procedure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Photostimulable storage phosphor (PSP)" means a material used to capture and store radiographic images in computed radiography systems.

"PID" (See "Position indicating device").

"Pitch" means the table incrementation, in CT, per x-ray tube rotation, divided by the nominal x-ray beam width at isocenter.

"Portable x-ray equipment" (See "X-ray equipment").

"Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure [beyond the patient and cassette holder] for protection purposes.^{*/}

^{*/} Based on Current FDA standards.

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

"Protocol" means a collection of settings and parameters that fully describe an examination.

"Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.^{*/}

"Qualified Expert (QE)" means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic medical physics by the Agency.

"Quality Assurance" means a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities as required.

"Qualified medical physicist (QMP) " means an individual who meets each of the following credentials:

1. Has earned a master's and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and
2. Has been granted certification in the specific subfield(s) of medical physics with its associated medical health physics aspects by an appropriate national certifying body and abides by the certifying body's requirements for continuing education;

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation Protocol Committee (RPC)" means the representative group of qualified individuals in a CT or FGI facility responsible for the ongoing review and management of CT or FGI protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.^{*/}

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiography" means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.^{*/}

"Recording" means producing a retrievable form of an image resulting from x-ray photons.^{*/}

"Reference plane" means a plane which parallel to and which can be offset (as specified in manufacturer information provided to users) from the location of the tomographic plane(s).

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.^{*/}

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.^{*/}

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.^{*/}

"Scan time" means the time elapsed during the accumulation of x-ray transmission data for a single scan.^{*/}

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

"Sensitivity profile" means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.^{*/}

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.^{*/}

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (See "Source-image receptor distance").

"Size-specific dose estimate (SSDE)" means a patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images.

"Source" means the focal spot of the x-ray tube.^{*/}

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source-skin distance (SSD)" means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.^{*/}

"Spot-film"^{2/} means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.^{*/}

^{*/} Based on Current FDA standards.

^{2/} Digital image receptors used in place of film with spot-film devices should be considered "spot-film".

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.^{*/}

"Stationary x-ray equipment" (See "X-ray equipment").

"Stray radiation" means the sum of leakage and scattered radiation.

"Substantial radiation dose level" (SRDL) means an appropriately-selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

"Technique factors" means the following conditions of operation:

- (1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperere-seconds (mAs);
- (2) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;
- (3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
- (4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
- (5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.^{*/}

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.^{*/}

"Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.^{*/}

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube" means an x-ray tube, unless otherwise specified.^{*/}

^{*/} Based on Current FDA standards.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.*/

"Unintended" radiation dose in diagnostic or interventional x-ray means a patient radiation dose resulting from a human error or equipment malfunction during the procedure.

"Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam limiting device when the exposure switch or timer is activated.*/

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.*/

"Volume Computed Tomography Dose Index (CTDI_{vol})" means a radiation dose parameter derived from the CTDI_w (weighted or average CTDI given across the field of view). The formula is:

$$CTDI_{vol} = (N)(T)(CTDI_w)/I, \text{ where}$$

N = number of simultaneous axial scans per x-ray source rotation,

T = thickness of one axial scan (mm), and

I = table increment per axial scan (mm).

Thus,

$$CTDI_{vol} = CTDI_w / \text{pitch}$$

"Weighted Computed Tomography Dose Index (CTDI_w)" means the estimated average CTDI₁₀₀ across the field of view (FOV). The equation is:

$$CTDI_w = 1/3 CTDI_{100, \text{center}} + 2/3 CTDI_{100, \text{edge}}.$$

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 cm acrylic phantom. CTDI_w uses CTDI₁₀₀ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.*/

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

- (1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with

wheels and/or casters for moving while completely assembled;

- (2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried; and
- (3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.
- (4) "Hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

"X-ray field" means that area of the intersection of the useful beam and any one of a set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.^{*/}

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.^{*/}

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.^{*/}

Sec. F.3 - General and Administrative Requirements.

- a. Radiation Safety Requirements. The registrant [licensee] shall be responsible for directing the operation of the x-ray system(s) under his or her administrative control and shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).
 - i. The registrant [licensee] shall have a radiation safety program. The radiation safety program shall include but not be limited to the following:
 - (1) The use of ionizing radiation within its purview is performed in accordance with existing laws and regulations.
 - (2) All persons are protected as required by Part D, Standards for Protection Against Radiation, of these regulations.

^{*/} Based on Current FDA standards.

- (3) Upon discovery of a medical event, the registrant [licensee] shall:
- (i) Contact the Agency regarding the medical event within one business day;
 - (ii) Provide a written report, including the analysis of the medical event, by a QMP [QE] to the Agency within 15 business days;
 - (iii) Provide a clinical summary to the prescribing physician and patient within 15 business days; and
 - (iv) Maintain record of the medical event as part of the patient's permanent medical record.
- ii. An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes unless the Agency or a QMP [QE] determines that the non-compliance shall not pose a significant radiation risk or significantly affect image quality, and arrangements have been made to correct the non-compliance within 30 days.
- iii. The QMP [QE], if required in this Part, shall complete initial and routine compliance evaluations following nationally recognized procedures or those recognized by the Agency. These evaluations shall include a review of the required QC tests.
- iv. All x-ray equipment shall be installed and used in accordance with the equipment manufacturer's specifications.
- v. Individuals operating the x-ray systems shall meet the qualifications required by the Agency.
- vi. A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.
- vii. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.
- viii. Each registrant [licensee] shall have a mechanism in place for the referring physician to access information on selecting the most appropriate diagnostic procedure to answer the clinical question.
- ix. Nationally recognized diagnostic reference levels (DRLs) shall be utilized when applicable.
- x. The registrant [licensee] shall use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.

- xi. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.
- xii. Neither the x-ray tube housing nor the collimating device shall be held during an exposure. Exceptions are allowed for [Agency approved] devices specifically designed to be hand-held.
- xiii. The useful x-ray beam shall be limited to the area of clinical interest.
- xiv. Consideration shall be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.
- xv. A facility shall have a documented procedure in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.
- xvi. For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include:
 - (1) Patient's (adult and pediatric, if appropriate) body part and anatomical size
 - (2) Technique factors
 - (3) Type of image receptor used
 - (4) Source to image receptor distance used (except for dental intraoral radiography)
 - (5) Type of grid, if any.
- xvii. The registrant [licensee] shall create and make available to x-ray operators written safety procedures, including instructions for patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.
- xviii. The registrant [licensee] shall restrict the presence of individuals in the immediate area of the patient being examined to those required or in training for the medical procedure, or the parent or guardian of a patient while the x-ray tube is energized. The following applies to all individuals, other than the patient being examined:
 - (1) All persons shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;
 - (2) All persons shall be protected from the secondary radiation by protective garments or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;

- (3) Instances may warrant having human patients other than the one being examined in the room during the exam. If the procedure results in scatter radiation in excess of 0.02 mSv (2 mR) in any one hour at the position of these patients, they shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be positioned so that the 0.02 mSv (2 mR) in any one hour limit is met.
- xix. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
 - (1) Exposure of an individual for training, demonstration, or other non-healing arts purposes; and
 - (2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Agency.
- xx. In cases where a patient or image receptor must be provided with auxiliary support, mechanical support devices shall be used whenever possible. If a patient or image receptor must be provided with auxiliary support during a radiation exposure:
 - (1) Written safety procedures, as required by F.3a.xv., shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 - (2) The human holder shall be instructed in personal radiation safety and protected as required by F.3a.xvi.;
 - (3) No individual shall be used routinely to hold the image receptor or patient during a radiation exposure;
 - (4) In those cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
- xxi. All individuals who are associated with the operation of an x-ray system are subject to the requirements of Part D of these regulations.
- xxii. Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix A of this Part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified. FDA/MQSA-certified facilities are registered with the Agency for the use of dedicated mammographic equipment to conduct mammography screening.

- xxiii. Maintenance of Records. The registrant [licensee] shall maintain the following information on each x-ray system for inspection by the Agency for a minimum of 5 years or as noted below:
- (1) Model and serial numbers of all major components, and user's manuals for those components, including software, shall be maintained for the life of the system.
 - (2) Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the x-ray system(s); and
 - (3) A copy of all correspondence with the Agency regarding the x-ray system.
- xiv. X-Ray Utilization Record. Each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed.
- b. Quality Assurance.
- i. The registrant [licensee] shall establish and maintain a quality assurance (QA) program. In addition to the standards in the modality specific sections, the registrant [licensee] shall:
 - (1) Maintain documentation of minimum qualifications for practitioners, medical physicists, and x-ray equipment operators.
 - (2) Designate an appropriately trained individual to manage the QA program.
 - (3) Establish and maintain written QA and quality control (QC) procedures, including evaluation frequencies and tolerances.
 - (4) Check each study for artifacts. If an artifact is present, the source shall be identified and appropriate action taken.
 - (5) Perform repeat / reject analysis of radiographic images at least quarterly following specifications of a nationally recognized organization.
 - (6) Complete preventative maintenance on the x-ray systems in accordance with manufacturer specifications at intervals not to exceed 12 months.
 - (7) Maintain documentation showing the testing instruments used in determining compliance with the provisions of this section are properly calibrated and maintained in accordance with the Agency minimum standard or accepted professional standards when no Agency minimum is defined.
 - (8) Complete and document an annual review of the QA program.

- (9) Retain QA/QC records of evaluations and reviews in accordance with state statutes, regulations, but in no case less than three years.
- ii. X-Ray Film Processing Facilities. A registrant [licensee] using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film:

- (a) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
- (b) Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.
- (c) The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Manual Film Developing Technique Chart				
Developer Temperature °C / °F	Developing Time (Minutes)		Developer Temperature °C / °F	Developing Time (Minutes)
26.7 / 80	2.0		20.6 / 69	4.5
26.1 / 79	2.0		20.0 / 68	5.0
25.6 / 78	2.5		19.4 / 67	5.5
25.0 / 77	2.5		18.9 / 66	5.5
24.4 / 76	3.0		18.3 / 65	6.0
23.9 / 75	3.0		17.8 / 64	6.5
23.3 / 74	3.5		17.2 / 63	7.0
22.8 / 73	3.5		16.7 / 62	8.0
22.2 / 72	4.0		16.1 / 61	8.5
21.7 / 71	4.0		15.6 / 60	9.5
21.1 / 70	4.5			

- (d) Devices shall be utilized which will indicate the actual temperature of the developer solution and signal the passage of a preset time.
- (2) Automatic processors and other closed processing systems:
- (a) Automatic processors shall be operated and maintained following

manufacturer specifications.

- (b) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time ^{a/}
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
^{a/} Immersion time only, no crossover time included.		

- (3) Processing deviations from the requirements of F.3b.ii. shall be documented by the registrant [licensee] in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

iii. Additional Requirements for Facilities using X-ray Film.

- (1) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.
- (2) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

- (3) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
 - (4) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary.
 - (5) Outdated x-ray film shall not be used for diagnostic radiographs.
 - (6) The film and intensifying screen shall be spectrally compatible.
 - (7) Facilities shall maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.
 - (8) Facilities other than dental, podiatry, and veterinary shall:
 - (a) Have a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog, These tests shall be performed according to specifications of the manufacturer, a QMP [QE], or a nationally recognized organization.
 - (b) Maintain a light-tight darkroom and use proper safelighting and safeguards such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in optical density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.
 - (c) Limit the base plus fog of unexposed film to an optical density less than 0.25 when developed by the routine procedure used by the facility.
- iv. Facilities Using Computed Radiography (CR) or Direct Digital Radiography (DDR).
- (1) When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.
 - (2) Facilities shall establish and follow an image quality control program in accord with the recommendations of a QMP [QE], the system manufacturer, or a nationally recognized organization.

- (3) Facilities other than dental, podiatric and veterinary, shall quarterly complete phantom image evaluation using a phantom approved by a QMP [QE], system manufacturer, or the Agency. The analysis at a minimum shall include: artifacts, spatial resolution, contrast/noise, workstation monitors, and exposure indicator constancy.
- (4) In addition to F.3b.iv.(1) through (3), CR facilities shall perform erasure of all CR cassettes, at least on a weekly basis.

c. Exemptions.

- i. Dental facilities. Dental facilities performing only intra-oral, panoramic, cephalometric or volumetric dental imaging are exempt from the following provisions of this Section: Sec.F.3a.viii (information available to referring physician) and Sec.F.3b.i.(5) (repeat analysis).
- ii. Podiatry facilities. Podiatry facilities are exempt from the following provisions of this Section: Sec.F.3a.vii. (information available to referring physician) and Sec.F.3b.i.(5) (repeat analysis).
- iii. Veterinary facilities. Veterinary facilities are exempt from the following provisions of this Section: Sec.F.3a.viii. (information available to referring physician), Sec.F.3a.ix. (use of reference levels), Sec.F.3a.xii. (use of dose reduction techniques), Sec.F.3a.xiii. (patient identification), Sec.F.3a.xiv. (protocol control), Sec.F.3a.xviii.(3) (routine holding of patient), Sec.F.3a.xx. (healing arts screening), Sec.F.3b.i.(5) (repeat analysis), and Sec.F.3b.iii.(8)(a) through (c) (use of sensitometric equipment).

Sec. F.4 - General Requirements for All Diagnostic and Interventional X-Ray Systems. In addition to other requirements of this Part, all diagnostic and interventional x-ray systems shall meet the following requirements. Requirements specific to dental intra-oral, panoramic, cephalometric, volumetric dental imaging equipment are included in Sec.F.7.

a. Warning Label.

- i. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement, or the warning statement in F.4a.ii., legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions are observed."
- ii. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

b. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the

source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters (21CFR1020.30(k)).

- c. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (vice 2 milliroentgens exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. (21CFR1020.30(l))
- d. Technique Indicators.
 - i. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. (21CFR1020.31(a)(1))
 - ii. The requirement of F.4d.i. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist. (21CFR1020.31(a)(1))
 - iii. The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within ± 10 percent.
- e. Beam Quality.
 - i. The half value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table 1 of this section, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. (21CFR1020.30(m)) 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 interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place. (21 CFR 1020.30)

TABLE 1
(21CFR1020.30(m))

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems \1\	Other X-Ray Systems\2\	Other X-Ray Systems\3\
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4
\1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980. \2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006. \3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.				

- ii. Optional filtration on fluoroscopic systems. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of this subsection. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided. (21CFR1020.30(m)(2))

- iii. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.
- f. Aluminum equivalent of material between patient and image receptor. Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table 2 in this paragraph, which are used between the patient and the image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in Table 1 of this section for the potential. This requirement applies to front panel(s) of image receptors and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE 2

Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of image receptor (total of all)	1.2
2. Film panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

- g. Battery charge indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- h. Modification of certified diagnostic x-ray components and systems.
 - i. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this Part.
 - ii. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this Part. The owner who causes such modification need not submit the reports required by this Part, provided the owner records the date and the details of the modification in the system records and maintains this information, and

provided the modification of the x-ray system does not result in a failure to comply with this Part.

- i. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
- j. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.
- k. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.
- l. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

Sec. F.5 - Fluoroscopic Equipment. The provisions of this Part apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor. (21CFR1020.32)

- a. Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.
- b. Primary Protective Barrier.
 - i. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation. (21CFR 1020.32(a)(1))
 - ii. Measuring compliance. The AKR shall be measured in accordance with F.5e. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm 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 cm. 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 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly. (21CFR 1020.32(a)(2))

c. Field Limitation.

- i. Angulation. For fluoroscopic 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 with F.5c.v. and F.5c.vi. shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. (21 CFR 1020.32(b)(1))
- ii. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of F.5c.v. and F.5c.vi. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than 300 cm², shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 cm² shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 cm² or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. (21CFR 1020.32(b)(2))
- iii. Spot-film devices. In addition to applicable regulations in F.6 (Radiographic Equipment), the following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system: (21CFR1020.31(h))
 - (1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which 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 image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation. (21CFR1020.31(h)(1))
 - (2) Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 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 length and width differences shall not exceed 4 percent of the SID. On 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. (21CFR1020.31(h)(2))

- (3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID. (21CFR1020.31(h)(3))
- (4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that: (21CFR1020.31(h)(4))
 - (a) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or (21CFR1020.31(h)(4)(i))
 - (b) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm. (21CFR1020.31(h)(4)(ii))
- iv. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure
(21CFR1020.31(h)(5))

- v. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.
 - (1) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies: (21CFR 1020.32(b)(4)(i))
 - (a) Neither the length nor 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. (21CFR 1020.32(b)(4)(i)(A))
 - (b) For rectangular x-ray fields used with circular image receptors, the error in 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. (21CFR 1020.32(b)(4)(i)(B))

- (2) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements: (21CFR 1020.32(b)(4)(ii))
 - (a) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or (21CFR 1020.32(b)(4)(ii)(A))
 - (b) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm. (21CFR 1020.32(b)(4)(ii)(B))
- vi. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies: (21CFR1020.32(b)(5))
 - (1) Neither the length nor 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. (21CFR1020.32(b)(5)(i))
 - (2) The error in 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. (21cfr1020.32(b)(5)(ii))
- vii. Override capability. If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE
(21CFR 1020.32(b)(6))

- d. Activation of Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor,

the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process. (21CFR 1020.32(c))

e. Air Kerma Rates. For fluoroscopic equipment, the following requirements apply:

i. Fluoroscopic equipment manufactured before May 19, 1995.

- (1) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in F.5e.iv., except as specified in F.5e.i.(5). (21CFR 1020.32(d)(1)(i))
- (2) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in F.5e.iv., except as specified in F.5e.i.(5). (21CFR 1020.32(d)(1)(ii))
- (3) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in F.5e.iv., except as specified in F.5e.i.(5). (21CFR 1020.32(d)(1)(iii))
- (4) Equipment may be modified in accordance with this Part to comply with F.5e.ii. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)
(21CFR 1020.32(d)(1)(iv))

- (5) Exceptions: During recording of fluoroscopic images.

ii. Fluoroscopic equipment manufactured on or after May 19, 1995.

- (1) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in F.5e.iv. Provision for manual selection of technique factors may be provided. (21CFR 1020.32(d)(2)(i))
- (2) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in F.5e.iv., except as specified in F.5e.ii.(3). (21CFR 1020.32(d)(2)(ii))
- (3) Exceptions:

- (a) For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode. (21CFR 1020.32(d)(2)(iii)(A))
 - (b) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded. (21CFR 1020.32(d)(2)(iii)(B))
- iii. Fluoroscopy equipment with optional high-level control
 - (1) When high-level control is selected and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in F.5e.iv. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.
- iv. Measuring compliance. Compliance with this subsection shall be determined as follows:
 - (1) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle. (21CFR 1020.32(d)(3)(i))
 - (2) If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. (21CFR 1020.32(d)(3)(ii))
 - (3) In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly. (21CFR 1020.32(d)(3)(iii))
 - (4) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD. (21CFR 1020.32(d)(3)(iv))
 - (5) In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray 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 cm to the centerline of the x-ray table. (21CFR 1020.32(d)(3)(v))

- v. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in F.5e. when used for therapy simulation purposes. (21CFR 1020.32(d)(4))
- f. Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer. (21CFR 1020.32(f))
- g. Source-skin distance.
 - i. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical or interventional applications that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.
 - ii. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical 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 10 cm.
- h. Fluoroscopic irradiation time, display, and signal.
 - i. Fluoroscopic equipment manufactured before June 10, 2006:
 - (1) Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of this paragraph. When the equipment is modified, it shall bear a label indicating the statement:

Modified to comply with 21 CFR 1020.32(h)(2)
(21CFR 1020.32(h)(1)(i))

- (2) As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations. (21CFR 1020.32(h)(1)(ii))
- ii. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:
 - (1) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply: (variation of 21CFR 1020.32(h)(2)(i))
 - (a) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds. (21CFR 1020.32(h)(2)(i)(A))
 - (b) The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset. (21CFR 1020.32(h)(2)(i)(B))
 - (c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure. (21CFR 1020.32(h)(2)(i)(C))
 - (2) A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least 2 seconds. (21CFR 1020.32(h)(2)(ii))
- i. Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure. (21CFR 1020.32(j))
 - i. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure. (21CFR 1020.32(j)(1))
 - ii. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure. (21CFR 1020.32(j)(2))
 - iii. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure,

unless separate displays are provided for the LIH radiograph and fluoroscopic images. (21CFR 1020.32(j)(3))

- j. Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure: (21CFR 1020.32(k))
- i. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second. (21CFR 1020.32(k)(1))
 - ii. The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds. (21CFR 1020.32(k)(2))
 - iii. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma. (21CFR 1020.32(k)(3))
 - iv. The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. (21CFR 1020.32(k)(4))
 - (1) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in F.5e.iv(1), F.5e.iv(2) or F.5e.iv(5) (21CFR 1020.32(k)(4)(i))
 - (2) For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin. (21CFR 1020.32(k)(4)(ii))
 - v. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure. (21CFR 1020.32(k)(5))
 - vi. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ± 35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds. (21CFR 1020.32(k)(6))
- k. Protection From Scatter Radiation.
- i. For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental

- protection for all individuals other than the patient in the room during a fluoroscopy procedure.
- ii. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.
 - (1) Shielding required under F5.k.i shall be maintained to the degree possible under the clinical conditions.
 - (2) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm.
 - (3) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest).
 - (4) Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or non-use of the protective drapes.

l. Operator Qualifications.

- i. In addition to the applicable sections of these regulations, the operation of a fluoroscopic x-ray system for clinical purposes shall be limited to:
 - (1) A licensed practitioner working within his or her scope of practice;
 - (2) A Radiologist Assistant (RA) (if recognized by the Agency) working within his or her scope of practice and under the direct supervision of a licensed practitioner meeting the conditions of F.5l.i.(1);
 - (3) An individual who passed the American Registry of Radiologic Technologists (ARRT) Fluoroscopy Exam (or equivalent) and holds a valid certification, and only under the personal supervision of the licensed practitioner meeting the conditions of F.5l.i.(1);
 - (4) A medical resident or radiologic technology student, in training, and only under the personal supervision of the licensed practitioner meeting the conditions of F.5l.i.(1).
- ii. All persons operating, or supervising the operation of, fluoroscopy systems shall have completed a minimum of 4 hours training that includes but is not limited to the following:
 - (1) Basic properties of radiation;
 - (2) Biological effects of x-ray;

- (3) Radiation protection methods for patients and staff;
 - (4) Units of measurement and dose, including DAP (dose-area product) values & air kerma;
 - (5) Factors affecting fluoroscopic outputs;
 - (6) High level control options;
 - (7) Dose management including dose reduction techniques, monitoring, and recording;
 - (8) Principles and operation of the specific fluoroscopic x-ray system(s) to be used;
 - (9) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and
 - (10) Applicable requirements of these regulations.
- iii. All persons operating, or supervising the operation of, fluoroscopy systems during FGI procedures shall have completed a minimum of 8 hours of training approved by the Agency. The topics shall include:
- (1) The topics provided in F.5l.ii.;
 - (2) Methods to reduce patient dose using advanced imaging and recording features;
 - (3) Procedures for recording pertinent data specified in F.5o.
 - (4) Minimum of one hour of hands-on fluoroscopic machine training demonstrating application of topics required in this subsection.
- iv. The training required in this subsection shall be provided by a QMP [QE] or another individual approved by the Agency.
- v. Two years after the effective date of this rule, the registrant [licensee] shall ensure that prior to performing fluoroscopy procedures each person operating, or supervising the operation of, fluoroscopy systems completed the training required in this subsection.
- vi. The registrant [licensee] shall either provide a minimum of 2 hours in-service training every 2 years for all individuals operating or supervising the operation of fluoroscopy systems used or require evidence of continuing medical education meeting the conditions of this subsection.

- vii. Documentation pertaining to the requirements of F.5 shall be maintained for review for three years.

m. Equipment Operation.

- i. All fluoroscopic images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.
- ii. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.
- iii. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.
- iv. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.
- v. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.
- vi. The registrant [licensee] shall use all methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.
- vii. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the *ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent.

n. Qualified Medical Physicist Evaluations.

- i. Fluoroscopic equipment shall be evaluated by a QMP [QE] within 30 days of installation and of any maintenance of the system that may affect the exposure rate. Thereafter, the measurements shall be made annually or at intervals not to exceed 12 months from the date of the prior measurement by or under the direction of a QMP [QE]. At a minimum these evaluations shall include:
 - (1) A measurement of entrance exposure rates that covers the full range of patient thicknesses, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, acquisition, digital subtraction and CINE, when available. These measurements shall:
 - (a) For systems without automatic exposure control, be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

- (b) For systems with automatic exposure control, be made utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system;
- (2) A measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with Sec F.5e.iv.
- (3) An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes
- (4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors.
- (5) An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes.
- (6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.
- (7) An evaluation of any changes that may impact patient and personnel protection devices.
- ii. Measurements required in Sec F.5n.i. shall be performed with a calibrated dosimetry system per manufacturer recommendations not to exceed 2 years and records maintained for 5 years for inspection by the Agency.
- o. Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures.
 - i. A registrant [licensee] utilizing FGI procedures shall establish a Radiation Protocol Committee (RPC) in accordance with the following.
 - (1) The registrant [licensee] may establish a system-wide committee if the registrant has more than one site.
 - (2) Two or more registrants [licensees] may form a cooperative RPC as long as each facility has a representative on the committee.
 - (3) If the registrant [licensee] has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of F.5o.iv.
 - ii. A quorum of the RPC shall meet as often as necessary, but at intervals not to exceed 12 months.

- iii. Record of RPC. A record of each RPC meeting shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant [licensee] shall maintain the record for inspection by the Agency.
- iv. Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,
- v. RPC Members. Members shall include but not be limited to the following individuals:
 - (1) A supervising physician of the healing arts who meets the requirements in Sec. F.51.;
 - (2) A QMP [QE];
 - (3) The lead technologist; and
 - (4) Other individuals as deemed necessary by the registrant [licensee].
- vi. Establish and implement FGI procedure protocols.
 - (1) The RPC shall establish and implement written protocols, or protocols documented in an electronic report system, that include but are not limited to the following.
 - (a) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.
 - (b) A method to be used to monitor patient radiation dose during FGI.
 - (c) Dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety.
 - (d) SRDL values following nationally recognized standards,
 - (e) Actions to be taken for cases when a SRDL is exceeded which may include patient follow-up.
 - (f) A review of the established protocols at an interval not to exceed 12 months.
 - (2) A record of each RPC protocol shall be maintained for inspection by the Agency. If the RPC revises a protocol, documentation shall be maintained that includes the justification for the revision and the previous protocol for inspection by the Agency.
- vii. Procedures for maintaining records.

- (1) A record of radiation output information shall be maintained so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:
 - (a) Patient identification;
 - (b) Type and date of examination;
 - (c) Identification of the fluoroscopic system used; and
 - (d) Peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.
 - (e) If the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following as necessary:
 - (i) Fluoroscopic mode, such as, high-level or pulsed mode of operation;
 - (ii) Cumulative fluoroscopic exposure time; and
 - (iii) Number of films or recorded exposures.
- (2) The registrant [licensee] shall maintain records required by this subparagraph for inspection by the Agency.

Sec. F.6 - Radiographic Equipment. The following regulations apply to all non-dental registrants [licensees] using diagnostic x-ray equipment. Requirements specific to using dental intra-oral, hand held, panoramic, and cephalometric equipment are in Sec.F.7.

- a. Digital radiographic systems shall be evaluated by a QMP [QE] within 30 days of clinical use and by or under the direction of a QMP [QE] at intervals not to exceed 12 months unless otherwise determined by the Agency. The evaluation shall follow nationally recognized procedures or those recognized by the Agency. Unless otherwise specified in this Part, dental, podiatric, and veterinary systems are exempt from this requirement.
- b. Control and indication of technique factors.
 - i. Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. (21CFR1020.31(a)(2))
 - (1) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall

not be possible to make an exposure when the timer is set to a zero or off position if either position is provided. (21CFR1020.31(a)(2)(i))

- (2) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process. (21CFR1020.31(a)(2)(ii))

ii. Automatic exposure controls. When an automatic exposure control is provided:

- (1) Indication shall be made on the control panel when this mode of operation is selected; (21CFR1020.31(a)(3)(i))
- (2) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliamperere-seconds (mAs), whichever is greater; (21CFR1020.31(a)(3)(ii))
- (3) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kW-s) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and (21CFR1020.31(a)(3)(iii))
- (4) A visible signal shall indicate when an exposure has been terminated at the limits described in F.6b.ii.(3), and manual resetting shall be required before further automatically timed exposures can be made. (21CFR1020.31(a)(3)(iv))

iii. Accuracy. Deviation of technique factors under Sec.F.6b. from indicated values shall not exceed the limits given by the manufacturer. (variation of 21CFR1020.31(a)(4))

c. Reproducibility.

- i. Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05. (21CFR1020.31(b)(1))
- ii. Measuring compliance. 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 setting after each measurement. The 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. (21CFR1020.31(b)(2))

- d. Linearity. The following requirements apply for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated. (variation of 21CFR1020.31(c))
- i. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection. (21CFR1020.31(c)(1))
 - ii. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection. (21CFR1020.31(c)(2))
 - iii. Measuring compliance. Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. 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. (21CFR1020.31(c)(3))
- e. Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements: (21CFR1020.31(d))
- i. Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm. (21CFR1020.31(d)(1))
 - ii. Visual definition.
 - (1) Means for visually defining the perimeter of the x-ray field shall be provided. 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. (21CFR1020.31(d)(2)(i))

- (2) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement. (21CFR1020.31(d)(2)(ii))
- (3) The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2 , where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 mm. (21CFR1020.31(d)(2)(iii))

f. Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in F.6e.: (21CFR1020.31(e))

- i. 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 of the SID, and to indicate the SID to within 2 percent; (21CFR1020.31(e)(1))
- ii. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; (21CFR1020.31(e)(2))
- iii. Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and (21CFR1020.31(e)(3))
- iv. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 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. (21CFR1020.31(e)(4))

g. Field limitation on x-ray equipment other than general purpose radiographic systems.

- i. X-ray systems designed for one image receptor size. 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 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 the edge of the image receptor.
- ii. Other x-ray systems. Radiographic systems not specifically covered in F.6e., F.6f., F.6g.ii., F.6g.iii., and systems covered in F.6g.i., which are also 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 alignment 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. These requirements may be met with: (21CFR1020.31(f)(4))
 - (1) A system which performs in accordance with F.6e. and F.6f.; or when alignment means are also provided, may be met with either; (21CFR1020.31(f)(4)(i))
 - (2) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or (21CFR1020.31(f)(4)(ii))
 - (3) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use. (21CFR1020.31(f)(4)(iii))
- h. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems which contain PBL. (21CFR1020.31(g))
 - i. Field size. When a PBL system is provided, it shall prevent x-ray production when: (21CFR1020.31(g)(1))
 - (1) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or (21CFR1020.31(g)(1)(i))

- (2) The sum of the length and width differences stated in F.6h.i.(1) without regard to sign exceeds 4 percent of the SID. (21CFR1020.31(g)(1)(ii))
 - (3) The beam-limiting device is at an SID for which PBL is not designed for sizing. (21CFR1020.31(g)(1)(iii))
- ii. Conditions for PBL. When provided, the PBL system shall function as described in F.6h.i. whenever all the following conditions are met: (21CFR1020.31(g)(2))
 - (1) The image receptor is inserted into a permanently mounted cassette holder; (21CFR1020.31(g)(2)(i))
 - (2) The image receptor length and width are less than 50 cm; (21CFR1020.31(g)(2)(ii))
 - (3) The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ± 3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive; (21CFR1020.31(g)(2)(iii))
 - (4) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees; and (21CFR1020.31(g)(2)(iv))
 - (5) Neither tomographic nor stereoscopic radiography is being performed. (21CFR1020.31(g)(2)(v))
- iii. Measuring compliance. Compliance with the requirements of F.6h.i. shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of F.6h.ii. are met. Compliance shall be determined no sooner than 5 second after insertion of the image receptor. (21CFR1020.31(g)(3))
- iv. Operator initiated undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm. Return to PBL function as described in F.6h.i. shall occur automatically upon any change of image receptor size or SID. (21CFR1020.31(g)(4))
- v. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-Ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is

such that the operator would consider it part of the operational controls. (21CFR1020.31(g)(5))

- vi. Disabling of PBL. A facility has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.
- i. Source-skin distance. The minimum source-skin distance shall not be less than 30 cm, except intraoral dental equipment covered under F.6i.ii. and veterinary equipment.
- j. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed: (21CFR1020.31(l))
 - i. An air kerma of 0.26 microGy (vice 0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm; and(21CFR1020.31(l)(1))
 - ii. An air kerma of 0.88 mGy (vice 100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm. (21CFR1020.31(l)(2))
- k. Radiation Exposure Control.
 - i. Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.
 - ii. Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
 - iii. Operator Protection, Except Veterinary Systems.
 - (1) Stationary Radiographic Systems. Stationary radiographic systems shall be required to have the x-ray control, including the exposure switch, permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.
 - (2) Mobile and Portable Systems. Mobile and portable x-ray systems which are:

- (a) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.6k.iii.(1);
- (b) Used for less than one week at the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.
- (3) Podiatry Systems. Podiatry facilities shall meet the protection requirements in F.6k.iii.(2)(b).

iv. Operator and Ancillary Personnel Protection for Veterinary Systems.

All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during exposures. Otherwise, in cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam. Refer to F.7 for hand-held intraoral dental x-ray units used in veterinary practice.

- l. Tube Stands for Portable X-Ray Systems. Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during an exposure.
- m. Systems designed for mammography. All systems designed for mammography shall comply with Mammography Quality Standards Act of 1998.
- n. Prohibitions. Capacity energy storage equipment shall not be used to image humans 2 years after the effective date of this Part.

Sec.F.7 Dental Facilities. In addition to the applicable provisions of Sec.F.3, the requirements of Sec.F.7 apply to dental facilities using intraoral, panoramic, and cephalometric x-ray equipment. Dental facilities using cone beam computed tomography (CBCT) technology shall follow applicable provisions of Sec.F.11h.

- a. Quality Assurance. In addition to the general quality assurance provisions in Sec.F.3, the following requirements apply to a dental facility:
 - i. If using film, maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.
 - ii. If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications.

- iii. Registrant [licensee] shall provide initial training and annual evaluations of x-ray operators to include but not limited to: positioning of the x-ray tube, image processing, operator location during x-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Agency.
- b. Warning Label.
 - i. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement or the warning statement in F.7b.ii, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions are observed."
 - ii. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."
- c. Radiation Exposure Control. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.
- d. Exposure Control Location and Operator Protection. Except for units designed to be hand-held, the exposure control shall allow the operator to be:
 - i. Behind a protective barrier at least 2 meters (6.5 feet) tall or
 - ii. At least 2 meters (6.5 feet) from the tube housing assembly, outside the path of the useful x-ray beam, while making exposures.
- e. Administrative Controls.
 - i. Patient and image receptor holding devices shall be used when the techniques permit.
 - ii. Except for units designed to be hand-held, the tube housing and position indicating device (PID) shall not be hand-held during an exposure.
 - iii. Dental fluoroscopy without image intensification shall not be used.
- f. Hand-Held Intraoral Equipment. In addition to the standards in this chapter, the following applies specifically to hand-held devices:
 - i. The hand-held x-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.

- ii. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer, and approved by the Agency.
 - iii. The facility shall adopt and follow protocols provided by the manufacturer, and approved by the agency, regarding the safe operation of the device.
 - iv. When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 mm lead equivalent apron, unless otherwise authorized by the Agency or a certified health or qualified medical physicist.
 - v. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.
 - vi. The registrant [licensee] shall secure the hand-held device from unauthorized removal or use.
- g. Beam-on indicators. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. (21CFR1020.31(j))
- h. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected. (21CFR1020.31(k))
- i. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.
- j. Battery charge indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation. (21CFR1020.30(o))
- k. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.
- l. Technique Indicators.
- i. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. (21CFR1020.31(a)(1))
 - ii. The requirement of F.7l.i. may be met by permanent markings on equipment having fixed technique factors. (21CFR1020.31(a)(1))

- m. Exposure Reproducibility. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05. (21CFR1020.31(b)(1))
- n. Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. (21CFR1020.31(a)(2))
- o. Kilovolt Peak. Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer. (variation of 21CFR1020.31(a)(4)) At a minimum, the kVp on variable kVp units shall be accurate to within 10 percent and within 20 percent on fixed kVp units.
- p. X-ray Beam Alignment.
 - i. The useful x-ray beam shall be limited to the area of clinical interest.
 - ii. Intraoral Dental Units
 - (1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm (21CFR1020.31(i)(1))
 - (2) The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm. (21CFR1020.31(f)(1)(i))
 - iii. Extraoral, Panoramic and Cephalometric Units
 - (1) X-ray 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 alignment 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. These requirements may be met with: (21CFR1020.31(f)(4))
 - (a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or (21CFR1020.31(f)(4)(ii))
 - (b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and

SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use. (21CFR1020.31(f)(4)(iii))

- q. **Beam Quality.** The Half Value Layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table 1 of this section, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. 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 interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place. (21 CFR 1020.30)

Table 1
(21CFR1020.30(m))

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems \1\	Other X-Ray Systems\2\	Other X-Ray Systems\3\
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4
\1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980. \2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006. \3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.				

- r. Intraoral dental x-ray machines shall not be operated at less than a measured 51 kVp effective 2 years after the publication of this rule.
- s. Modification of certified diagnostic x-ray components and systems.

- i. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this Part. (21CFR1020.30(q) but doesn't mention variance option)
- ii. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this Part. The owner who causes such modification need not submit the reports required by this Part, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with this Part. (21CFR1020.30(q)(2))
- t. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. (21CFR1020.30(k))
- u. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (vice 2 milliroentgens exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. (21CFR1020.30(l))
- v. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

Sec. F.11 - Computed Tomography Equipment.

- a. Requirements for CT Equipment.
 - i. Accreditation. All diagnostic CT x-ray systems for human use shall be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency.

- ii. Technical and Safety Information. The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility.
- iii. Termination of Exposure.
 - (1) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function. (21cfr1020.33(f)(2)(i))
 - (2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Subsection F.11a.iii.(1). (21cfr1020.33(f)(2)(i))
 - (3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration. (first part of 21cfr1020.33(f)(2)(ii))
- iv. Tomographic Plane Indication and Alignment.
 - (1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane. (21cfr1020.33(g)(1))
 - (2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes. (version of 21cfr1020.33(g)(2))
 - (3) If a mechanism using a light source is used to satisfy the requirements of Subsections F.11a.iv.(1) or F.11a.iv.(2), the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux. (21cfr1020.33(g)(5))
- v. Beam-On and Shutter Status Indicators and Control Switches.
 - (1) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed. (First part of 21cfr1020.33(h)(1))
 - (2) Each emergency button or switch shall be clearly labeled as to its function.
- vi. Indication of CT Conditions of Operation.
 - (1) The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior

to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible. (21cfr1020.33(f))

vii. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.

- (1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters. (21cfr1020.33(g)(3))
- (2) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible. (second part of 21cfr1020.33(h)(1))
- (3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel. (21cfr1020.33(i))
- (4) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan. (second part of 21cfr1020.33(f)(2)(ii))

b. CT Facility Design Requirements.

- i. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
- ii. Viewing Systems.
 - (1) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
 - (2) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

c. CT Surveys, Performance Evaluations, Routine QC, and Operating Procedures.

- i. Radiation Protection Surveys.

- (1) All CT x-ray systems installed after [insert the effective date of the regulations] shall have a radiation protection survey completed by, or under the direct supervision of, the QMP [QE] within 30 days of installation. Existing systems not previously surveyed shall have a survey made by, or under the direct supervision of, a QMP [QE] within 12 months of the effective date. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- (2) The registrant [licensee] shall obtain a written report of the survey from the QMP [QE], and a copy of the report shall be made available to the Agency upon request.

ii. System Performance Evaluations.

- (1) The annual testing of the CT x-ray system shall be performed by, or under the personal supervision of, a QMP [QE] who assumes the responsibility and signs the final performance evaluation report.
- (2) Evaluation standards and tolerances shall be established by the QMP [QE] and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT x-ray system.
- (3) The evaluation of a CT x-ray system shall be performed after initial installation and before use on human patients, and at intervals not to exceed 12 months. In addition, the QMP [QE] shall complete an evaluation of the CT system within 30 days or after any change or replacement of components which, in the opinion of the QMP [QE], could cause a change in the radiation output or image quality.
- (4) The evaluation shall include but not be limited to:
 - (a) Geometric factors and alignment including:
 - (i) Alignment light accuracy;
 - (ii) Table increment accuracy.
 - (b) Image localization from scanned projection radiograph (localization image);
 - (c) Radiation beam width;
 - (d) Image quality including:
 - (i) High-contrast (spatial) resolution;
 - (ii) Low-contrast resolution;

- (iii) Image uniformity;
 - (iv) Noise;
 - (v) Artifact evaluation.
 - (e) CT number accuracy;
 - (f) Image quality for acquisition workstation display devices;
 - (g) A review of the results of the routine QC required under F.11a.iii.;
 - (h) A safety evaluation of audible and visual signals, posting requirements;
 - (i) Dosimetry.
- (5) The measurement of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.
- iii. Routine Quality Control. A routine QC program on the CT system shall:
- (1) Be developed by a QMP [QE] and include acceptable tolerances for points evaluated;
 - (2) Incorporate the use of a water equivalent phantom. At a minimum, noise, CT number, and artifacts shall be evaluated.
 - (3) Be completed at time intervals and under system conditions specified by the QMP [QE]. The interval shall not to exceed 1 week.
 - (4) Be documented and maintained for inspection by the Agency.
- iv. Operating Procedures.
- (1) The operator of the CT x-ray system shall meet the minimum operator requirements of these regulations and be specifically trained on the operational features of the unit by a manufacturer's applications specialist, QMP [QE], or someone deemed qualified by the Agency.
 - (2) The following information shall be readily available to the CT operator:
 - (a) Instructions on performing routine QC, including the use of the CT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the QMP [QE] for the indicated

parameters, and the results of at least the most recent routine QC completed on the system; and

(b) Scanning protocols established by the RPC, including instructions on reporting deviations .

(3) If the QMP [QE] evaluation or routine QC of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the QMP [QE], use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the QMP [QE].

d. CT Radiation Protocol Committee (RPC). The registrant [licensee] shall develop and maintain an RPC in accordance with the following:

i. Members of the RPC.

(1) Members of the RPC shall include but not be limited to the:

(a) Lead CT radiologist;

(b) Lead CT technologist;

(c) QMP [QE]; and

(d) Other individuals as deemed necessary by the registrant [licensee] (e.g., Radiation Safety Officer, Chief Medical or Administrative Officer, Radiology Department Administrator/Manager).

(2) If the registrant [licensee] has more than one site with CT, they may establish a system-wide RPC.

(3) Two or more registrants [licensees] may form a cooperative RPC as long as each facility has a representative on the committee.

(4) If the registrant [licensee] has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of F.11d.i.

ii. Responsibilities of the RPC. The RPC shall:

(1) Review existing CT protocols along with the evaluation and implementation of new and innovative technologies that can improve image quality and/or lower patient dose in comparison with the older protocol.

(2) Review the capabilities of the individual CT scanner to ensure maximum performance is achieved.

- (3) Determine and review the protocols used frequently or could result in significant doses. This review shall include acquisition and reconstruction parameters, image quality, and radiation dose. At a minimum, the facility shall review the following clinical protocols, if performed, at intervals not to exceed 12 months:
 - (a) Pediatric Head;
 - (b) Pediatric Abdomen;
 - (c) Adult Head;
 - (d) Adult Abdomen;
 - (e) Adult Chest;
 - (f) Brain Perfusion.
- (4) Establish and implement written protocols, or protocols documented in an electronic reporting system, that include but are not limited to the following:
 - (a) A method to be used to monitor the CT radiation output.
 - (b) A standardized protocol naming policy.
 - (c) A DRL, notification value, and alert value for CT procedures reviewed in F.11d.ii.3. Notification and alert values may be applied by using trigger values in conformance with NEMA XR-29 or facility-established values and procedures as defined by the QMP [QE].
 - (d) Actions to be taken for cases when the dose alert value was exceeded which may include patient follow-up.
 - (e) A process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.
- (5) If CT fluoroscopy is performed, the RPC shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.
- (6) Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,
- (7) At a minimum the RPC members in F.11d.i.(1)(a) through (c) shall meet as often as necessary to conduct business but at intervals not to exceed 12 months.

iii. Records.

- (1) A record of each RPC meeting shall be maintained. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any action taken.
- (2) The registrant [licensee] shall maintain a record of RPC policies and procedures.
- (3) The registrant [licensee] shall maintain a record of radiation output information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include:
 - (a) Patient identification;
 - (b) Type and date of examination;
 - (c) Identification of the CT system used; and
 - (d) The dose values the CT system provides (e.g., CTDIvol, DLP, SSDE).

e. CT systems used in treatment planning. CT systems solely used for treatment planning in radiation oncology shall meet the requirements in Part X.10 of these regulations.

f. PET CT and SPECT CT Systems. CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in Sections F.11.a. through F.11d. unless otherwise exempted below:

i. F.11a.i. (Accreditation)

ii. In lieu of F.11c.ii., a QMP [QE] shall complete a performance evaluation on the CT system following nationally recognized guidelines or those approved by the Agency at intervals not to exceed 12 months.

iii. In lieu of F.11c.iii., routine QC checks shall be completed at intervals not to exceed 1 week. These checks shall be established and documented by a QMP [QE] following nationally recognized guidelines or those approved by the Agency.

iv. F.11c.iv.(2)(b) (RPC)

g. Veterinary CT Systems. CT systems, including CBCT systems, solely used in non-human imaging shall meet the requirements of F.11c.i. (radiation protection surveys) and are otherwise exempt from the standards of Section F.11.

h. Cone Beam Computed Tomography Systems.

i. CBCT facilities shall meet F.4., F.6i. and k., and F.11a.ii through F.11a.vii., as applicable.

- ii. Beam alignment. The x-ray field in the plane of the image receptor shall not exceed beyond the edge 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, the center of the x-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID.
- iii. A performance evaluation shall be performed by, or under the direct supervision of, a QMP [QE]. The evaluation shall follow nationally recognized standards and tolerances or those recognized by the Agency. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 12 months, and within 30 days after any change or replacement of components which, in the opinion of the QMP [QE], could cause a change in the radiation output or image quality. The facility shall maintain documentation of the established standards and tolerances and testing results.
- iv. The registrant [licensee] shall follow the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer provided QC recommendations, the registrant [licensee] shall implement and document QC guidelines established by a QMP [QE] in accordance to nationally recognized guidelines or those recognized by the Agency.
- v. The registrant [licensee] or RPC, if established, shall implement and document a policy addressing deviations from established protocols.
- vi. The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.
- vii. The following information shall be readily available to the CBCT operator:
 - (1) Instructions on performing routine QC, including the use of the CBCT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the QMP [QE], if required, for the indicated parameters, and the results of at least the most recent routine QC completed on the system.
- viii. Exemption. A QMP [QE] performance evaluation on CBCT systems capable of operating at no greater than 100 kV or 20 mA shall be performed at intervals not to exceed 24 months, or an interval approved by the Agency.
- ix. Exemption. The registrant [licensee] using fluoroscopy systems capable of CBCT shall meet F.11.h, except F.11.a.ii through F.11.a.vii in F.11.h.i.

Sec. F.15 - Dual-Energy X-ray Absorptiometry (DXA) (Bone Densitometry).

- a. DXA systems shall be:
 - i. Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug

and Cosmetic Act.;

- ii. Registered [licensed] in accordance with Part B of these regulations; and
 - iii. At a minimum, maintained and operated in accordance with the manufacturer's specifications.
- b. Operator Requirements. In addition to the minimum qualifications outlined in Part Z of these regulations, operators shall complete training specific to patient positioning and the operation of the DXA system.
- c. During the operation of any DXA system:
- i. In the absence of a survey performed by or under the supervision of a QMP [QE] determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public shall be positioned at least two meters from the patient and DXA system during the examination.
- e. Quality Assurance. In addition to the applicable requirements in Part F.3b.i, a facility performing DXA shall:
- i. Conform to the DXA system manufacturer recommendations and recommendations of recognized professional societies such as the International Society for Clinical Densitometry or the American College of Radiology;
- f. Records. The registrant [licensee] shall keep the following records for a minimum of 3 years:
- i. The maintenance and QC tests as prescribed by F.15a.iii. and F.15e.

PART F**APPENDIX A****INFORMATION TO BE SUBMITTED BY PERSONS
PROPOSING TO CONDUCT HEALING ARTS SCREENING**

Persons requesting that the Agency approve a healing arts screening program shall submit the following information for evaluation and approval:

- a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;
- b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;
- c. A description of the x-ray examinations proposed in the screening program i.e., type and number of views;
- d. Description of the population to be examined in the screening program, i.e., age range, sex, physical condition, and other appropriate information;
- e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;
- f. An evaluation by a QMP [QE] of the x-ray system(s) to be used in the screening program. The evaluation shall include the following:
 1. Documentation that such system(s) satisfy all applicable requirements of these regulations;
 2. Measurement of appropriate patient exposures from the x-ray examinations to be performed;
- g. A description of the x-ray quality control program;
- h. A copy of the protocol information for the x-ray examination procedures to be used;
- i. The qualifications of each individual who will be operating the x-ray system(s);
- j. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;
- k. The name and address of the practitioner licensed in the state who will interpret the radiograph(s);

- l. Procedures to be used in advising the individuals screened and their practitioner of the healing arts or health care provider of the results of the screening procedure and any further medical needs indicated;
- m. Procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;
- n. Frequency of screening of individuals; and
- o. The duration of the screening program.

**2015
RATIONALE FOR REVISIONS**

**PART F
DIAGNOSTIC X-RAYS AND IMAGING SYSTEMS IN THE HEALING ARTS**

Introduction

This amendment to Part F includes the addition of requirements specific to fluoroscopically guided interventional (FGI) procedures, medical events in diagnostic and interventional x-ray, expanded QA/QC for CR/DR systems, and updated suggested standards for computed tomography. During the revision process, the working group reviewed recent publications and drafts, including Federal Guidance Report No. 14 (the draft provided for public peer review), NCRP Report No. 168 and No. 172, and numerous AAPM and ACR reports.

Specific Provisions:

X-ray is used for guidance during fluoroscopically guided interventional procedures rather than diagnostic purposes. Therefore, the name of Part F has been changed to: “Part F - Medical Diagnostic and Interventional X-ray and Imaging Systems.”

Section F.1 - Purpose and Scope.

Interventional procedures are added to better describe these important procedures that do not technically use the radiation for diagnostic purposes.

Section F.2 - Definitions.

There are significant additions to the definitions as well as a decision to combine the definitions specific to computed tomography (CT) which originally were standalone in the CT section with the main set of definitions.

Our FDA partners expressed throughout the revision process that they continue to have difficulty revising their own standards. The FDA is in the process of referencing International Electrotechnical Commission (IEC); believing this is the best way to assure new radiation producing equipment being manufactured and marketed in the U.S. will meet the latest recognized minimum standard. They advised the SR-F working group (WG) against using existing FDA definitions and standards and recommended we use IEC safety standards. As of the date of this SR-F revision, the FDA has not completed the process of formalizing the referencing of IEC safety standards.

The WG understands why FDA is pursuing the referencing of IEC standards. The IEC can revise their standards very quickly compared to the time it takes FDA to update their regulations. Unfortunately, even with the assistance of our FDA representatives, the WG

has not received open access to IEC safety standards and definitions so that we could complete a comparison and determine if following FDA's path to referencing them was appropriate. State radiation control programs (SRCP) must regulate not only new radiation producing machines, but equipment manufactured 20+ years ago. It is the understanding of the WG that the SRCPs would need access to the IEC safety standard in effect at the time of manufacturer, if it exists. The IEC safety standards are copyrighted and available for purchase. Since the FDA's efforts to reference IEC safety standards is not final and the WG believes it is important to provide updated suggested standards SRCPs can readily implement, the decision was made to continue using relevant FDA regulations and suggested standards developed by the SR-F committee.

The new definitions for DLP and the different types of CTDI were extracted from the AAPM Report 96. A further explanation of these indices is found in the AAPM report. Any definition directly from current FDA standards is now followed with “^{*}”.

Section F.3 - General and Administrative Requirements.

Section F.3 has been significantly revised. In subsection F.3.a., a registrant [licensee] is required to have a radiation safety program. New to this section are standards addressing medical events in diagnostic and interventional x-ray. A suggested standard that facilities use Diagnostic Reference Levels (DRLs) is added. A new suggested standard, F.3.a.iii, was created to hopefully clarify when a Qualified Medical Physicist (QMP) is required to verify compliance with a standard pertaining to something unlikely to change without an incident (e.g., tube leakage).

Most of the Quality Assurance (QA) requirements for facilities using film are retained. QA for facilities using computed radiography (CR) or direct digital radiography (DDR) is expanded. F.3.b.i.6. is a new suggested standard requiring the facility to have a preventative maintenance evaluation completed on all x-ray machines at least every 12 months.

Section F.4 - General Requirements for All Diagnostic and Interventional X-Ray Systems.

The title of the section was updated by adding “and Interventional”.

In line with noting the definitions in Section F directly out of 21 CFR, this revision of Section F provides the reference to 21 CFR if a standard's origin is the current federal code. The suggested standard on the warning label, F.4.a., has been amended to reflect the change in 21 CFR in 2006.

Section F.5 - Fluoroscopic X-Ray Systems.

The suggested standard was amended to prohibit the use of non-image intensified fluoroscopes. That is, only image-intensified or direct-digital receptor fluoroscopic equipment shall be used. It is suggested that all fluoroscopic machines equipped with

high-level control be limited to a maximum AKR of 176 mGy per minute (20 R/min). Minimum operator qualifications, F.5.l., for those using or supervising the use of fluoroscopy equipment has been significantly amended. Subsection F.5.n. now requires the facility to evaluate all modes clinically used on each fluoroscopic unit at intervals not to exceed 12 months.

Subsection F.5.n.i.4 requires an evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors by the QMP [QE]. The use of the term “interlock” does not imply that the SR-F committee believes interlocks should be installed on fluoroscopy room entry doors. Entrances to fluoroscopy rooms should not be equipped with interlocks designed to terminate x-ray production when triggered.

Subsection F.5.o. provides additional requirements for facilities performing FGI. These facilities are required to have a Radiation Protocol Committee (RPC) with the responsibility of adopting a method to monitor patient dose, setting dose notification levels, and establishing actions to be taken for cases when a substantial radiation dose level (SRDL) is exceeded.

Section F.6 - Radiographic Systems.

The title of Section F.6. was shortened from *Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Bone Densitometry or Computed Tomography X-ray Systems*.

Subsection F.6.a. is a new suggested standard requiring facilities using digital radiography to have an evaluation completed by or under the direction of a QMP within 30-days of clinical use and at intervals not exceeding 12-months unless otherwise determined by the Agency. Dental, podiatric, and veterinary facilities, with exceptions, are exempt.

Section F.7 - Dental Facilities.

The title of the Section was changed from *Intraoral Dental Radiographic Systems* and it was written to serve as a standalone chapter for dental facilities using traditional intraoral, panoramic, or cephalometric dental x-ray equipment. Due to the decision to make this a standalone chapter for these facilities, there are redundancies in some of the operational and equipment standards found elsewhere in this Part.

The appendix providing suggested standards for hand-held dental equipment was eliminated and these standards, with amendments, were included in this Section.

Section F.11 - Computed Tomography X-Ray Systems.

As noted in Section F.2., the definitions originally in this Section were moved to F.2.

Subsection F.11.a. requires all diagnostic CT x-ray systems for human use be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency, and that all technical and safety information relating to the CT system be maintained.

The title of Subsection F.11.c. is amended for clarity. For example, a system performance evaluation rather than a calibration better describes what a QMP performs on a CT system. The role of the QMP is substantially amended. Subsection F.11.d. requires the facility to have an RPC responsible for reviewing CT policies, procedures, and protocols, establishing DRLs, notification & alert levels for the commonly used projections, and managing the access and authority to change a CT protocol. The facility is required to maintain a method to estimate dose to a given patient from a CT study.

The section provides further details on minimum requirements and exemptions for CT systems used solely for treatment planning, calculating attenuation coefficients in PET/CT & SPECT/CT, and non-human (veterinary) use.

Subsection F.11.h. provides minimum suggested standards for CBCT. Included is a requirement that CBCT systems be evaluated annually by a QMP. It was determined by the WG that an annual performance evaluation may not be necessary for the less-powerful systems commonly used in dental practices, etc., so an exemption was written for CBCT systems with a maximum operating potential of 100 kV or 20 mA requiring an evaluation every 24 months or at an interval approved by the Agency.

Fluoroscopy systems capable of CBCT are required to meet a minimum source to skin distance (SSD) requirement of 30 cm in Subsection F.6.i. During federal concurrence, the FDA raised the concern with fluoroscopy systems intended for specific applications (typically extremities) where they allow exceptions to the 30 cm minimum SSD in their regulations. To date, there are no examples of fluoroscopy systems capable of CBCT with a minimum SSD less than 30 cm. The SR-F committee elected to leave the SSR unchanged, and will address certified systems specifically designed to operate at a SSD less than 30 cm if they become available.

Section F.15 - Dual-Energy X-ray Absorptiometry (DXA) (Bone Densitometry).

The title of the Section was amended to provide a more general description of this type of x-ray system.

The operator requirements were amended with reference to Part Z.

Section F.16 - Quality Assurance Program.

This Section was deleted and the QA as added to Section F.3, with modality-specific QA also added to the appropriate sections.

Appendix A - Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

Only minor editorial changes were made to this appendix.

Appendix B - Hand-Held Intraoral Dental Radiographic Unit Requirements for Use

As noted above, this appendix was deleted and standard for hand-held dental were inserted in Section 7.

**2009
RATIONALE FOR REVISIONS**

**PART F
DIAGNOSTIC X-RAYS AND IMAGING SYSTEMS IN THE HEALING ARTS**

Introduction

This amendment to Part F includes the addition of revised performance standards specified in Title 21, Code of Federal Regulations (CFR), Part 1020, effective June 10, 2006, quality assurance program requirements, and hand-held dental units. In addition, Sections F.13 - Mammography Definitions for States with Certifying Authority. and Sec. F.14 - Mammography Requirements for States with Certifying Authority. have been deleted.

Specific Provisions:

"Part F - Diagnostic X-Rays and Imaging Systems in the Healing Arts"

Throughout Part F, "license, " "licensee, " and "licensed, " have been added alongside "registration, " "registrant, " and "registered," respectively, as an optional term. State radiation control programs differ in the regulation of diagnostic and imaging systems by utilizing registration or licensure of machines and/or facilities.

In addition, "qualified expert" has been replaced by "qualified medical physicist. "

Section F.1 - Purpose and Scope.

Part Z is added to recognize medical credentialing of operators utilizing diagnostic x-ray and imaging systems.

Section F.2 - Definitions.

The following definitions were added, revised, or replaced in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006:

- "Accessory component" - Added
- "Air kerma" -Added
- "Air kerma rate" -Added
- "Articulated joint" -Added
- "Automatic exposure rate control" -Added
- "C-arm x-ray system" –Replaced with "C-arm fluoroscope"
- "Cantilevered tabletop" -Added
- "Cassette holder" –Added w/option for computed radiography (CR)
- "Coefficient of variation (C)" -Amended

"Computed tomography (CT)" -Amended
"Cradle"-Added
"CT gantry" -Added
"Cumulative air kerma" -Added
"Dose" -Added
"Exposure (X) " -Added
"Fluoroscopic air kerma display device" -Added
"Fluoroscopic imaging assembly" -Amended
"Fluoroscopic irradiation time" -Added
"Fluoroscopy" -Added
"Half-value layer (HVL)" -Amended
"Image receptor" -Amended
"Image receptor support device" -Added
"Isocenter" -Added
"Kerma" -Added
"Last image hold (LIH) radiograph" -Added
"Lateral fluoroscope" -Added
"Leakage technique factors" -Amended
"Line-voltage regulation" -Amended
"Mode of operation" -Amended
"Movable tabletop" -Amended
"Non-image-intensified fluoroscopy" -Amended
"Primary protective barrier" -Added with clarification
"Protective barrier" -Deleted
"Pulsed mode" -Added
"Quick change x-ray tube" -Added
"Radiography" -Added
"Rated line voltage" -Added
"Rated output current" -Added
"Rating" -Amended
"Recording" -Amended
"Scan" -Added
"Scan time" -Added
"Secondary protective barrier" -Deleted
"Solid state x-ray imaging device" -Added
"Source-skin distance (SSD)" -Added
"Spot film device" -Amended
"SSD" -Deleted
"Stationary tabletop" -Added
"Technique factors" -Amended
"Useful beam" -Amended
"X-ray control" -Added
"X-ray field" -Added
"X-ray subsystem" -Added
"X-ray table" -Amended
"X-ray tube" -Amended

The following definitions were added or changed for clarification:

- "Diagnostic x-ray system" –Option added for veterinary use
- "Hand-held x-ray equipment" –Added
- "Qualified expert" replaced with "Qualified medical physicist"

Editorial change was made in the following definition:

- "Leakage radiation"

The following definitions were deleted because they are not used in Part F:

- "Added filtration"
- "Cephalometric device"
- "Certified components"
- "Certified system"
- "Changeable filters"
- "Dead-man switch"
- "Diagnostic imaging system"
- "Entrance exposure rate"
- "Inherent filtration"
- "Maximum line current"
- "Radiographic imaging system"
- "Termination of irradiation"

Section F.3 - General and Administrative Requirements.

Changes are as follows:

- F.3a.ii.: Changed to reflect the upcoming Part Z – Medical Credentialing.
- F.3a.iii.(3): Changed to recognize CR systems.
- F.3a.viii.: Changed to recognize CR systems.
- F.3a.viii.(6): Editorial correction.
- F.3a.ix(1): Changed to recognize CR systems.
- F.3a.xi.: Editorial correction.

Section F.4 - General Requirements for All Diagnostic X-Ray Systems.

The entire Section F.4 was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

- F.4a.: Updated.
- F.4b.: Deleted.
- F.4c.: Redesignated F.4b. and updated.
- F.4d.: Redesignated F.4c. and updated.

F.4e.: Redesignated F.4d. and updated.
New F.4e.: Added.
New F.4f.: Added.
New F.4g.: Added.
F.4f.: Redesignated F.4h.
F.4g.: Redesignated F.4i.
F.4h.: Redesignated F.4j.
F.4i.: Redesignated F.4k.
F.4j.: Redesignated F.4l.

Section F.5 - Fluoroscopic X-Ray Systems.

Section F.5, including title, was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

New F.5a.: Added.
F.5a.: Redesignated F.5b.
F.5a.i thru iii: Deleted.
F.5a.iv.: Amended.
F.5b.: Redesignated F.5c. and amended.
New F.5d.: Added.
New F.5e.: Added.
New F.5f.: Added.
New F.5g.: Added.
New F.5h.: Added.
New F.5i.: Added.
New F.5j.: Added.
New F.5k.: Added.
F.5c.: Deleted.
F.5d.: Deleted.
F.5e.: Deleted.
F.5f.: Deleted.
F.5g.: Deleted.
F.5h.: Redesignated F.5l and amended.
F.5i.: Deleted.
F.5j.: Deleted.
F.5k.: Redesignated F.5m.
F.5l.: Redesignated F.5n.

The following were amended to reflect recommendations from the Task Force on Fluoroscopic Use:

F.5m.
F.5n.

Section F.6 - Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Bone Densitometry or Computed Tomography X-Ray Systems.

Section F.6, including title, was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

New F.6a.: Added.
New F.6b.: Added.
New F.6c.: Added.
New F.6d.: Added.
New F.6e.: Added.
New F.6f.: Added.
New F.6g.: Added.
New F.6h.: Added.
New F.6i.: Added.
New F.6j.: Added.
New F.6k.: Added.
New F.6l.: Added.
New F.6m.: Added.
F.6a.: Redesignated F.6o. and amended.
F.6a.i. thru iv.: Deleted.
F.6b.: redesignated F.6p.
F.6b.iii. thru v.: Deleted.
F.6b.vi.: Redesignated F.6.p.iii.
F.6b.vii.: Redesignated F.6.p.iv.; added reference to hand-held radiographic devices.
F.6c.: Deleted.
F.6d.: Deleted.
F.6e.: Deleted.
F.6f.: Deleted.
F.6g.: Deleted.
F.6h.: Deleted.
F.6i.: Redesignated F.6q.

Section F.7 - Intraoral Dental Radiographic Systems.

Title was changed to reflect categorical change from “x-ray systems” in Sections F.5 and F.6 to “equipment.”

Performance standards for intraoral equipment are now specified in Section F.6. This will facilitate future revisions of 21 CFR Part 1020. Therefore, Section F.7 only includes requirements not specifically identified as performance standards.

F.7a.: Deleted.
F.7b.: Deleted.
F.7c.i.(2): Deleted.

- F.7c.ii. thru iv.: Deleted.
- F.7c.v.: Redesignated F.7b.
- F.7d.: Deleted.
- F.7e.: Deleted.
- F.7f.: Deleted.
- F.7g.: Redesignated F.7c.
- F.7h.: Redesignated F.7d.
- F.7h.ii.: Redesignated as F.7d.ii.; specifies Appendix B for hand-held dental radiographic units.
- F.7h.iii.: Deleted since beam limitation requirements are in Section F.6.
- F.7h.iv.: Redesignated F.7d.iii.

Section F.11 - Computed Tomography X-Ray Systems.

Section F.11, including title, was modified in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

F.11d.ii.(2): Amended to clarify the necessity for appropriate and timely calibration.

Section F.13 – Mammography Definitions for States with Certifying Authority.

This section was deleted in conjunction with the deletion of text in Section F.14.

Section F.14 – Mammography Requirements for States with Certifying Authority.

The text in this section was deleted and replaced by a statement incorporating 21 CFR Part 900 in F.14. Incorporation can include the “current” version or a “dated” version. The inclusion of the full text in Part F in 2001 resulted in the adoption of a version which was outdated when adopted. This was due to periodic changes to 21 CFR Part 900 which could not be included during the adoption process. States desiring to have certifying authority should develop rules or regulations directly from 21 CFR Part 900.

Section F.15 - Bone Densitometry.

Changes are as follows:

- F.15c.iii.: Amended to recognize certification.
- F.15e.: Editorial correction.
- F.15g.: Editorial correction.

Section F.16 - Quality Assurance Program.

This section was added to address the necessity for quality assurance programs in facilities with diagnostic x-ray and imaging systems. General requirements are specified in accordance with type of x-ray equipment, mode of imaging processing, and radiation protection practices. The text was developed generically to assure current and future

application for all types of facilities, programs, and use. This precludes the use of overly prescriptive requirements which may be outdated upon adoption.

Appendix A - Determination of Competence

This appendix was deleted in deference to the anticipated Part Z Medical Credentialing.

Appendix B - Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

This appendix was redesignated Appendix A. In addition, changes were made to clarify paragraphs c., d., f., k., l., m., and n. Paragraphs e. and g. were designated optional. Paragraph o. was added to specify program duration.

Appendix B (New)- Hand-Held Intraoral Dental Radiographic Unit Requirements for Use

This appendix was added to provide guidance to states on the use of hand-held dental radiographic units.

Appendix C - Exemptions from Shielding for Certain Fluoroscopic Procedures

This appendix is now inappropriate, and therefore, deleted in its entirety.

Appendix D - Focal Spot Tolerance Limit

This appendix is now inappropriate, and therefore, deleted in its entirety.

Appendix E - X-Ray Tube Voltage (Kilovolt Peak) and Minimum HVL

This appendix is now inappropriate, and therefore, deleted in its entirety.

2001
RATIONALE FOR REVISIONS
PART F
DIAGNOSTIC X-RAYS AND IMAGING IN THE HEALING ARTS

Introduction

This amendment to Part F includes requirements for mammography for states with and without certifying authority under the Mammography Quality Standards Act of 1992 (MQSA), use of bone densitometry systems, operators of fluoroscopic x-ray systems, as well as housekeeping changes to correct typographic errors and/or missing verbiage. In order to enhance the concept of the Suggested State Regulations for Control of Radiation (SSRCR) as a dynamic document, these changes are presented at this time. Thus, anticipated proposed changes to Title 21, Code of Federal Regulations, Sections 1020.30 through 1020.33, relative to digital imaging, digital recording, solid-state x-ray imagers, increased beam quality, fluoroscopic systems, and computerized tomography, will be incorporated on a subsequent amendment to Part F.

The title of Part F was changed from “Use of Diagnostic X-Rays in the Healing Arts” to “Diagnostic X-Rays and Imaging in the Healing Arts” to reflect changes in terminology and technology, and to categorically include bone densitometry systems.

Specific Provisions:

Section F.1 - Purpose and Scope. “And imaging systems” was added between “...x-ray” and “by...” in the first sentence to reflect the change in the title of Part F.

Section F.2 - Definitions.

A definition for “bone densitometry system” was added to differentiate this medical device from conventional diagnostic x-ray systems.

A definition for “diagnostic imaging system” was added to accommodate the change in terminology and technology.

The definition of “entrance exposure rate” was modified for consistency with the text.

The definition for “image receptor support” was removed in that it has been replaced with “image receptor support device.” The new definition was moved to Section F.13, Mammography Definitions.

Section F.3 - General and Administrative Requirements.

F.3a.ix.(5)(b) “The grid is” was added between “If” and “of the focused...”.

Section F.5 - Fluoroscopic X-Ray Systems.

F.5a.ii.(2) Verbiage was corrected to reflect intent. “Minimum” was replaced with “maximum.”

F.5c.i. The entrance exposure rates were updated for consistency with 21 CFR Part 1020.

F.5k. was added to specify qualifications for operators of fluoroscopic x-ray systems. In order to minimize unnecessary use and exposure, it was deemed appropriate to restrict operators of fluoroscopic x-ray systems to be from certain professions and that these individuals undergo a minimum level of training in radiation protection and equipment use.

F.5l. was added to specify requirements for the operation of fluoroscopic x-ray systems aside from operator qualifications. The interpretation of fluoroscopic imaging by a licensed practitioner was deemed necessary to restrict diagnostic practice to practitioners. The supervision specifications for radiologic technologists and radiologic technology students were included to ensure that these individuals are not placed in a position where there is an incursion into the diagnostic practice of licensed practitioners. The prohibition of using fluoroscopy as a positioning tool for general purpose radiography was added to minimize unnecessary exposure. The specification to record exposure information was included to place emphasis on the amount of patient exposure by fluoroscopic procedure.

Section F.6 - Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography.

F.6 “Bone densitometry” was added to the title to reflect its exclusion.

F.6b.iii. The sentence, “It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.” is added for clarification.

F.6g.ii “Consecutive” was added between “...the average values obtained at any two” and “mAs selector settings...” to reflect consistency with the standard.

Section F.12 - Mammography for States without FDA Certifying Authority.

The existing section was replaced in its entirety by a streamlined version of mammography requirements for facilities in states which do not have certifying authority from FDA under MQSA.

Section F.13 - Mammography Definitions.

The following definitions were added relative to mammography in Section F.14:

- “Accreditation body”
- “Action limits”
- “Action levels”
- “Adverse event”
- “Air kerma”
- “Body”
- “Breast implant”
- “Calendar quarter”
- “Category I”

“Certificate”
“Certification”
“Clinical image”
“Consumer”
“Contact hour”
“Continuing education credit”
“Continuing education unit”
“Control limits”
“Control levels”
“Diagnostic mammography”
“Direct instruction”
“Direct supervision”
“Established operating level”
“Facility”
“FDA”
“First allowable time”
“Image receptor support device”
“Interim regulations”
“Interpreting physician”
“Kerma”
“Laterality”
“Lead interpreting physician”
“Mammogram”
“Mammographic modality”
“Mammography”
“Mammography equipment evaluation”
“Mammography medical outcomes audit”
“Mammography unit(s)”
“Mean optical density”
“Medical physicist”
“MQSA”
“Multi-reading”
“Patient”
“Phantom”
“Phantom image”
“Physical science”
“Positive mammogram”
“Provisional certificate”
“Qualified instructor”
“Quality control technologist”
“Radiologic technologist”
“Screening mammography”
“Serious adverse event”
“Serious complaint”
“Standard breast”
“Survey”
“Time cycle”
“Traceable to a national standard”

Section F.14 - Mammography for States with FDA Certifying Authority.

A bracketed, optional section was specifically added for states which have certifying authority from FDA under MQSA. Non-certifying states may also utilize this section if specific requirements for mammography are desired for state enforcement. This section complies with the final MQSA regulations, Title 21, Code of Federal Regulations, Part 900, as amended October 22, 1998, April 14, 1999, and June 17, 1999. The order and context of subject areas are consistent with Part 900 to enhance future revisions of Section F.12.

Section F.15 - Bone Densitometry.

F.15 was added as a new section to specify minimum requirements for the utilization of a radiation-emitting medical device which differs from the conventional diagnostic x-ray system. This section pertains to all fixed, mobile, or portable bone densitometry systems with an x-ray source. This section does not pertain to bone densitometry systems with radioactive materials which are under the purview of Parts C and G.

F.15a. was added to ensure that only bone densitometry systems with certification could be obtained, registered, and utilized for human patients.

F.15b. was added for systems which have stepless collimators.

F.15c. was added to specify that the operator of bone densitometry systems meets certain professional, technological, educational, and training requirements.

F.15d.i. was added in ensure that the operator, ancillary personnel, and members of the general public are not unnecessarily exposed.

F.15d.ii. was added to ensure that the patient is made aware that densitometry systems use x-rays.

F.15e. was added to ensure that bone densitometry systems are properly maintained and documented.

F.15f. was added to ensure that densitometry is only conducted under a prescription or under an approved screening program.

F.15g. was added to specify information required for approval of screening programs utilizing bone densitometry systems.

1995 RATIONALE FOR REVISIONS

SECTION F.12 - MAMMOGRAPHY

Introduction

The SSRs have for a long time contained a few specific, minor provisions for mammography, but no coherent and comprehensive set of regulations. The American College of Radiology introduced their voluntary accreditation program a few years ago, and the federal government's Health Care Financing Administration and now the Food and Drug Administration through the Mammography Quality Standards Act have been developing certification and inspection procedures. The American Cancer Society has conducted a number of screening programs aimed at getting asymptomatic women to come in for mammograms, and the referral process has demanded that women be provided with choices of quality diagnostic facilities. Several states, under intense pressure from the public, developed regulations of their own early on during these years; meanwhile, technology and standards have evolved, as mammography machines from various manufacturers became more capable of delivering high quality images and screen-film manufacturers created fast systems that were capable of high contrast and detail. The concept of quality assurance, although around for many years in large institutions, came into its own here even in a relatively small, one-machine facility where the need for meticulous, documented monitoring of the entire imaging chain was recognized as vital in the assurance of high quality diagnostic care. Expectations in mammography for reducing false negatives and false positives ran very high, since the primary target was detecting cancer (versus broken bones). Additionally, the training and experience of x-ray operators was brought further into the limelight than ever before. National credentialing bodies such as the American Registry of Radiologic Technologists developed specific exams for mammography. In like manner, the physicians who interpret mammographic images were expected to have had training and experience in the art, usually through the American College of Radiology. These SSRs were written using American College of Radiology requirements and Health Care Financing Administration requirements, as well as other states' pioneering work. The regulations are meant to cover most details of a mammographic practice, but each state should of course modify them to their own philosophy.

Specific Provisions

F.12a.i. System Design. The use of equipment specifically designed for mammography is recommended by organizations such as the American College of Radiology, the American Association of Physicists in Medicine, the Health Care Financing Administration and the National Council on Radiation Protection and Measurements.

F.12a.ii. Image Receptor. *NCRP Report 85* recommends use of only screens designed specifically for mammography. The film and screen combination should also be compatible.

F.12a.iii. kVp/Target/Filter. The kVp and filtration are dependent on target material. In some machines the operator may select either a molybdenum target, which requires a molybdenum filter or a tungsten target, which requires additional filtration, usually aluminum. The working group noted that other combinations may be appropriate as technology changes, and the regulations should not be

written to make introduction of new technology difficult.

F.12a.iv. Beam Quality. The energy of x-rays used in mammography is lower than that used in general radiography and the compression device may significantly contribute to the half-value-layer (HVL) of the system. *AAPM Report 29* recommends including the compression device in the beam during HVL measurements. This provision also requires the HVL of screen-film systems to fall within the limits specified. A maximum HVL limit was established since image quality may deteriorate with increasing HVL. The National Emergency Management Association suggested that pure aluminum be specified for this standard, but F.4 of the SSRs specifies Type 1100 alloy, as does the Food and Drug Administration. Even though xeromammography is not that common, the Committee has added it here for completeness.

F.12a.v. Resolution. X-ray tubes with various focal spot sizes designed for mammography machines are available that are capable of producing images with a resolution of 12 line pairs per millimeter depending on SID and magnification factor. A test for resolution will confirm that the x-ray tube is appropriate for mammography and is not the limiting factor in the production of a good radiographic image. The resolution standard is based on using film with no accompanying intensifying screen, with no attenuating material placed in the beam, and without using the magnification mode. *AAPM Report #29* was used as a guideline for this regulation.

F.12a.vi.(1) Compression. Compression of the breast is necessary to obtain an equal thickness throughout the imaging area for quality mammograms. The American Association of Physicists in Medicine recommends a compression force of 35 to 55 pounds (Section 6.1.2 of *AAPM Report #29*). The Committee believes that for small breasted women, a compression force of 25 pounds is adequate. In addition, the Committee believes the value of 55 pounds for a compression force is too high. Instead the American College of Radiology maximum value of 40 was chosen. This compression must be held for a minimum of 15 seconds to ensure the technician has enough time to set up and take the x-ray.

F.12a.vi.(2) Paddle Alignment. To assist in the proper positioning of the patient, it is necessary that the compression paddle be properly aligned with the chest wall edge of the image receptor. If the compression paddle extends over the chest wall edge or the image receptor, the chest wall tissue will not be drawn into the image. If the compression paddle does not extend far enough toward the chest wall of the image receptor, the breast tissue toward the chest wall will not be compressed adequately and the image quality in that area will be compromised.

F.12a.vii.(1) System Capabilities. Anti-scatter grids are necessary to obtain quality mammograms in screen-film radiography. To be effective, these grids must be specifically designed for mammography. In addition, the grids should be integral to the x-ray system itself as opposed to those grids which are placed in the cassettes. The reason behind this is that the "integral" grids provide a considerable dose reduction over the in-cassette type, and superior image quality (better contrast). The Committee recognizes the fact that some particular examinations in mammography may necessitate that anti-scatter grids not be used; however, the majority of the exposures will employ grids. The Committee therefore believes that grids should be available for all image receptor sizes utilized at the facility.

F.12a.vii.(2) System Capabilities. Due to the variability in dense vs. fatty tissue composition of breast tissue, the Committee felt that the capability of automatic exposure control was necessary to provide for consistency in film density.

F.12a.vii.(3) System Capabilities. A post mAs meter is necessary to provide a means to determine individual patient exposure, and when there is a fluctuation in the x-ray system using AEC or manual techniques. In addition, older mammographic units have AECs which do not necessarily track well over different thicknesses of breast tissue. The post mAs meter provides a tool to aide in the development of a "workable" technique chart.

F.12a.viii. Milliampere-Second Read-Out Accuracy. In order for a post-mAs read-out meter to be of value, it must be accurate.

F.12a.ix. Transmission. To prevent unnecessary exposure to the patient, and the surrounding environment, the image receptor and its supporting device used for mammography should effectively minimize transmission of the beam through the image receptor and its supporting structure. The Food and Drug Administration Performance Standard requires this. The new requirement limits the exposure due to transmission through the image receptor supporting device for systems designed only for mammography. At the shortest SID for which the system is designed, the exposure beyond the plane of the image receptor supporting device would be limited to not more than 0.1 milliroentgen at 5 centimeters from any accessible surface of the image receptor supporting device when the system is operated at specified technique factors selected to produce maximum exposure for a single activation of the tube. The limit of 0.1 milliroentgen is proposed with the aim of keeping unnecessary exposure to the patient and adjacent areas as low as practicable during mammography. This limit is met, or is achievable with minor modifications, by currently manufactured mammography systems and is proposed to prevent the introduction of systems whose image receptor supporting devices provide inadequate attenuation of the primary x-ray beam. Exit exposures at the lower surface of the breast of patients undergoing mammography examinations before the beam strikes the image receptor have been shown to be on the order of hundreds of milliroentgens depending on the technique employed. In addition, exposure at the position of the umbilicus with the image receptor and supporting device in place has been measured to be on the order of 50 milliroentgens for a complete mammographic examination when minimal shielding was employed with the image receptor, indicating the desirability of additional shielding in the image receptor supporting device to reduce the unnecessary exposure.

F.12a.x.(1) X-Ray Beam/Image Receptor Alignment. The rationale for this requirement is that there is no reason why the beam should extend beyond the sides and back of the image receptor in mammography; a beam of excessive size can create excess scatter and excess radiation to the patient. It is acceptable for the beam to be within the image receptor edges. It is, however, very important that the beam be properly aligned with the chest wall edge of the image receptor, so that no breast tissue is unimaged; thus, we allow for a small excess beam size on that side to ensure that the full extent of the image receptor is used. It is required, of course, that no state regulation could be either less restrictive or more restrictive on this or any other requirement addressed by the Food and Drug Administration; thus, this alignment standard is no different than that of the Food and Drug Administration.

F.12a.x.(2) Light Field/X-Ray Beam Alignment. This requirement conforms to the Food and Drug Administration Performance Standard.

F.12a.xi. Accuracy of kVp. The accuracy of the kVp is important in mammography since it influences contrast, image quality and dose. Some may argue that the standard should be even more restrictive, i.e., 5 percent; at around 28 kVp, a 5 percent limit would yield a kVp allowance of only about 1.5. Many

non-invasive kVp test instruments may not be able to achieve that precision. The manufacturer's specifications for kVp accuracy will apply when provided; otherwise, the limit of ± 2 kV is reasonable.

F.12a.xii. Automatic Exposure Control Performance. This requirement came out of the American College of Radiology physicist's manual and is meant to provide some standard that AEC systems should meet. In the past, some automatic exposure control systems in mammographic machines were not capable of "tracking" kVp changes and tissue thickness and density changes, so that uniform and consistent film densities were obtained. This standard is a fair expectation of performance. The National Emergency Management Association suggested that, since film processing plays such an important role in the standard, additional language be added to this requirement, using the current limit "when the average film gradient is no more than 3.0. The permissible density difference is a function of the average gradient. If the average gradient is 4.0, then the optical density shall be maintained to within ± 0.4 of the average optical density." The Committee chose, however, to keep the language as simple as possible, with the assumption that film processing has been optimized and is consistent.

F.12a.xiii. Radiation Output Minimum. Output requirements are quite common in technical standards, and this one came from page 9 of *AAPM Report #29* on mammography system recommendations; its rationale is that the mammographic machine should be capable of delivering an intense enough amount of radiation to reduce reciprocity law failure and blurring caused by motion which could occur in low-mA machines used on large, thick breasts necessitating long exposure times.

F.12a.xiv. Screen-Film Contact. It is important to check for good screen-film contact because of the possibility that areas of poor contact might coincide with microcalcifications or other significant details, resulting in a loss of diagnostically important information. The 40 mesh specified in the American College of Radiology *Mammography Quality Control Radiologic Technologist's Manual* should be used.

F.12a.xv. Image Quality. Standards for image quality are at the heart of this whole set of regulations, and everything that is done is aimed at this "bottom line." The image quality has to be the very best possible (within reasonable dose limits); this standard is derived from the latest American College of Radiology phantom requirements. If these fibers, specs and masses cannot be seen, then a facility should not risk the increased likelihood of failing to detect cancer.

F.12a.xvi. Glandular Tissue Dose. Dose used to be of major concern in mammography years ago when direct exposure industrial film was used (to achieve high detail), so much so that people had a concern that significant numbers of cancers could be caused by the very modality used to detect them. With the development of intensifying screens and film designed especially for mammography, however, the dose has dropped dramatically through the years. The Food and Drug Administration and the Conference of Radiation Control Program Directors have conducted a nationwide evaluation of mammography and the results (*Nationwide Evaluation of X-Ray Trends (NEXT) Tabulation and Graphical Summary of 1992 Mammography Survey*) gives us a mean glandular tissue dose for screen-film systems with grid of 159 millirads. The American College of Radiology has a limit of 300 millirads but with this new data, the limit can be lowered to 250. Data on non-grid technique has also shown that 150 millirads is easily achievable.

F.12a.xvii. Technique Settings Specified. Here the Committee has inserted the requirement that image quality and dose limits are to be based on the use of a standard phantom, which represents a hypothetical average breast, and the clinically used techniques at a given facility.

F.12b.i. Quality Assurance Program Required. Mammography is clearly one of the most demanding of all radiographic procedures. In order for mammography facilities to maintain high quality imaging and to keep radiation doses low, constant vigilance is required. It is necessary that all the equipment and accessories used in mammography meet stringent requirements related to their design and performance capabilities. However, this is not in itself sufficient to assure quality. Mammography facilities must also work vigorously to assure that the equipment, accessories and the facility itself continue to meet high standards of performance.

In order to provide such assurance, it is essential that all mammography facilities establish and maintain a strong and comprehensive quality assurance program designed specifically to address the parameters critical to high quality mammography imaging. Such a quality assurance program obviously involves conducting appropriate tests at appropriate frequencies and it is important that specific responsibility for testing is assigned to one or more individuals. However, it is equally clear that conducting the tests themselves is insufficient to assure acceptable equipment performance and thus high quality imaging. It is also necessary for the test results to be analyzed and examined for indications of performance or quality problems. If such analysis is not carried out the simple accumulation of test results will leave performance problems undetected. It is also necessary to carry out corrective actions, or to arrange for others to do so when such actions are indicated by the analysis of the test results. Finally, it is essential that records be maintained documenting the testing, analysis and corrective action. Such records are necessary in order for the facility to identify long term trends in equipment performance as well as to assess the performance of those providing any corrective actions that may be necessary. Such records also provide documentation that the facility has been fulfilling its quality assurance responsibilities.

F.12b.ii. Quality Assurance Program Review Required. In order for a facility quality assurance program to continue being effective, it must be dynamic not static. It must have the flexibility to change to meet the changing needs of the facility as well as advances in technology. Periodic review of a quality assurance program is essential in providing this flexibility. The periodic review must address the effectiveness of the program including whether the tests were performed using the required procedures at the required frequency, whether the test results were analyzed and appropriate corrective actions were taken, whether the corrective actions were effective, and whether all the aspects of the program were properly documented. The review must also include an assessment of the continued appropriateness of the tests incorporated in the program as well as of the test procedures and frequencies. Without such a periodic review, the quality assurance program will stagnate and it will be difficult to maintain the motivation required to support the continued attention to detail necessary for an effective quality assurance program.

F.12b.iii. Equipment Quality Control Tests. Mammography, perhaps more than any other x-ray study, requires that the x-ray generator and imaging system be operating at peak effectiveness to be able to visualize subtle indications of disease on film. Great care must therefore be taken to assure that the equipment is monitored to preclude operational problems before they affect diagnostic ability. Conduct of equipment quality control tests is deemed necessary by most authorities prior to use of equipment on patients. These tests assure that the equipment is operating properly and that good images can be produced prior to daily use on patients. Some aspects of performance can change rapidly while others are affected only by major changes in equipment. This section requires that registrants perform certain tests which are designed to assure proper operation of both the x-ray generator and the imaging system upon installation and at intervals thereafter.

Processor testing is listed first since the processor is most likely to suffer frequent variations in operation, and sensitometric testing is required, being the only objective testing method available now. The deviation limits listed, which require that action be taken if exceeded, are established at values which should be attainable with reasonable care and which will result in little visible variation in film density. Current target deviation limits are actually ± 0.10 optical density, for both speed and contrast, and the base plus fog deviation limit is no more than the facilities' established operational limit $+0.03$ in optical density.

Processor testing is called for on a daily basis, since the processor is quite capable of varying considerably in operational effectiveness in a short time period. The remainder of the test frequencies have been based on the anticipated periods over which the performance aspect will reasonably remain stable. These typically will be a 6 or 12 month period and are in general agreement with the time recommendations of the American College of Radiology.

One notable exception to this 6 or 12 month test frequency is the test of image quality, which is called for on a monthly basis or whenever a mobile system is set up at a new location. Movement of a system from one location to another presents many opportunities to affect imaging system performance. The image quality test, using a breast phantom, is an overall test of many critical aspects of system performance and will expose serious problems with imaging ability before the system is used on patients.

Another exception is the testing of resolution and/or focal spot size, which is called for only upon installation or replacement of the tube. This is done more to make sure that the equipment is in agreement with the manufacturer's specifications as installed. While continued testing might indicate a problem with focal spot size, it was felt that such problems would be discovered with the image quality test which is much easier to accomplish.

Checking for primary and secondary transmission through the inherent barriers of the mammographic x-ray system was also one of those items which was felt not to need frequent checking. A test upon installation and following significant modification seems adequate.

F.12b.iv. Additional Quality Control Requirements. Retake rate was thought to be very dependent upon personnel changes and other subtle factors, and therefore needs frequent checks to assure that it is not too high. A quarterly check was called for here, since the check itself takes several weeks to accomplish. Comments on this requirement suggested that a limit might be counter-productive, since it may force a facility to accept borderline quality radiographs to keep within a certain reject limit. The American College of Radiology says between 2 percent and 5 percent would be normal. If a very high reject limit is found, e.g., 10-15 percent, this would indicate problems that need solving. Thus, a limit seems appropriate.

Viewbox uniformity and darkroom integrity were required to be checked on a 6 month basis. Inadvertent changes (such as the development of a slight leak or the improper replacement of a lightbulb) can lead to changes which affect image quality. Routine checks can pick up the subtle changes, while major changes should be more immediately apparent.

Screen cleaning was thought to be necessary on a weekly basis. Ordinary use subjects screens to dust particles and fingerprints which could affect film quality. Weekly cleaning should be sufficient to

preclude problems from this source. Note that dry cleaning or wet cleaning is not specified (some would say that wet cleaning weekly would be too hard on the screen surfaces).

F.12c. Additional Facility Requirements.

F.12c.i. Masks. Contrast is extremely critical in a mammographic image. Extraneous light degrades this contrast. Therefore, masking extraneous light is essential for optimizing viewing conditions, and to enhance the film reader's ability to read the film.

F.12c.ii. Film Processing. Following the film manufacturer's specifications for processing mammographic films is critical in maintaining correct contrast, speed and fog levels. By not processing at optimal levels, contrast is reduced, diagnostic image quality suffers and increased radiation dose to the patient results.

F.12c.iii. Instruments and Devices. Processor quality control tests are unquestionable in their necessity. Yet these tests are only as accurate/valid as the instrumentation used to perform them. An annual calibration of instruments is necessary to ensure their accuracy.

F.12c.iv. Operator Qualifications. Of all radiographic procedures performed, mammography is one of the most technically exacting. Minute deviations in patient positioning, technique selection and film processing can have significant effects on image quality and patient dose. In-depth education and specialized training of the operator are necessary to help prevent these potential problems. Many states, of course, have licensure requirements for x-ray operators, which may address the issue of qualifications. The Committee noted, of course, that the American College of Radiology and the Health Care Financing Administration have stringent requirements for operators.

F.12c.v. Physician Qualifications. In order to accurately interpret mammographic images on a consistent basis, specialized training and education of the physician reading the film is required. The American College of Radiology and the Health Care Financing Administration, again, have requirements of Board certification.

F.12c.vi. Physicist Qualifications. People called upon to make measurements of mammographic machine performance must have the experience and training to provide these services. The people must be familiar with quality assurance programs and able to oversee a facility's quality assurance program. American Board of Radiology Board certification in radiological physics is not mandatory; state agencies and mammographic facilities themselves may recognize experience and training to be sufficient.

F.12c.vii. Film Retention. Mammographic screening programs are highly recommended by every major organization in the health community. These programs require routine mammograms be performed at specified frequencies. Retention of previous mammograms provides the radiologist with a tool for comparison of change over time, a vital component of these programs.

F.12c.viii. Retake Rate. In an ideal world, the reject rate would be zero. Recognizing that we do not live in one, some rejects, and thus retakes, are inevitable. A 5 percent or less rate is consistent with the ALARA principle and American College of Radiology standards, although every effort should be made to make each mammogram optimal from the start.

F.12c.ix. Darkroom Fog. Contrast is reduced when darkroom fog levels exceed an optical density of 0.05. This could degrade the image and impair the ability to detect masses and lesions. The American College of Radiology recommends a limit of 0.02 in the 1990 *Mammography Quality Control Radiologic Technologist's Manual*, but the Committee feels that for a 2-minute test, 0.05 is more realistic.

1995 RATIONALE FOR REVISIONS

SECTION F.12 - MAMMOGRAPHY

Introduction

The SSRs have for a long time contained a few specific, minor provisions for mammography, but no coherent and comprehensive set of regulations. The American College of Radiology introduced their voluntary accreditation program a few years ago, and the federal government's Health Care Financing Administration and now the Food and Drug Administration through the Mammography Quality Standards Act have been developing certification and inspection procedures. The American Cancer Society has conducted a number of screening programs aimed at getting asymptomatic women to come in for mammograms, and the referral process has demanded that women be provided with choices of quality diagnostic facilities. Several states, under intense pressure from the public, developed regulations of their own early on during these years; meanwhile, technology and standards have evolved, as mammography machines from various manufacturers became more capable of delivering high quality images and screen-film manufacturers created fast systems that were capable of high contrast and detail. The concept of quality assurance, although around for many years in large institutions, came into its own here even in a relatively small, one-machine facility where the need for meticulous, documented monitoring of the entire imaging chain was recognized as vital in the assurance of high quality diagnostic care. Expectations in mammography for reducing false negatives and false positives ran very high, since the primary target was detecting cancer (versus broken bones). Additionally, the training and experience of x-ray operators was brought further into the limelight than ever before. National credentialing bodies such as the American Registry of Radiologic Technologists developed specific exams for mammography. In like manner, the physicians who interpret mammographic images were expected to have had training and experience in the art, usually through the American College of Radiology. These SSRs were written using American College of Radiology requirements and Health Care Financing Administration requirements, as well as other states' pioneering work. The regulations are meant to cover most details of a mammographic practice, but each state should of course modify them to their own philosophy.

Specific Provisions

F.12a.i. System Design. The use of equipment specifically designed for mammography is recommended by organizations such as the American College of Radiology, the American Association of Physicists in Medicine, the Health Care Financing Administration and the National Council on Radiation Protection and Measurements.

F.12a.ii. Image Receptor. *NCRP Report 85* recommends use of only screens designed specifically for mammography. The film and screen combination should also be compatible.

F.12a.iii. kVp/Target/Filter. The kVp and filtration are dependent on target material. In some machines the operator may select either a molybdenum target, which requires a molybdenum filter or a tungsten target, which requires additional filtration, usually aluminum. The working group noted that other combinations may be appropriate as technology changes, and the regulations should not be

written to make introduction of new technology difficult.

F.12a.iv. Beam Quality. The energy of x-rays used in mammography is lower than that used in general radiography and the compression device may significantly contribute to the half-value-layer (HVL) of the system. *AAPM Report 29* recommends including the compression device in the beam during HVL measurements. This provision also requires the HVL of screen-film systems to fall within the limits specified. A maximum HVL limit was established since image quality may deteriorate with increasing HVL. The National Emergency Management Association suggested that pure aluminum be specified for this standard, but F.4 of the SSRs specifies Type 1100 alloy, as does the Food and Drug Administration. Even though xeromammography is not that common, the Committee has added it here for completeness.

F.12a.v. Resolution. X-ray tubes with various focal spot sizes designed for mammography machines are available that are capable of producing images with a resolution of 12 line pairs per millimeter depending on SID and magnification factor. A test for resolution will confirm that the x-ray tube is appropriate for mammography and is not the limiting factor in the production of a good radiographic image. The resolution standard is based on using film with no accompanying intensifying screen, with no attenuating material placed in the beam, and without using the magnification mode. *AAPM Report #29* was used as a guideline for this regulation.

F.12a.vi.(1) Compression. Compression of the breast is necessary to obtain an equal thickness throughout the imaging area for quality mammograms. The American Association of Physicists in Medicine recommends a compression force of 35 to 55 pounds (Section 6.1.2 of *AAPM Report #29*). The Committee believes that for small breasted women, a compression force of 25 pounds is adequate. In addition, the Committee believes the value of 55 pounds for a compression force is too high. Instead the American College of Radiology maximum value of 40 was chosen. This compression must be held for a minimum of 15 seconds to ensure the technician has enough time to set up and take the x-ray.

F.12a.vi.(2) Paddle Alignment. To assist in the proper positioning of the patient, it is necessary that the compression paddle be properly aligned with the chest wall edge of the image receptor. If the compression paddle extends over the chest wall edge or the image receptor, the chest wall tissue will not be drawn into the image. If the compression paddle does not extend far enough toward the chest wall of the image receptor, the breast tissue toward the chest wall will not be compressed adequately and the image quality in that area will be compromised.

F.12a.vii.(1) System Capabilities. Anti-scatter grids are necessary to obtain quality mammograms in screen-film radiography. To be effective, these grids must be specifically designed for mammography. In addition, the grids should be integral to the x-ray system itself as opposed to those grids which are placed in the cassettes. The reason behind this is that the "integral" grids provide a considerable dose reduction over the in-cassette type, and superior image quality (better contrast). The Committee recognizes the fact that some particular examinations in mammography may necessitate that anti-scatter grids not be used; however, the majority of the exposures will employ grids. The Committee therefore believes that grids should be available for all image receptor sizes utilized at the facility.

F.12a.vii.(2) System Capabilities. Due to the variability in dense vs. fatty tissue composition of breast tissue, the Committee felt that the capability of automatic exposure control was necessary to provide for consistency in film density.

F.12a.vii.(3) System Capabilities. A post mAs meter is necessary to provide a means to determine individual patient exposure, and when there is a fluctuation in the x-ray system using AEC or manual techniques. In addition, older mammographic units have AECs which do not necessarily track well over different thicknesses of breast tissue. The post mAs meter provides a tool to aide in the development of a "workable" technique chart.

F.12a.viii. Milliampere-Second Read-Out Accuracy. In order for a post-mAs read-out meter to be of value, it must be accurate.

F.12a.ix. Transmission. To prevent unnecessary exposure to the patient, and the surrounding environment, the image receptor and its supporting device used for mammography should effectively minimize transmission of the beam through the image receptor and its supporting structure. The Food and Drug Administration Performance Standard requires this. The new requirement limits the exposure due to transmission through the image receptor supporting device for systems designed only for mammography. At the shortest SID for which the system is designed, the exposure beyond the plane of the image receptor supporting device would be limited to not more than 0.1 milliroentgen at 5 centimeters from any accessible surface of the image receptor supporting device when the system is operated at specified technique factors selected to produce maximum exposure for a single activation of the tube. The limit of 0.1 milliroentgen is proposed with the aim of keeping unnecessary exposure to the patient and adjacent areas as low as practicable during mammography. This limit is met, or is achievable with minor modifications, by currently manufactured mammography systems and is proposed to prevent the introduction of systems whose image receptor supporting devices provide inadequate attenuation of the primary x-ray beam. Exit exposures at the lower surface of the breast of patients undergoing mammography examinations before the beam strikes the image receptor have been shown to be on the order of hundreds of milliroentgens depending on the technique employed. In addition, exposure at the position of the umbilicus with the image receptor and supporting device in place has been measured to be on the order of 50 milliroentgens for a complete mammographic examination when minimal shielding was employed with the image receptor, indicating the desirability of additional shielding in the image receptor supporting device to reduce the unnecessary exposure.

F.12a.x.(1) X-Ray Beam/Image Receptor Alignment. The rationale for this requirement is that there is no reason why the beam should extend beyond the sides and back of the image receptor in mammography; a beam of excessive size can create excess scatter and excess radiation to the patient. It is acceptable for the beam to be within the image receptor edges. It is, however, very important that the beam be properly aligned with the chest wall edge of the image receptor, so that no breast tissue is unimaged; thus, we allow for a small excess beam size on that side to ensure that the full extent of the image receptor is used. It is required, of course, that no state regulation could be either less restrictive or more restrictive on this or any other requirement addressed by the Food and Drug Administration; thus, this alignment standard is no different than that of the Food and Drug Administration.

F.12a.x.(2) Light Field/X-Ray Beam Alignment. This requirement conforms to the Food and Drug Administration Performance Standard.

F.12a.xi. Accuracy of kVp. The accuracy of the kVp is important in mammography since it influences contrast, image quality and dose. Some may argue that the standard should be even more restrictive, i.e., 5 percent; at around 28 kVp, a 5 percent limit would yield a kVp allowance of only about 1.5. Many

non-invasive kVp test instruments may not be able to achieve that precision. The manufacturer's specifications for kVp accuracy will apply when provided; otherwise, the limit of ± 2 kV is reasonable.

F.12a.xii. Automatic Exposure Control Performance. This requirement came out of the American College of Radiology physicist's manual and is meant to provide some standard that AEC systems should meet. In the past, some automatic exposure control systems in mammographic machines were not capable of "tracking" kVp changes and tissue thickness and density changes, so that uniform and consistent film densities were obtained. This standard is a fair expectation of performance. The National Emergency Management Association suggested that, since film processing plays such an important role in the standard, additional language be added to this requirement, using the current limit "when the average film gradient is no more than 3.0. The permissible density difference is a function of the average gradient. If the average gradient is 4.0, then the optical density shall be maintained to within ± 0.4 of the average optical density." The Committee chose, however, to keep the language as simple as possible, with the assumption that film processing has been optimized and is consistent.

F.12a.xiii. Radiation Output Minimum. Output requirements are quite common in technical standards, and this one came from page 9 of *AAPM Report #29* on mammography system recommendations; its rationale is that the mammographic machine should be capable of delivering an intense enough amount of radiation to reduce reciprocity law failure and blurring caused by motion which could occur in low-mA machines used on large, thick breasts necessitating long exposure times.

F.12a.xiv. Screen-Film Contact. It is important to check for good screen-film contact because of the possibility that areas of poor contact might coincide with microcalcifications or other significant details, resulting in a loss of diagnostically important information. The 40 mesh specified in the American College of Radiology *Mammography Quality Control Radiologic Technologist's Manual* should be used.

F.12a.xv. Image Quality. Standards for image quality are at the heart of this whole set of regulations, and everything that is done is aimed at this "bottom line." The image quality has to be the very best possible (within reasonable dose limits); this standard is derived from the latest American College of Radiology phantom requirements. If these fibers, specs and masses cannot be seen, then a facility should not risk the increased likelihood of failing to detect cancer.

F.12a.xvi. Glandular Tissue Dose. Dose used to be of major concern in mammography years ago when direct exposure industrial film was used (to achieve high detail), so much so that people had a concern that significant numbers of cancers could be caused by the very modality used to detect them. With the development of intensifying screens and film designed especially for mammography, however, the dose has dropped dramatically through the years. The Food and Drug Administration and the Conference of Radiation Control Program Directors have conducted a nationwide evaluation of mammography and the results (*Nationwide Evaluation of X-Ray Trends (NEXT) Tabulation and Graphical Summary of 1992 Mammography Survey*) gives us a mean glandular tissue dose for screen-film systems with grid of 159 millirads. The American College of Radiology has a limit of 300 millirads but with this new data, the limit can be lowered to 250. Data on non-grid technique has also shown that 150 millirads is easily achievable.

F.12a.xvii. Technique Settings Specified. Here the Committee has inserted the requirement that image quality and dose limits are to be based on the use of a standard phantom, which represents a hypothetical average breast, and the clinically used techniques at a given facility.

F.12b.i. Quality Assurance Program Required. Mammography is clearly one of the most demanding of all radiographic procedures. In order for mammography facilities to maintain high quality imaging and to keep radiation doses low, constant vigilance is required. It is necessary that all the equipment and accessories used in mammography meet stringent requirements related to their design and performance capabilities. However, this is not in itself sufficient to assure quality. Mammography facilities must also work vigorously to assure that the equipment, accessories and the facility itself continue to meet high standards of performance.

In order to provide such assurance, it is essential that all mammography facilities establish and maintain a strong and comprehensive quality assurance program designed specifically to address the parameters critical to high quality mammography imaging. Such a quality assurance program obviously involves conducting appropriate tests at appropriate frequencies and it is important that specific responsibility for testing is assigned to one or more individuals. However, it is equally clear that conducting the tests themselves is insufficient to assure acceptable equipment performance and thus high quality imaging. It is also necessary for the test results to be analyzed and examined for indications of performance or quality problems. If such analysis is not carried out the simple accumulation of test results will leave performance problems undetected. It is also necessary to carry out corrective actions, or to arrange for others to do so when such actions are indicated by the analysis of the test results. Finally, it is essential that records be maintained documenting the testing, analysis and corrective action. Such records are necessary in order for the facility to identify long term trends in equipment performance as well as to assess the performance of those providing any corrective actions that may be necessary. Such records also provide documentation that the facility has been fulfilling its quality assurance responsibilities.

F.12b.ii. Quality Assurance Program Review Required. In order for a facility quality assurance program to continue being effective, it must be dynamic not static. It must have the flexibility to change to meet the changing needs of the facility as well as advances in technology. Periodic review of a quality assurance program is essential in providing this flexibility. The periodic review must address the effectiveness of the program including whether the tests were performed using the required procedures at the required frequency, whether the test results were analyzed and appropriate corrective actions were taken, whether the corrective actions were effective, and whether all the aspects of the program were properly documented. The review must also include an assessment of the continued appropriateness of the tests incorporated in the program as well as of the test procedures and frequencies. Without such a periodic review, the quality assurance program will stagnate and it will be difficult to maintain the motivation required to support the continued attention to detail necessary for an effective quality assurance program.

F.12b.iii. Equipment Quality Control Tests. Mammography, perhaps more than any other x-ray study, requires that the x-ray generator and imaging system be operating at peak effectiveness to be able to visualize subtle indications of disease on film. Great care must therefore be taken to assure that the equipment is monitored to preclude operational problems before they affect diagnostic ability. Conduct of equipment quality control tests is deemed necessary by most authorities prior to use of equipment on patients. These tests assure that the equipment is operating properly and that good images can be produced prior to daily use on patients. Some aspects of performance can change rapidly while others are affected only by major changes in equipment. This section requires that registrants perform certain tests which are designed to assure proper operation of both the x-ray generator and the imaging system upon installation and at intervals thereafter.

Processor testing is listed first since the processor is most likely to suffer frequent variations in operation, and sensitometric testing is required, being the only objective testing method available now. The deviation limits listed, which require that action be taken if exceeded, are established at values which should be attainable with reasonable care and which will result in little visible variation in film density. Current target deviation limits are actually ± 0.10 optical density, for both speed and contrast, and the base plus fog deviation limit is no more than the facilities' established operational limit $+0.03$ in optical density.

Processor testing is called for on a daily basis, since the processor is quite capable of varying considerably in operational effectiveness in a short time period. The remainder of the test frequencies have been based on the anticipated periods over which the performance aspect will reasonably remain stable. These typically will be a 6 or 12 month period and are in general agreement with the time recommendations of the American College of Radiology.

One notable exception to this 6 or 12 month test frequency is the test of image quality, which is called for on a monthly basis or whenever a mobile system is set up at a new location. Movement of a system from one location to another presents many opportunities to affect imaging system performance. The image quality test, using a breast phantom, is an overall test of many critical aspects of system performance and will expose serious problems with imaging ability before the system is used on patients.

Another exception is the testing of resolution and/or focal spot size, which is called for only upon installation or replacement of the tube. This is done more to make sure that the equipment is in agreement with the manufacturer's specifications as installed. While continued testing might indicate a problem with focal spot size, it was felt that such problems would be discovered with the image quality test which is much easier to accomplish.

Checking for primary and secondary transmission through the inherent barriers of the mammographic x-ray system was also one of those items which was felt not to need frequent checking. A test upon installation and following significant modification seems adequate.

F.12b.iv. Additional Quality Control Requirements. Retake rate was thought to be very dependent upon personnel changes and other subtle factors, and therefore needs frequent checks to assure that it is not too high. A quarterly check was called for here, since the check itself takes several weeks to accomplish. Comments on this requirement suggested that a limit might be counter-productive, since it may force a facility to accept borderline quality radiographs to keep within a certain reject limit. The American College of Radiology says between 2 percent and 5 percent would be normal. If a very high reject limit is found, e.g., 10-15 percent, this would indicate problems that need solving. Thus, a limit seems appropriate.

Viewbox uniformity and darkroom integrity were required to be checked on a 6 month basis. Inadvertent changes (such as the development of a slight leak or the improper replacement of a lightbulb) can lead to changes which affect image quality. Routine checks can pick up the subtle changes, while major changes should be more immediately apparent.

Screen cleaning was thought to be necessary on a weekly basis. Ordinary use subjects screens to dust particles and fingerprints which could affect film quality. Weekly cleaning should be sufficient to

preclude problems from this source. Note that dry cleaning or wet cleaning is not specified (some would say that wet cleaning weekly would be too hard on the screen surfaces).

F.12c. Additional Facility Requirements.

F.12c.i. Masks. Contrast is extremely critical in a mammographic image. Extraneous light degrades this contrast. Therefore, masking extraneous light is essential for optimizing viewing conditions, and to enhance the film reader's ability to read the film.

F.12c.ii. Film Processing. Following the film manufacturer's specifications for processing mammographic films is critical in maintaining correct contrast, speed and fog levels. By not processing at optimal levels, contrast is reduced, diagnostic image quality suffers and increased radiation dose to the patient results.

F.12c.iii. Instruments and Devices. Processor quality control tests are unquestionable in their necessity. Yet these tests are only as accurate/valid as the instrumentation used to perform them. An annual calibration of instruments is necessary to ensure their accuracy.

F.12c.iv. Operator Qualifications. Of all radiographic procedures performed, mammography is one of the most technically exacting. Minute deviations in patient positioning, technique selection and film processing can have significant effects on image quality and patient dose. In-depth education and specialized training of the operator are necessary to help prevent these potential problems. Many states, of course, have licensure requirements for x-ray operators, which may address the issue of qualifications. The Committee noted, of course, that the American College of Radiology and the Health Care Financing Administration have stringent requirements for operators.

F.12c.v. Physician Qualifications. In order to accurately interpret mammographic images on a consistent basis, specialized training and education of the physician reading the film is required. The American College of Radiology and the Health Care Financing Administration, again, have requirements of Board certification.

F.12c.vi. Physicist Qualifications. People called upon to make measurements of mammographic machine performance must have the experience and training to provide these services. The people must be familiar with quality assurance programs and able to oversee a facility's quality assurance program. American Board of Radiology Board certification in radiological physics is not mandatory; state agencies and mammographic facilities themselves may recognize experience and training to be sufficient.

F.12c.vii. Film Retention. Mammographic screening programs are highly recommended by every major organization in the health community. These programs require routine mammograms be performed at specified frequencies. Retention of previous mammograms provides the radiologist with a tool for comparison of change over time, a vital component of these programs.

F.12c.viii. Retake Rate. In an ideal world, the reject rate would be zero. Recognizing that we do not live in one, some rejects, and thus retakes, are inevitable. A 5 percent or less rate is consistent with the ALARA principle and American College of Radiology standards, although every effort should be made to make each mammogram optimal from the start.

F.12c.ix. Darkroom Fog. Contrast is reduced when darkroom fog levels exceed an optical density of 0.05. This could degrade the image and impair the ability to detect masses and lesions. The American College of Radiology recommends a limit of 0.02 in the 1990 *Mammography Quality Control Radiologic Technologist's Manual*, but the Committee feels that for a 2-minute test, 0.05 is more realistic.

1988
Rationale for Revisions

Part F
X-Rays in the Healing Arts

General

This edition of the SSRCCR contains a new Section F.11 on Computed Tomography X-Ray Systems in Part F. The Federal standard for computed tomography (CT) x-ray systems was published as a proposed rule on October 31, 1980 (45 FR 72204) with its rationale. The final rule was published in the ~~Federal Register~~ on August 31, 1984 (49 FR 34698). This Federal standard is not applicable to the approximately 3,500 existing CT x-ray systems in the United States manufactured before the effective date of the Federal standard (September 3, 1985, except for selected provisions which became effective November 29, 1984) and does not address maintenance and operating procedures after installation. Both certified and noncertified CT x-ray systems should meet radiation safety equipment standards. In addition, all such systems should meet maintenance and operating standards related to radiation safety. These aspects are the responsibility of the State or local radiation control program. The basis for the Section F.11 draft are the Federal standard and the format utilized in Sections F.8 and F.9 of Part F. In addition to the inclusion of and changes related to Section F.11, certain editorial and technical changes were made throughout Part F for greater clarity and consistency with the Federal standard. The following is a description of the changes to Part F and the rationale for these changes.

Specific Changes

~~F.2 Definitions.~~ The general definitions added to Section F.2 are from the Federal standard with the exception of "Linear attenuation coefficient" which is used but not defined in the Federal standard. That definition is from ICRU Report 33, Radiation Quantities and Units, of the International Commission on Radiation Units and Measurements.

~~F.3 General Requirements and F.4 General Requirements for All Diagnostic X-Ray Systems~~ are not changed and will be applicable to CT x-ray systems.

~~F.5(c)(1)(iii) Entrance Exposure Rate Allowable Limits.~~ The original wording of this subdivision was as follows: "In addition to the other requirements of Section F.5, certified systems which do not incorporate an automatic exposure control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control." The subdivision was changed as this original wording would permit an exposure rate in excess of 5 R/min if an optional high level control was provided even though it was not activated.

~~F.5(c)(1)(iv)(d) Entrance Exposure Rate Allowable Limits.~~ This revised subdivision incorporates the language in a March 24, 1986 letter from FDA to manufacturers which makes clear how entrance ~~exposure~~ rate is to be measured for systems employing a variable SID.

~~F.5(c)(1)(v)(d)(3) and (4) Entrance Exposure Rate Allowable Limits.~~ The word "rate" was added after "exposure" in both of these subdivisions as the requirements apply to the ~~exposure~~ rate, not the ~~exposure~~.

~~F.5 Fluoroscopic X-Ray Systems (previous edition) and F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Veterinarian Systems (previous edition)~~ regarding fluoroscopic and radiographic x-rays have title changes to exempt CT x-ray systems from the provisions of those sections. The new titles are "Fluoroscopic X-Ray Systems Except for Computed Tomography X-Ray Systems" for Section F.5 and "Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, or Computed Tomography X-Ray Systems" for Section F.6.

~~F.6(a)(2) Additional Requirements for Stationary General Purpose X-Ray Systems.~~ In the first sentence of this subparagraph, the word, "all" was deleted and the words, "both certified and noncertified," were inserted after "systems" so that the sentence now reads: "In addition to the requirements of Subparagraph F.6(a)(1), stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:" There was some confusion as to which requirements apply to certified and noncertified equipment; the adjectives were added for clarification.

~~F.6(a)(5) Special Purpose X-Ray Systems (previous edition).~~ The heading of this subparagraph was changed from "Special Purpose X-Ray Systems" to "X-Ray Systems Other Than Those Described in Subparagraphs F.6(a)(1), (2), (3) and (4)." The term, "Special Purpose X-Ray Systems," is not defined, and the intent of Subparagraph F.6(a)(5) is to cover all systems not previously covered in Subparagraphs F.6(a)(1), (2), (3), and (4).

~~F.11 Definitions.~~ The definitions of terms found in Section F.11 are identical to the definitions of the same terms within the Federal standard with the following exceptions:

"CT gantry" was not in the Federal standard but was defined in an FDA advisory bulletin to manufacturers. The F.11 definition is identical to that advisory bulletin definition.

"CT number." A formula and footnote were added to the Federal definition of "CT number" for clarity. "CTN" was included in the list of definitions to be used as an abbreviation for "CT number".

"CT dosimetry phantom" is not defined in Paragraph F.11(a). The specifications which are part of the Federal standard are included in Subdivision F.11(d)(2)(iv).

Definitions were included for the following items which are not defined in the Federal standard:

"Elemental area"

"Reference plane"

~~F.11(b)(1)(i) and (ii) Termination of Exposure.~~ Not all units will meet the requirements. However, a simple retrofit, such as the addition of a cumulative timer and an indicator light, is not considered an unreasonable requirement.

~~F.11(b)(1)(iii) Termination of Exposure.~~ The ability to terminate an exposure at any time parallels similar requirements for other x-ray systems.

~~F.11(b)(2) Tomographic Plane Indication and Alignment.~~ Most existing CT x-ray systems incorporate a means of indicating the tomographic plane position. The accuracy of the indicators is questionable. The accuracy statement was placed in Subparagraph F.11(b)(7) which covers additional requirements for systems manufactured after September 3, 1985. The Part F Working Group was advised that many systems constructed prior to September 3, 1985, could not economically be altered to meet the criteria in Subparagraph F.11(b)(7).

~~F.11(b)(3) Beam-On and Shutter Status Indicators and Control Switches.~~ Exact Federal wording is not used here, but the requirement is the same. The Federal requirement is divided with parts appearing in Subparagraph F.11(b)(3) and Subdivisions (b)(7)(ii) and (iii). A provision was added in response to a comment to label emergency buttons and switches.

~~F.11(b)(4) Indication of CT Conditions of Operation.~~ Wording is the same as in the Federal standard.

~~F.11(b)(5) Extraneous Radiation.~~ Although the Federal CT x-ray systems standard wording is not used in this subparagraph, the requirement is the same. Leakage radiation is subject to Paragraph F.4(c).

~~F.11(b)(6) Maximum Surface CTDI Identification.~~ This is a rephrasing of the Federal standard. It allows placement of a dosimeter at the specified point of maximum surface CTDI and is necessary for reproducible calibration.

~~F.11(b)(7) Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.~~ These are Federal criteria for systems which are certified under 21 CFR 1020.33.

~~F.11(c) Facility Design Requirements.~~ Generally applicable requirements taken from Sections F.8 and F.9 are necessary for patient and operator safety.

~~F.11(d)(1) Surveys.~~ The provisions are similar to those found in Sections F.8 and F.9. The high work load of the units indicates that the associated scatter dose rates need evaluation.

~~F.11(d)(2) Radiation Calibrations.~~ The format used is similar to that found in Sections F.8 and

F.9. The radiation dose delivered by these systems to the patient justifies the requirements for continued calibrations. The frequency that the full calibrations should be performed is not specified but is addressed by requiring the qualified expert to state such intervals. However, intervals of calibrations should include upon installation and after major repair and should be based on knowledge of use conditions. The calibration procedures have not incorporated the full equivalent of the CT x-ray systems standard. The calibration procedure stated is applicable to all systems but does not include the sensitivity profile which the Federal standard requires the manufacturer to provide.

~~F.11(d)(2)(iv) Radiation Calibrations.~~ This subdivision requires the use of the phantom specified in the Federal standard.

~~F.11(d)(2)(v) Radiation Calibrations.~~ This subdivision requires calibration for each type of scan performed.

~~F.11(d)(2)(vii) Radiation Calibrations.~~ This subdivision requires that records of calibrations be kept.

~~F.11(d)(3) Spot Checks.~~ Subdivisions (i) and (iii) refer to procedure development by a qualified expert and frequency of spot checks. Subdivisions (ii) and (iv) use the wording of the Federal standard regarding quality assurance. Use conditions should indicate the extent and frequency of spot checks to be performed; therefore, the qualified expert is given the responsibility of developing the procedures for a given facility. This generally parallels similar requirements and spot checks required in Section F.8.

~~F.11(d)(4) Operating Procedures.~~ Subdivision (i) requires that a trained individual operate the system, and (ii) requires that the operator be provided with information referring to that specific system. Subdivision (iii) specifies conditions under which the system's use may be limited. All these requirements are necessary to minimize patient radiation doses and repeat examinations.

Matters for Future Consideration

1. The requirement in Subparagraph F.11(b)(5) (Extraneous Radiation) of Part F is redundant with the requirement of Paragraph F.4(c) (Leakage Radiation from the Diagnostic Source Assembly). Consideration should be given to deleting Subparagraph F.11(b)(5).
2. Guidance should be provided for shielding requirements in the CT room.
3. The composition of dosimetry phantoms is spelled out and very restrictive in both the SSRCR and the Federal standard. Discussion should include concern about insert costs and type of phantoms needed for measurement.

4. The U.S. Environmental Protection Agency has issued radiation protection guidance to Federal agencies for diagnostic x-rays (February 1, 1978 Part IV). The 12 recommendations of this report should be considered for addition to Section F.3 (General Requirements) of the SSRCR with emphasis on item 10 relating to ESE guidelines.
5. The leakage radiation limit for therapy systems in Subparagraphs F.9(b)(1) and (2) is 0.1 percent of the x-ray beam output. Some x-ray therapy units cannot meet this requirement. Study is needed to see if this limit could be raised to 0.5 percent.
6. Consideration should be given in Subdivision F.11(d)(2)(i) (Radiation Calibrations) to the interval required between calibrations of CT x-ray systems.
7. Consideration should be given for evaluation of CT systems containing a gantry manufactured before September 3, 1985, to meet the requirements in Subparagraph F.11(b)(7). This should include what modifications would be required to meet Subparagraph F.11(b)(7) and at what cost.
8. The SSRCR Technical Review Committee recommends that the Part F Working Group should evaluate the appropriateness that extraoral dental examinations meet the requirements of Section F.6 (See page 10 of the 1974 Rationale for Part F.)
9. The SSRCR Technical Review Committee recommends that consideration be given to adding a statement to Section F.1 providing an option for the States to adopt the Federal diagnostic x-ray equipment performance standard by reference (i.e., to maintain certified diagnostic x-ray equipment in compliance with the Federal standard, rather than incorporating those provisions (as written in Part F) into their regulations). The statement could be similar to the following: "Diagnostic x-ray systems containing one or more certified components and their associated certified components manufactured after August 1, 1974, shall be maintained in compliance with the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968 (21 CFR Part 1020). Diagnostic x-ray systems and associated components manufactured prior to the effective date of the Federal regulations (August 1, 1974) shall meet the provisions of this part [state code]. For x-ray systems consisting of both certified components and components not certified by reason of a manufacturing date earlier than the effective date of Federal regulations, the x-ray systems shall meet the provisions of this part [state code] except for the certified components, which shall meet the applicable provisions of the Federal regulations."
10. Additional consideration should be given to leakage radiation through beam limiting devices. Presently, there are no provisions addressing leakage through such devices that are used with machines capable of large area (area greater than 500 cm²) treatment fields.
11. Additional consideration should be given to the provisions for leakage radiation

outside the patient area. Applicability of such provisions should be evaluated on the basis of patient protection (radiation scattered back into the plane of the patient), environmental considerations, or public health considerations.

12. Additional consideration should be given to the requirement that a "radiological physicist," as defined in Section F.2, be the qualifications as stated in the definition for performing said duties. Other individuals may be equally but not specifically qualified.

1984
Rationale for Revisions

Part F
X-Rays in the Healing Arts

Introduction

The x-ray beam limitation devices for radiographic and fluoroscopic x-ray systems of the Federal Diagnostic X-Ray Systems and Their Major Components standard (21 CFR 1020.30, 1020.31, and 1020.32) were amended by publication of a final rule in the Federal Register on November 5, 1982 (47 FR 50211) and became effective December 1, 1983. Further background information on the rationale for these amendments is contained in the proposed rule published in the Federal Register on May 9, 1978 (43 FR 19879) and in the final rule published on November 5, 1982. These amendments to the Federal diagnostic x-ray standard are being incorporated into Sections F.5 and F.6. In addition, Paragraph F.7(b) and Appendix B are being revised.

Specific Provisions

~~F.5(a)(2) X-Ray Field.~~ A subdivision (iv) was inserted to state provisions for an override to any automatic field sizing. The equivalent provisions of the Federal standard are codified as 21 CFR 1020.32(b)(3) and 1020.31(g). As written, Subdivision F.5(a)(2)(iv) is applicable to both certified and non-certified equipment.

~~F.6(f)(6) Field Limitation and Alignment on Stationary General Purpose X-Ray Systems.~~ Changes were made in both content and format to place the requirements for positive beam limitation in agreement with the Federal diagnostic x-ray standard amendments. The changes include: (a) rearrangement of the section in a more logical format; (b) incorporation of interpretations that have been made with respect to this section; and (c) relaxation of certain requirements where manufacturers have encountered legitimate problems. These changes will not require modification of existing units. Subparagraph F.6(f)(6) is applicable to only certified units. The equivalent provisions of the Federal standard are codified as 21 CFR 1020.31(e)(2). The only additional requirement in amended Subparagraph F.6(f)(6) is the labeling of the user override key or key switch. This was required in the amended Federal standard to indicate the proper function of these switches and to discourage their inappropriate use. The label is only required for systems manufactured after November 30, 1983. Subdivision F.6(f)(6)(i)(f) is not in the Federal diagnostic x-ray standard but was added for clarification and is consistent with the Federal standard.

~~F.7(b) Field Limitation.~~ The provision for intraoral dental units to have an open ended shielded position indicating device (PID) was removed (Subparagraph F.7(b)(2) of the 1982 Edition). Federal studies indicated that the use of an open ended shielded PID in conjunction

with the bisecting-angle technique may result in larger doses to patients than if a closed ended PID had been used with this technique. Unless the paralleling technique were to become predominant, the required use of an open ended shielded PID could actually lead to increased doses to patients. The studies are summarized in an FDA draft analysis dated August 1, 1975 and transmitted to state radiation control program directors by letter of August 12, 1975.

Appendix B4 (b) Viewing System Requirements. Wording was changed to remove the 4.5-foot-limitation.

**1982
Rationale for Revisions**

**Part F
X-Rays in the Healing Arts**

General

Sections F.1 through F.7 in the 1982 SSRCR have been changed from the 1978 version with the insertion of SI units, changes resulting from amendments to the Federal diagnostic x-ray standard, changes in x-ray log requirements, and changes in dental x-ray beam quality. Section F.8 and F.9 have been extensively rewritten. Many constructive comments were received, and these comments have formed the basis of the 1982 Edition. In particular, the standards for leakage radiation in Section F.9 were changed after the National Council on Radiation Protection and Measurements (NCRP) Scientific Committee 3 and the Committee on Radiation Oncology Studies (CROS) stated positions on the matter. Drafts of Sections F.8 and F.9 have been widely distributed, and the 1982 Edition of Sections F.8 and F.9 reflect comments received as a result of those drafts being circulated.

Specific Changes

E.1 Scope. The term "licensee" which was enclosed in brackets in the 1978 edition was eliminated. Few if any states are licensing x-ray facilities. The number of bracketed terms should be minimized and reserved for areas where a number of agencies would be affected.

E.2 Definitions. The alpha designators for each defined term are eliminated. The alpha designators are not necessary to reference the terms. A reference to Section F.2 is sufficient. Changes made in definitions include the following:

"Assembler." The changes in 21 CFR 1020.30(b)(3) are incorporated into the definition (44 FR 49667).

"Entrance exposure rate." Terminology was corrected by changing roentgen to **exposure**.

"Exposure" (1978 Edition). The definition of **exposure** was removed from Part F. The term is defined in Part A.

"Focal spot." Inserted and defined as a result of comments received. The Federal standard does not define focal spot.

"Full beam detector" (1978 Edition). The definition was eliminated as it is no longer used in Sections F.8 and F.9.

~~"Interlock" (1978 Edition).~~ The term is removed from Part F. It is defined in Part A in the 1982 Edition.

~~"Leakage technique factors."~~ The changes incorporated in 21 CFR 1020.30(b)(21) are incorporated in the definition (44 FR 29653).

~~"Mobile equipment" (1978 Edition).~~ The defined term was changed to "Mobile x-ray equipment" for clarity.

~~"Portable x-ray equipment."~~ The term was inserted and referred to the definition of "X-ray equipment" where it is defined.

~~"Primary dose monitoring system."~~ The phrase "quantity of radiation" was changed to "useful beam" to improve the clarity of the meaning. This definition was moved from Section F.9 to Section F.2.

~~"Radiation detector."~~ The phrase "by direct or indirect means" was struck as unnecessary.

~~"Radiation therapy simulation system."~~ The term "radiographic" was inserted to clarify the definition. An identical change was made in 21 CFR 1020.30(b)(50) (45 FR 27927).

~~"Radiological physicist."~~ A definition of radiological physicist was constructed for use in Section F.9. The term is not used in Section F.8 where "Qualified expert" continues to be used. The provisions of Subparagraphs (1), (2), and (3) parallel the requirements of 10 CFR 35.24.

~~"Recording."~~ The example terms in the definition were struck as unnecessary.

~~"Registrant" (1978 Edition).~~ The term was removed from Section F.2. It is defined in Part A.

~~"Spot check."~~ The words "an abbreviated calibration" were eliminated from the definition to delineate clearly the difference between "spot check" and "calibration".

~~"SSD."~~ The term is used in Part F and should be defined. The term was inserted into Section F.2.

~~"Stationary x-ray equipment."~~ The word "x-ray" was added to "stationary equipment" for clarity.

~~"Traceable to a national standard."~~ The phrase is defined for use in Section F.8 and F.9. It is more general than the definition found in NCRP Report No. 69, Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV (1981).

~~"Transmission detector" (1978 Edition).~~ The term was deleted as it is not used in the 1982

Edition.

~~"Treatment volume" (1978 Edition).~~ The term was deleted as unnecessary.

~~"Useful beam."~~ The definition was modified to make it acceptable for use in Section F.9. The modified wording does not change the meaning of useful beam when it is used in reference to diagnostic x-rays.

The following definitions were transferred from Section F.9 to Section F.2. The reason for such transfer was to further consolidate definitions in Section F.2.

1. Patient,
2. Phantom,
3. Secondary dose monitoring system, and
4. Termination of irradiation.

~~F.3(a)(1)(viii)(e) of the 1978 Edition. Holding of patients.~~ The subdivision was eliminated as unenforceable.

~~F.3(a)(1)(viii)(g) of the 1978 Edition and F.3(a)(3) X-Ray log.~~ These provisions have been rewritten and have simplified the requirements for the x-ray log. The rewritten subparagraph is coded as Subparagraph F.3(a)(3) and accomplishes the original intent of Subdivision F.3(a)(1)(viii)(g) and Subparagraph F.3(a)(3) in the 1978 Edition.

~~F.3(a)(1)(ix) Patient exposure.~~ A bracket was placed around the provisions of (ix). It has been repeatedly questioned whether the provisions are enforceable. The working group, however, deems them important where practice diverges sharply from accepted practice.

~~F.3(a)(1)(x) Exposure of personnel.~~ A reference to the monitoring requirements of Section D.202 was inserted. This was done for informational purposes.

~~F.4(e)(1)(iii) Minimum filtration.~~ A new minimum filtration is stated for dental systems. The provision for at least 1.5 mm aluminum filtration is a feasible requirement and reduces patient exposure. The requirement is slightly less stringent than the requirements stated in 21 CFR 1020.30(m) (44 FR 68822).

~~F.5(a)(2)(ii)(a) and (b) Fluoroscopic field size.~~ The wording of 21 CFR 1020.32(b)(2)(iv) was inserted (44 FR 29653).

~~F.5(a)(2)(iii) Spot-film field size.~~ The wording of 21 CFR 1020.31(g)(1) was inserted in subdivision (a) (44 FR 29653).

~~F.5(c)(1)(v)(e) Periodic measurement of entrance exposure rate.~~ The language was simplified by eliminating the explanatory phrase and substituting "personnel" monitoring devices.

~~F.5(f)(4) Source-to-skin distance.~~ The phrase "user's operating manual" was changed to "written safety procedures" to conform with the terminology used in Subdivision F.3(a)(1)(iv).

~~F.6(f)(4) Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.~~ An exemption for radiation therapy simulation systems was inserted in accordance with a change in the Federal standard (45 FR 27927).

~~F.7(g)(5) Beam Quality.~~ The changes made in 21 CFR 1020.30(m) were inserted (44 FR 68822).

~~F.8(a)(1) Leakage Radiation.~~ Subdivision (iv) was changed to utilize language used in Subparagraphs F.9(b)(1) and (2).

~~F.8(a)(3) Removable and Adjustable Beam Limiting Devices.~~ Wording was inserted to clarify that auxiliary blocks are not considered as removable beam limiting devices. Brackets were placed around "the effective date of Section F.8" to note that additional consideration may be necessary.

~~F.8(a)(4)(iii) of the 1978 Edition. Filter system.~~ The provision regarding wedge filter orientation was eliminated. The practicability and useability of such requirement initiated its deletion.

~~F.8(a)(4)(iii) Wedge filter marking.~~ Additional wording was inserted to permit the wedge angle to appear on the wedge tray. This provision was coded as Subdivision F.8(a)(4)(ii) in the 1978 Edition.

~~F.8(a)(8)(i) Beam monitor system.~~ The requirements for the detector to be a full beam detector were eliminated. The necessary radiation monitoring can be accomplished by other type detectors.

~~F.8(b)(1) of the 1978 Edition. Warning lights.~~ The subparagraph was deleted from the 1982 Edition. Entry into high radiation areas is covered by Section D.203.

~~F.8(b)(2) Viewing Systems.~~ Language was inserted to clarify that the backup viewing system may also be electronic.

~~F.8(b)(3)(iv) Additional requirements.~~ Subdivisions F.8(b)(4)(iii) and F.8(b)(4)(v) of the 1978 Edition have been combined into one requirement. Both 1978 requirements addressed the same topic.

~~F.8(b)(3)(iv) Additional requirements.~~ Subdivision F.8(b)(4)(iv) of the 1978 Edition was rewritten because the requirement was impractical to measure.

~~F.8(c)(2)(iii) Calibrations.~~ "Directly" of "directly traceable" was deleted. See rationale of Subdivision F.9(d)(2)(iii).

~~F.8(c)(2)(v)(d) Calibrations.~~ The wording was simplified, and the portion regarding tube orientation was eliminated. Due to tube head construction, field uniformity will be independent of tube orientation. The greatest non-uniformity will be represented by the largest field.

~~F.8(c)(2)(vi) Calibrations.~~ The time period for record retention was changed to 5 years to agree with the requirement made in Section F.9.

~~F.8(c)(3)(i) Spot checks.~~ The qualified expert is required to review spot check results within 15 days if he does not actually perform the test.

~~F.8(c)(3)(iii) Spot checks.~~ A requirement was inserted requiring that an acceptable deviation from a nominal value be stated in the spot-check procedures.

~~F.8(c)(3)(iv) Spot checks.~~ A requirement was inserted requiring action when the result of a spot check is not acceptable.

~~F.8(c)(3)(vii) Spot checks.~~ A requirement was inserted for instrument calibration. Radiation measurements should be performed with calibrated instruments.

~~F.9(a) Definitions.~~

~~"Central axis of the beam."~~ To make the definition correct technically, the "first" rather than the "final" beam limiting device determines the central axis of the beam.

~~"Dose monitoring system."~~ The word "measurement" was added. The dose monitoring system measures as well as detects and displays.

~~"Existing equipment."~~ See "New equipment."

~~"Field-flattening filter."~~ The word "homogenize" was eliminated. The words "dose uniformity" were utilized in its place, and the words "at a specified depth" were added. The new wording was added to make the definition technically correct and more precise.

~~"Field size."~~ The wording was changed to be more precise. Another sentence was added to specify that field size at dose maximum includes radiation buildup.

~~"Isocenter."~~ The definition was changed to that given by the International Electrotechnical Commission (IEC).

~~"Moving beam therapy."~~ A sentence was added to give examples of moving beam therapy.

~~"New equipment."~~ The date was changed to January 1, 1985, to provide lead time for manufacturers.

~~"Normal treatment distance."~~ The definition was changed to agree with the IEC wording.

~~"Radiation treatment prescription" (1978 Edition).~~ The definition was eliminated as the term is not used in the 1982 Edition.

~~F.9(b)(1) and (2) Requirements for equipment.~~ The concept stated by Scientific Committee 3 of the NCRP was used as the basis for changing the units from "rems" to "rads." The measurement area for neutrons was changed from 100 to 200 cm². Neutrons are unlikely to exist in narrow intense beams under these conditions.

~~F.9(b)(2) Leakage radiation.~~ The subparagraph was made applicable to new equipment. Existing equipment is not subject to the requirement but is subject to provisions of Part D. Brackets were placed around Subparagraph F.9(b)(2) because the Technical Review Committee questioned the regulatory applicability of this provision.

~~F.9(b)(4) Filters.~~ The requirements were rewritten to incorporate a new and existing equipment concept. Cost and practicability of modifying existing equipment to meet the requirements caused the subparagraph to be modified. The requirement for indication of the orientation of the wedge filter with regard to the field was eliminated entirely.

~~F.9(b)(6)(i) Beam monitors.~~ The language of primary-primary, primary-secondary was eliminated as unnecessary and confusing. The incorporated wording requires two separate monitoring systems.

~~F.9(b)(6)(iii)(a) Beam monitors.~~ The requirement for a detector to be a full-beam transmission detector was eliminated. It was concluded that safety did not require such a detector and that the type of detector should be a manufacturer's decision.

~~F.9(b)(6)(iii)(e) Beam monitors.~~ The majority of the subdivision regarding display at the control panel was made applicable to new equipment only. Costs of modifying existing equipment initiated the change. A concept of retaining the dose monitoring information for 20 minutes in the event of power failure was incorporated. This agrees with the IEC concept.

~~F.9(b)(7) Beam symmetry.~~ The requirement was reworded to give a more general requirement. The rewording resulted from comments received after circulation of the draft.

~~F.9(b)(8) Selection and display of dose monitor units.~~ The subdivisions have been rearranged from the 1978 Edition. A requirement is stated for new equipment whereby the preset number of dose monitor units would have to be reset manually after termination of irradiation, before

irradiation can be resumed. This is in agreement with the IEC publication 601-2-1.

F.9(b)(9) Termination of irradiation. The title of Subparagraph F.9(b)(9) was changed to include "or Systems during stationary beam therapy." Termination during moving beam therapy may conform to criteria stated in Subparagraph F.9(b)(15). Many comments were received regarding Subparagraphs F.9(b)(9). After discussion, it was concluded that for new equipment, a leeway of 25 monitor units was practical and feasible for a secondary system to terminate the useful beam. For existing equipment, the figure of 40 monitor units, stated by the IEC was accepted. The requirement for termination by the secondary system is stated in terms of original equipment design as existing equipment is not required to have a second dose monitoring system. The termination requirement for the secondary systems also incorporates a percentage of the preset dose provisions. This method is acceptable, and the regulations should permit it.

F.9(b)(14) Selection of Energy. Subdivision F.9(b)(14)(ii) of the 1978 Edition was reworded and made a requirement for new equipment. The rewritten subdivision designated as Subdivision F.9(b)(14)(iv) states the same permitted tolerances as does the IEC publication 601-2-1. The word "nominal" was inserted before "energy" in Subdivision F.9(b)(14)(iii) of the 1982 Edition (Subdivision F.9(b)(14)(iv) of the 1978 Edition) to clarify that measuring the radiation energy is not being required.

F.9(b)(15) Moving beam therapy. Subdivision F.9(b)(15)(v) of the 1982 Edition has been rewritten to consider movement of the gantry during stationary treatment. The provision is made applicable to new equipment only. Subdivision F.9(b)(15)(vi) of the 1982 Edition was rewritten to permit termination of the useful beam "by angle" which is the preference of many radiotherapists.

F.9(b)(17) Location of Virtual Source and Beam Orientation. Subdivision F.9(b)(17)(iii) of the 1978 Edition was struck as unnecessary.

F.9(c)(3) Viewing Systems. The provision was rewritten to clarify that the backup system may also be electronic.

F.9(d)(1) Surveys. Subdivision F.9(d)(1)(ii) was amended to state a time period limitation for transmitting the survey results to the Agency.

F.9(d)(2) Calibrations. In Subdivision F.9(d)(2)(i), the time period was extended to 1 year which is in agreement with NCRP recommendations. A requirement that the calibration protocol be acceptable to the Agency was added to allow Agency evaluation. In Subdivision F.9(d)(2)(ii), the term "radiological physicist" is utilized. The hazard of the high energy accelerator justifies the additional training and the presence of the individual supervising the calibration of the system. Subdivision F.9(d)(2)(iii) was rewritten and states "traceable" rather than "directly traceable". "Traceable to a national standard" is defined in Section F.2. A constancy check is also specified for the instrument. The radiological physicist specifies what

constancy checks are necessary to assure that the instrument retains its calibration. This is in agreement with recommendations found in NCRP Report No. 69.

~~F.9(d)(2)(v) Calibrations.~~ In Paragraph (b), the phrase "dose rate in air" was eliminated as unnecessary. In Paragraph (d), calibration should include review of tables and charts utilized with the therapy beam.

~~F.9(d)(2)(vi) Calibrations.~~ The record retention period was changed from 2 years to 5 years. This is in agreement with the NRC policy stated in 10 FR 35.25. The requirement is applicable to both the instrument calibration and the therapy unit calibration.

~~F.9(d)(2)(vii) Calibrations.~~ The wording was inserted such that a copy of the calibration is available in the area of the control panel for use should the need arise.

~~F.9(d)(3) Spot checks.~~ Spot checks are stated to be part of the calibration and shall be performed at intervals not to exceed one month thereafter. NCRP Report No. 69 recommends both weekly and monthly checks. Subdivision F.9(d)(3)(ii) and (iii) require the radiological physicist to develop the spot-check procedure and to state a time period for the performance of spot checks. It is anticipated that the previous requirements of Subdivision F.9(d)(2)(v)(c) of the 1978 Edition will be incorporated in the spot-check procedures. This will allow a flexibility in daily, weekly, and monthly spot checks. In Subdivision F.9(d)(3)(ii), the radiological physicist is not required to perform the spot checks but must review the measurements within 15 days. This parallels 10 CFR 35.22. In Subdivision F.9(d)(3)(iii), procedures are required to specify a range of acceptable values for a particular spot check. If the physicist is not performing the test, the person performing the test must be provided with guidance as to what the physicist would regard as an acceptable value. This will avoid unnecessary system "shut down." In Subdivision F.9(d)(3)(iv), requirements for absorbed dose measurements were added as recommended by NCRP Report No. 69. In Subdivision F.9(d)(3)(v), the language was changed to clarify that a spot check is an independent measurement. In Subdivision F.9(d)(3)(viii), records of spot checks are to be maintained for a period of 2 years. This is in agreement with the NRC policy for sealed-source teletherapy units stated in 10 CFR 35.25. In Subdivision F.9(d)(3)(ix), a requirement is stated for calibration of a system used to perform spot-check radiation measurements. The requirement parallels 10 CFR 35.23.

Matters for Future Consideration

1. Additional consideration should be given to leakage radiation through beam limiting devices. Presently, there are no provisions addressing leakage through such devices that are used with machines capable of large area (area greater than 500 cm²) treatment fields.
2. Additional consideration should be given to the provisions for leakage radiation

outside the patient area. Applicability of such provisions should be evaluated on the basis of patient protection (radiation scattered back into the plane of the patient), environmental considerations, or public health considerations.

3. Additional consideration should be given to the requirement that a "radiological physicist," as defined in Section F.2, be the qualifications as stated in the definition for performing said duties. Other persons may be equally but not specifically qualified.

**1978
Rationale for Revisions**

**Part F
X-Rays in the Healing Arts**

Introduction

Part F as published in 1974 has been modified in response to changes in the Federal x-ray standard, comments received, and changes in therapeutic x-ray sections. The reasons for significant changes are outlined below. Many editorial and grammatical changes have also been made which will not be contained in this rationale.

Specific Provisions

F.2 Definitions. Definitions were inserted or changed to incorporate changes in the Federal standard or to utilize the Federal wording:

- (k) "Cephalometric device"
- (ac) "Fluoroscopic imaging assembly"
- (ak) "Image intensifier"
- (am) "Image receptor support"
- (an) "Inherent filtration"
- (aw) "Leakage technique factors"
- (bn) "Radiation therapy simulation system"
- (cc) "Spot-film device"
- (cn) "Visible area"
- (cp) "X-ray control"

Definitions were added because of need or changed to provide clarification:

- (b) "Added filtration"
- (p) "Contact therapy system"
- (af) "Gonad shield"
- (ah) "Healing arts screening"
- (ai) "Heat unit"
- (ao) "Interlock"
- (ar) "kV"
- (at) "kWs"
- (az) "mA"
- (ba) "mAs"
- (bf) "PID"
- (bw) "Shutter"
- (cv) "X-ray tube"

Definitions which were not utilized were deleted:

"Density (D)"
"Line pair"
"Repair person (Service person)"
"Therapeutic-type protective tube housing"
"X-ray equipment, transportable"

Definitions were added for use in therapeutic x-ray sections:

(j) "Beam monitoring system"
(t) "Detector"
(ad) "Full beam detector"
(ap) "Irradiation"
(bm) "Radiation detector"
(ca) "Spot check"
(cg) "Transmission detector"
(ch) "Treatment volume"
(co) "Wedge filter"

F.3 General Requirements

~~F.3(a)(1)(i) Administrative Controls, Registrant.~~ Brackets are inserted around the phrase "if so directed by the Agency." The effect of the phrase if included is to negate to a considerable extent the effect of the regulations.

~~F.3(a)(1)(iii) Administrative Controls, Registrant.~~ Editorial and format changes are made. "Gonadal" changed to "gonad".

~~F.3(a)(1)(v)(d) of the 1974 SSRCR~~ was eliminated as maximum personnel exposures are covered by Part D and Subdivision F.3(a)(1)(v)(b).

~~F.3(a)(1)(vi) Administrative Controls, Registrant.~~ "Useful beam" is utilized rather than "direct beam" as direct beam is not defined.

~~F.3(a)(1)(vii) Administrative Controls, Registrant.~~ Editorial and format changes together with changes to incorporate Subdivision F.3(a)(1)(xi).

~~F.3(a)(1)(viii) Administrative Controls, Registrant.~~ Editorial and format changes.

~~F.3(a)(1)(ix) Administrative Controls, Registrant.~~ Italics removed and a provision added regarding minimum source to patient distance. The last change is related to a change in Paragraph F.6(c).

~~F.3(a)(1)(x) Administrative Controls, Registrant.~~ Editorial changes.

~~F.3(a)(1)(xi) Administrative Controls, Registrant.~~ A requirement for healing arts screening was inserted in response to comments received.

~~F.3(a)(2) Information and Maintenance Record and Associated Information.~~ The subparagraph was revised in response to comments received to allow for either a radiation survey or a description of the barriers.

~~F.3(a)(3) X-Ray Log.~~ Changes have been made in response to comments received regarding legality and practicality. The italics have been removed from the rewritten requirement.

~~F.3(c) of the 1974 SSRCR~~ regarding image reception devices has been deleted. The working group was of the opinion that the major points described in the "Concepts for Resolution" of 1974, will be better incorporated in quality control programs.

~~F.4 General Requirements for All Diagnostic X-Ray Systems.~~ Editorial changes are made and the codings for focal spot indication and accuracy of technique factors are eliminated. Sufficient information to construct a regulatory requirement is not available.

~~F.5 Fluoroscopic X-Ray Systems~~

~~F.5(a) Limitation of Useful Beam.~~ A number of changes are made to incorporate better language and format, changes in the Federal standard and the concept of a minimum field size.

~~F.5(c)(1)(v) Entrance Exposure Rate Allowable Limits.~~ Changes are editorial except in Paragraph (d) where the concept is changed from monitoring at peak values to monitoring at clinical techniques. This change was made in response to comments received, to guard against tube damage, and to provide useable data to the facility.

~~F.5(j) Radiation Therapy Simulation Systems.~~ This paragraph was added to incorporate changes in the Federal standard.

~~F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Veterinarian Systems~~

~~F.6(a)(1)(i) of the 1974 SSRCR.~~ The requirement for a minimum field size of 5 centimeters by 5 centimeters was shifted to Subdivision F.6(f)(4)(i) in this revision of Part F.

~~F.6(a)(1)(iii) Beam Limitation, General Purpose Stationary and Mobile X-Ray Systems.~~ The exemption to the requirement for a variable aperture collimator was inserted in consideration of low workload facilities where the cost of a PBL system would be prohibitive.

~~F.6(b)(1) of the 1974 SSRCR.~~ The provision for automatic resetting of timers to initial settings or to zero was transferred to Subparagraph F.6(f)(7) in this revision. Costs of modifying existing timers to meet this provision was the primary reason for the change.

~~F.6(b)(2) X-Ray Control.~~ Grammatical changes.

~~F.6(b)(3) Automatic Exposure Controls.~~ Grammatical changes.

~~F.6(b)(4) Reproducibility.~~ This subparagraph was formerly coded as Subparagraph F.6(b)(5). The subparagraph is reworded but the intent remains the same. The coding of the 1974 SSR CR regarding timer accuracy is eliminated at this time.

~~F.6(c) Source-to-Skin Distance.~~ The paragraph was reworded to agree with the Federal wording. The intent of the paragraph to provide at least a 30 centimeter source to patient distance is incorporated in this paragraph and Subdivision F.3(a)(1)(ix)(d). The coding reserved for determining receptor distance is eliminated at this time.

~~F.6(d) Exposure Reproducibility.~~ The paragraph regarding reproducibility is reworded. The intent was changed slightly by inserting the language "or equal to".

~~F.6(e) Radiation from Capacitor Energy Storage Equipment in Standby Status.~~ The title was changed to better describe the subject of the paragraph.

~~F.6(f) Additional Requirements Applicable to Certified Systems Only.~~ Changes are made in this paragraph to reflect changes made in other paragraphs regarding minimum use of the x-ray field and timers.

~~F.7 Intraoral Dental Radiographic Systems~~

~~F.7(c) of the 1974 SSR CR.~~ The resetting of the timer to zero after an exposure was shifted to the paragraph regarding special requirements for certified units. The cost of modifying existing timers was the primary reason for this change. The coding for timer accuracy was eliminated.

~~F.7(g) Additional Requirements Applicable to Certified Systems Only.~~ Resetting of the timer which was eliminated in Paragraph F.7(c) was added to this paragraph.

~~F.8 Therapeutic X-Ray Systems of Less Than One MeV~~

This section was constructed to consider existing x-ray therapy systems and new x-ray therapy systems. Principal references cited will be the 1970 SSR CR, NCRP Report No. 33, (Medical X-Ray and Gamma-Ray Protection for Energies Up to 10 MeV - Equipment Design and Use - 1968) and comments received on initial draft.

(a) ~~Equipment Requirements~~

- (1) ~~Leakage Radiation.~~ Reference to 1970 SSR CR. Standards stated parallel requirements of the 1970 SSR CR, except in the case of new x-ray therapy systems having a kVp of 150 or less. It appears practical that machines in this kVp range meet the diagnostic x-ray tube housing standard. Copies of the proposed regulation were furnished to known manufacturers with no return answer.

- (2) ~~Permanent Beam Limiting Devices.~~ Reference Subparagraph F.8(a)(2) of the 1970 SSRCR.
- (3) ~~Removable and Adjustable Beam Limiting Devices.~~ A more stringent standard was written for these beam limiting devices. The inadequacy of the 5 percent transmission figure has been noted in the ICRP Committee 3, Publication 15 (November 1969). Dodson in "The Use of Electron Linear Accelerators in Medical Radiation Therapy" on Page 55 of Overview Report No. 1 states that manufacturers have noted the problem caused by 5 percent transmission and have reduced their transmission values to less than 0.5 percent (on accelerators). Copies of the proposed regulation were furnished to manufacturers with no response.
- (4) ~~Filter System.~~ The requirements stated appear in different language in the 1970 SSRCR. The principal addition is the inclusion of marking of wedge angles and of wedge filter orientation.
- (5) ~~Tube Immobilization.~~ Reference Subparagraph F.8(a)(6) of 1970 SSRCR.
- (6) ~~Focal Spot Marking.~~ Reference 3.4.1(f) of NCRP Report No. 33. A criteria for the accuracy of such marking is stated.
- (7) ~~Beam Block (Contact Therapy).~~ Reference 3.4.3(f) of NCRP Report No. 33 and Subparagraph F.9(b)(2) of 1970 SSRCR.
- (8) ~~Beam Monitor System.~~ This requirement is applicable to only new equipment having a kVp greater than 150. NBS Handbook No. 41 published in 1949 recommended a beam monitor. Subsequent publications have also recommended such a monitor. The subparagraph was written to parallel the beam monitor requirements which had been written for accelerators, in response to a comment noting that therapy requirements for the dosimetric system for ortho-voltage x-ray systems should parallel that required for accelerators.
- (9) ~~Timer.~~ Comments and paralleling requirements of other sections indicated the format and language used. Reference 3.4.1(j) of NCRP No. 33. A provision is included to prevent exposure when the timer is set at zero. A provision is also included to state when the timer shall begin operation, when the exposure is controlled by a shutter.
- (10) ~~Control Panel Functions.~~ The subparagraph was written to parallel similar requirements in Section F.9. The items stated are necessary for radiation safety. The requirement for a display of filters present in the useful beam for new equipment was suggested by a comment.

- (11) ~~Multiple Tubes.~~ Requirements are stated which will identify which tube may be activated.
 - (12) ~~Source-to-Patient Distance.~~ Patient safety indicates the need to identify this parameter.
 - (13) ~~Shutters.~~ Reference Subparagraph F.8(a)(8) of 1970 SSR CR and 3.4.1(k) of NCRP No. 33. Comments received indicated expansion of the wording to provide clarification.
 - (14) ~~Low Filtration X-Ray Tubes.~~ The marking of tube head assemblies containing low filtration windows was suggested by a comment.
- (b) ~~Facility Design Requirements for Systems Capable of Operating Above 50 kVp~~
- (1) ~~Warning Lights.~~ Reference Subparagraph F.8(b)(8) of 1970 SSR CR.
 - (2) ~~Voice Communication.~~ Reference Subparagraph F.8(b)(7) of 1970 SSR CR. Reworded to reflect comments.
 - (3) ~~Viewing Systems.~~ Reference Subparagraph F.8(b)(6) of 1970 SSR CR. A back-up system is required if the viewing system is electronic.
 - (4) ~~Additional Requirements (for Systems Capable of Operating Above 150 kVp)~~
 - (i) ~~Fixed Shields.~~ Reference Subparagraph F.8(b)(3) of 1970 SSR CR. The 1970 version used 50 kVp as a point where fixed barriers would be required.
 - (ii) ~~Control Panel.~~ Reference Subparagraph F.8(b)(4) of 1970 SSR CR.
 - (iii) ~~Interlocked Doors.~~ Reference Subparagraph F.8(b)(5) of 1970 SSR CR.
 - (iv) ~~Machine Shutdown.~~ Reference Subparagraph F.8(b)(5) of 1970 SSR CR. The requirement was relaxed somewhat by eliminating the 2 mR/hr average and using the high radiation area level stated in Part D. A statement is made for how fast the radiation field must be reduced. It was the working group's opinion that if a machine shut down within a second of a door opening to 100 mR/hr, that no significant exposure could occur before other action could be taken.
 - (v) ~~Reinitiating Treatment.~~ Reference Subparagraph F.8(b)(5) of 1970

SSRCR.

(c) ~~Surveys, Calibrations, Spot Checks, and Operating Procedures~~

- (1) ~~Surveys.~~ Reference Subparagraph F.8(c)(1) of 1970 SSRCR.
- (2) ~~Calibrations.~~ The calibration subparagraph was written to parallel that constructed for the accelerator section in response to a comment. Many constructive comments were received regarding calibrations.
- (3) ~~Spot Checks.~~ The subparagraph was constructed to require that the qualified expert specify what the spot check would entail and how often they would be performed for a particular machine.
- (4) ~~Operating Procedures~~
 - (i) ~~Securing of the system~~
 - (ii) ~~Holding of patients~~
 - (iii) ~~Holding of tube housing.~~ Reference Subparagraph F.9(b)(4) of 1970 SSRCR and 3.4.3(f) of NCRP Report No. 33.
 - (iv) ~~Persons in treatment room.~~ Reference 3.4.3(e) of NCRP No. 33. As opposed to the reference the requirement does not permit patient holding when the kVp exceeds 150.

~~F.9 X-Ray and Electron Therapy Systems with Energies of One MeV and Above~~

The regulations in Section F.8, Therapeutic X-Ray Installations, of the 1970 Edition of the SSRCR were designed primarily for radiation therapy in energy ranges well below 1 MeV. During the years since most of the regulations were first written, the design and use of therapy equipment above 1 MeV has proliferated, and has presented radiation safety problems which are not adequately covered by the old regulations. As a result, the working group has divided the therapy regulations into two sections - Section F.8 on therapy use below 1 MeV and Section F.9 on therapy use at 1 MeV and above.

The regulations for use of therapy machines at 1 MeV and above were developed by the working group after consultation with standards from numerous organizations, such as the National Council on Radiation Protection and Measurements, the American Association of Physicists in Medicine, the International Electrotechnical Commission (IEC), and the Bureau of Radiological Health, as well as individual experts in the field. Most of the regulations on equipment are based upon IEC draft recommendations or are modified versions of the IEC recommendations.

In developing the model regulations which will apply to megavoltage medical therapy

machines, the working group has attempted to achieve the greatest safety consistent with practicality and reasonable expense. With this in mind, those standards which are likely to provide substantial safety and can be achieved with reasonable expense are made applicable to both existing and new equipment. Conversely, those standards which involve considerable expense or inconvenience are made applicable only to equipment manufactured after the effective date of the regulations.

Rationale for Applying Part I to Medical Therapy Machines. The regulations in Part I were developed to cover all types of particle accelerators, including those used on humans. Where a section in Part I is not appropriate for human use accelerators, the section is worded to exclude applicability to human use. Exceptions are Paragraphs I.11(c) and I.11(d) which require, at the control panel and entrances to the treatment room, continuous readout of high radiation levels in the room. Such independent readout systems at each entrance are considered unnecessary as all doors are already interlocked and there is a warning light at each entrance indicating radiation is being produced. A readout of patient exposure at the control panel is provided for in Section F.9. The working group has therefore specified that all applicable sections of Part I shall apply to human use accelerators except Paragraphs I.11(c) and I.11(d).

(b) **Requirements for Equipment**

- (1) **Leakage Radiation to the Patient Area.** The concept of providing greater protection from leakage radiation for the patient (i.e., plane circular surface of 2 meters radius) than for other areas is taken from a draft of the IEC Sections 6.2 and 6.3. However, these SSRCR standards do not allow as much latitude on leakage levels as do the IEC standards. The ICRP (No. 15, 1969) has set a leakage standard of 0.1 percent of the useful beam for high energy therapy machines. The working group believes that this standard should not be compromised without very good cause.

The neutron problem in equipment operating above 13 MeV can pose a very serious problem in meeting the 0.1 percent leakage standard. At the same time, neutrons can be a serious hazard for the patient. In the present state of the art there is insufficient knowledge of the magnitude, nature, and effects of the neutrons from high energy machines. The working group feels that the established maximum leakage level of 0.1 percent should not be exceeded until the ICRP addressess the problem. However, the working group recognizes that some existing high energy accelerators cannot meet the 0.1 percent criteria and

has opted to insert a standard for these machines which does not consider the neutron component of the leakage radiation.

- (2) **Leakage Radiation Outside the Patient Area.** The maximum x-ray leakage of 0.1 percent outside of the patient area is required because it is not excessively difficult to achieve in design and it establishes a reasonable level upon which shielding around the therapy room can be designed. Leakage of 0.5 percent for

neutrons outside the patient area is achievable.

- (3) ~~Beam Limiting Devices.~~ A maximum leakage of 5 percent through adjustable collimators can result in a very substantial integral dose (defined by the product of dose times volume of tissue irradiated) to the patient. Under typical conditions of a small treatment field using a unit with a large maximum field size capability, the integral dose to the patient due to transmission through the collimators can approach or exceed the integral dose due to the useful beam. This high potential for patient exposure plus good shielding feasibility are reasons for lowering the maximum permissible collimator leakage.
- (4) ~~Filters.~~ The standards for fixed and removable filters are based upon the IEC recommendations.
- (5) ~~Beam Quality.~~ Because of the high potential for stray radiation in the useful beam at high energies, it is necessary to specify maximum contamination levels. Neutron exposures can be significant at high energy therapy and must be known. These standards are essentially from the IEC recommendations.
- (6) ~~Beam Monitors.~~ The high dose rates of high energy therapy machines require that the delivered dose be known accurately for each treatment. To help ensure this, particularly during and following conditions of equipment failure, or beam interruption, two independent monitoring systems with accumulated response retention capabilities are required. A backup timer switch is also required. ICRP recommends one exposure meter plus a timer, while the British Code of Practice requires two separate dose integrating systems plus a backup timer. The standards for new beam monitoring are based upon IEC draft recommendations.
- (7) ~~Beam Symmetry.~~ The requirement for new equipment is similar to the language utilized in IEC drafts.
- (8) ~~Selection and Display of Dose Monitor Units.~~ These standards are from IEC recommendations.
- (9) ~~Termination of Irradiation by the Dose Monitoring System.~~ The requirement is similar to IEC recommendations but differs in that a secondary system is required to terminate irradiation when 102 percent of the pre-set dose monitor units has been reached rather than 115 percent.
- (10) ~~Interruption Switches.~~ From IEC recommendations.
- (11) ~~Termination Switches.~~ From IEC recommendations.
- (12) ~~Timer.~~ See rationale for Subparagraph F.9(b)(6) Beam Monitors. It differs from

IEC recommendations where a timer is only a suggested device.

- (13) ~~Selection of Radiation Type.~~ This standard is required to help ensure against accidental use of the wrong type of irradiation and is taken from IEC recommendations.
- (14) ~~Selection of Energy.~~ Parallels IEC recommendations.
- (15) ~~Selection of Stationary Beam Therapy or Moving Beam Therapy.~~ From IEC recommendations.
- (16) ~~Absorbed Dose Rate.~~ Parallels IEC draft recommendations. A portion of the last IEC draft regarding a device to terminate irradiation if the dose rate exceeds 10 times maximum was not incorporated.
- (17) ~~Location of Focal Spot and Beam Orientation.~~ From IEC recommendations.
- (18) ~~System Checking Facilities.~~ Parallels IEC draft recommendations.
- (19) ~~Shadow Trays.~~ A comment suggested this provision.

(c) ~~Facility and Shielding Requirements~~

- (1) ~~Shielding Barriers.~~ Portable barriers are not considered to offer adequate protection for high energy, high dose rate therapy installations.
- (2) ~~Control Station Shielding.~~ The high dose rates involved indicate that the operator should be provided with maximum security.
- (3) ~~Viewing System.~~ Continuous observation of the patient is essential, and a backup viewing system is required to ensure continuity of this function in the event of electronic failure.
- (4) ~~Aural Communication With Patient.~~ Aural communication with the patient is necessary to allow instructions to the patient before, during, and after treatment, as necessary, and to help avoid premature beam interruption or termination due to lack of communication.
- (5) ~~Warning Lights.~~ The warning lights are required to warn persons not to enter a treatment room during beam-on conditions and cause an unnecessary beam interruption.
- (6) ~~Interlocked Doors.~~ Radiation protection of persons other than the patient requires this provision.

(d) ~~Surveys, Calibrations, Spot Checks, and Operating Procedures~~

- (1) All new and revised therapy facilities should be surveyed for safety by a qualified expert to help ensure against unplanned exposures from accelerator operation. The findings of the survey must be reported in writing to the facility and the Agency. Requiring the qualified expert to indicate the areas of noncompliance provides valuable information to the facility and to the Agency in locating and correcting safety deficiencies.
- (2) ~~Calibrations.~~ Calibrations must be performed by or under the direct supervision of a qualified expert. Direct supervision as used here means that the supervising qualified expert is present at the facility and is readily available to give consultation or assistance to the person doing the actual calibration. The British Code of Practice recommends monthly recalibrations while the NCRP recommends annual recalibrations. The working group has selected an interim period and required full recalibrations once each six months, providing periodic spot checks indicate stable output. Many determinations are needed for a complete calibration. The items of calibration listed in this subparagraph are not intended to be a complete list of all necessary determinations, but to specify the major items of calibration and to indicate the scope of calibration. Many constructive comments were received regarding calibrations.
- (3) ~~Spot Checks.~~ For megavoltage units, periodic spot checks are considered necessary to assure that the dose is unchanged from what it was at calibration.
- (4) ~~Operating Procedures.~~ The provisions prohibit persons from being in the treatment room during irradiation. The procedures also disallow operation of the accelerator if the calibrations are not current.

~~Appendix A, Information on Radiation Shielding Required for Plan Reviews.~~ Language changes but no change of intent. Brackets are added.

~~Appendix B, Suggested Design Requirements for an Operator's Booth.~~ Language and format changes. 4(b)(1) changes 5 feet to 4.5 feet.

~~Appendix C, Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening.~~ Added for use in mass screening programs.

**1974
Rationale for Revisions**

**Part F
X-Rays in the Healing Arts**

A draft of the Suggested State Regulations, Part F was distributed by the Bureau of Radiological Health (BRH) in cooperation with the Conference of Radiation Control Program Directors, Inc. (CRCPD) to the States in February, 1973 and comments were solicited. Over 200 separate comments were received. These comments reflected opinions which both affirmed portions of the draft and pointed out deficiencies. Many comments were directed to areas which were totally omitted. Some items had comments both pro and con. Following a meeting between the BRH and the Executive Committee of the CRCPD, an ad hoc Task Force was appointed by the CRCPD to consider the comments received and to make appropriate revisions in Part F, as well as to assure compatibility of the model regulations with the Federal performance standards.

To clarify the basis for inclusion by the task force of certain of the new provisions in Part F, this rationale is submitted along with the revised Part F. The general philosophy of the task force is to reduce unnecessary radiation wherever it is possible and by whatever means practicable. We recognize that this is synonymous with the goals of radiation protection practice. The differences and discussions result from the degree to which regulations are to be used to accomplish these goals. The more "controversial" concepts were very carefully considered by the task force and discussed with the BRH. In the section entitled Concepts for Resolution are listed problem areas recommended by the task force for consideration by the BRH and which eventually may lead to amendments to the Federal diagnostic x-ray standard.

Several areas of concern to the task force which have not met with the accord of the BRH at least in application are concepts involving gonadal shielding and film and screen information. The final application of the model regulation will in any case be dependent upon its applicability by the individual state.

Areas such as film development are included in the appendix because of the need for a standard by which the state can more accurately determine if excessive exposure, repeats, etc., occur. This same principle prompted the requirement of the patient log. While it is evident that additional record keeping is time consuming, it is equally true that failure to adjust operating techniques for the individual patient results in unnecessary exposure and the need for repeat exposures.

The general concept used within Sections F.4, F.5 and F.6 was to develop one standard rather than two standards. Where the Federal standard stated the criteria which in the task force's opinion could be made applicable to all units, it was incorporated into the draft. Where it was the consensus that the Federal requirement could not reasonably be met by all units, it was included as an additional requirement for "certified" units. While these sections were being assembled consideration was given to the cost and feasibility of applying a given new

equipment standard to existing equipment. The task force recognizes that some of the provisions included in the draft are going to require a phase-in period. However, no phase-in period was included within the suggested draft, as it was the consensus that each state should take the model regulations and further adapt them to their own use and purposes.

For the purposes of this document the phrase "Federal wording" means wording found in 21 CFR 1020.30, .31, or .32. The initials SSRCR means Suggested State Regulations for Control of Radiation as amended in 1970.

Much discussion has accompanied many of the regulations incorporated in the model. The following is an attempt to relate some of the reasons the task force chose the specific regulation in the form found in the model.

~~Sec. F.1 Scope.~~ Because some States may wish to license (rather than register) an x-ray system, both terms are used.

~~Sec. F.2 Definitions.~~ The terms defined here were those used in the main body (Sections F.3 - F.9) which for clarity's sake were deemed necessary by the task force. In general, they should all be self-explanatory. For definition (az) "Qualified expert," each Agency may wish to add more specific requirements for a qualified expert.

~~Sec. F.3 General Requirements.~~ Comments regarding the general safety provisions contained in Section F.3 of the February 1973 draft were reviewed by the task force for content. About 45 comments were submitted regarding the content of that section. After review, it was the task force's opinion that the entire section should be rewritten.

The views of commenters on the 1973 draft were used as partial guidelines in assembling the section. An effort was made throughout to construct the provisions such that enforcement would be practical. Because this is not always possible some provisions are included which can be enforced only in the case of a flagrantly poor procedure.

The revised Part F does not propose any alternates within Section F.3 and does not reference any other standards. The scope is far wider than previous draft versions. Thus a point-by-point comparison with the February 1973 draft would serve no purpose.

(a) ~~Administrative Controls.~~ The subparagraphs within the paragraph state general procedures which may be applicable to management and others. The role of administrative personnel in radiation protection is clarified.

(1) ~~Registrant.~~ The subparagraph states provisions which management must provide, adhere to, authorize, oversee, etc.

(i) ~~Conformance to the Regulations.~~ The Agency must have authority to forbid the operation of a system that does not meet the regulations. The registrant must be responsible for assuring that maintenance is performed

in accord with manufacturer's instructions.

- (ii) ~~Instruction of Personnel.~~ It is a responsibility of the registrant or his delegate to ascertain that personnel are aware of the hazards of radiation and competent to perform the necessary work. It is similar to SSRCR Subparagraph F.3(a)(1). States wanting to license personnel may wish to administratively interpret "adequately instructed" as requiring licensing.
- (iii) ~~Technique Chart.~~ This chart is generally available within x-ray departments, but not to the extent called for in this subdivision. The need was felt to assure availability of these charts at the time of operation. This requirement is interrelated to the requirement for a patient log.
- (iv) ~~Written Safety Procedures.~~ Administrative personnel must have procedures established which will provide guidelines to all personnel for additional safety procedures which are not universally accepted criteria, but will be in effect at that facility. The requirement is somewhat similar to SSRCR Subparagraph F.3(a)(2).
- (v) ~~Persons in the X-Ray Room.~~ The exposure of persons to scattered radiation should be minimized. The exposure of other patients in a hospital ward or infants in a nursery was of particular interest to the task force. The requirement parallels SSRCR Subparagraph F.5(c)(2).
- (vi) ~~Gonadal Protection.~~ The task force wrote more explicit and stringent regulations on gonadal shielding. However, the BRH expressed concern that the proposed regulations would hamper the program the BRH is initiating. The gonadal shielding regulation in the model is the same as in the previous SSRCR.
- (vii) ~~Authorization of Exposures.~~ These provisions were written after discussing exposures for training and mass screening. Note that screening is not prohibited, but does require approval by the Agency. This regulation is also intended to deter practitioners from ordering an examination unless each of the exposures is specifically intended. The initial statement requiring authorization parallels the requirement made in SSRCR Section F.1.
- (viii) ~~Patient or Film Holding.~~ This subdivision was constructed to incorporate the ideas stated in SSRCR Subparagraph F.5(c)(1). A record is required of the fact that the patient or film was held. It was the task force's opinion that without such a record, enforcement would not be practical and even the facility may not have a good concept of the amount of holding which occurs. The use of lead gloves and apron in no way is meant to preclude the use of adequate collimation.

- (ix) ~~Minimizing Exposures.~~ The provisions of this subdivision are probably not enforceable except in the case of flagrantly poor procedures. The subdivision was included for use in those cases.
- (x) ~~Personnel Monitoring.~~ The requirement is in agreement with a CRCPD workshop report. Portions of this requirement are already found in Part D. However, additional clarification on location for wearing the film badge, critical organ and whole body dose is required. Until such time as this information can be found in Part D or other appropriate section, it was included here.
- (2) ~~Machine Record.~~ This information is needed to allow both the registrant and the Agency to evaluate an x-ray system. Part of the information required is also required by Federal regulations in 1020.30(h) to be furnished by the manufacturer to the user.
- (3) ~~Patient Log.~~ A record should exist of the fact that an x-ray examination occurred. This will enable the facility as well as the Agency a method to determine the number of exposures an individual has received at that facility. When the examinations are routine, a minimum of additional record keeping is required. However, repeat exposures and non-routine techniques will have to be recorded. The required log is interrelated to the technique chart and will provide workload data for evaluation of the facility shielding.
- (b) ~~Plan Review.~~ It is not anticipated that all states would elect to adopt such a provision. It was placed in Part F on the stipulation that the rationale note that no state is obligated to adopt any portion of the model. This section is regarded as unpractical for some states at this time. There is no question as to the appropriateness of including the provision in radiation protection regulations, but the question is monies and staff to conduct such a program. A convincing argument for including the section was that with such a provision in a national model, underfunded programs may be enabled to make a more successful effort obtaining monies for such a program. Note that the provisions are applicable only to new installations or facilities being remodeled. The booth requirements were included after discussions emphasizing that the booth was intended to protect personnel and not the x-ray console.
- (c) ~~Image Reception Devices.~~ Provisions for information on image receptors were debated. The BRH has projects initiated which should make incorporation of regulatory provisions feasible in the future, but not at this time. The coding was left for future usage. There are many factors concerning film, screens, etc., that will require future regulation.
- (d) ~~Processing of Film.~~ The subparagraph on film processing was put in the appendix because several states expressed difficulties with enforcement. The principal addition to standard recommendations regarding film processing are the required maintenance provisions for automatic processors and the periodic evaluation of a test film. The task

force originally specified weekly on the test film evaluation but after further consultation concluded that daily would be appropriate on manual developing systems. Note that a full size film is not required for test purposes.

The task force also considered processing chemicals but deferred action at this time by placing the item in the concepts section. It was readily agreed that some regulation of these factors is necessary. However, it is premature to regulate these portions until more of the on-going research provides substantiating data.

Sec. F.4 General Requirements for All Diagnostic X-Ray Systems

- (a) Warning Label. The wording is identical to that found in 1020.30. There is no equivalent SSRCR requirement. It is feasible to apply this requirement to all units.
- (b) Battery Charge Indicator. The wording is that found in 1020.30(o). There is no current equivalent SSRCR requirement. This requirement is needed to prevent retakes. The cost to modify a unit which does not presently comply is not excessive.
- (c) Leakage Radiation from the Diagnostic Source Assembly. This is the wording found in 1020.30(k) which is a restatement of the present SSRCR requirement in Paragraph F.2(f).
- (d) Radiation from Components Other Than the Diagnostic Source Assembly. This is the wording used in 1020.30(l). The SSRCR covers this subject in Section B.2 although it is somewhat indirect.
- (e) Beam Quality
 - (1) Half-Value Layer
 - (i) The wording used is that found in 1020.30(m).
 - (ii) This subdivision permits use of the SSRCR criteria for useful beam filtration to be used to show compliance to (i) above.
 - (iii) This requirement on beryllium window tubes is applicable only to diagnostic units. It is equivalent to a recommendation made by BRH. To the task force's knowledge, it should not interfere with any diagnostic procedure. A question might exist in regard to mammography; however, references can be found in the literature showing that using a tungsten target tube the optimum aluminum equivalent filtration is between a half millimeter and 0.75 millimeter aluminum equivalent.
 - (iv) This is a note on compliance monitoring. It is identical to the wording used in 1020.30(m)(2).
 - (v) This is a note on compliance monitoring and is a clarification statement.

Special Note:

The Federal requirement found in 1020.30(n) regarding aluminum equivalence of material between patient and image receptor is not included any place within the revised Part F. The difficulties of determining this aluminum equivalence in the practitioner's office is the primary reason the requirement was not included.

- (2) **Filtration Controls.** This is a requirement which is stated in 1020.30(m)(1). Conclusion was reached after discussion that this is a requirement that should be applied to all units. X-ray service companies were contacted during the discussion and it was concluded that the cost of complying with this requirement was not excessive.
- (f) **Multiple Tubes.** This wording is that contained in 1020.31(j) which is applicable only to radiographic equipment. In the revised Part F draft this is applicable to all equipment, both radiographic and fluoroscopic. The operator should always be aware of which x-ray tube is being activated.
- (g) **Mechanical Support of Tube Head.** A requirement regarding tube stability is found in the current SSRCR Subparagraph F.7(a)(8), which was applicable only to dental equipment. The paragraph regarding mechanical stability found in the revised Part F draft is applicable to all equipment. The question of how stable was asked. The task force's response is that this is normally a question of the inspector's judgment. If a legitimate question did arise, the final determination could be made using a resolution plate.
- (h) **Focal Spot Indication.** This was deferred for future action as the BRH personnel felt that this would be a more restrictive equipment requirement than appears presently within Federal regulations.
- (i) **Technique Indicators.** This uses the wording of 1020.31(a)(1) which in the case of the Federal regulations is applicable only to radiographic equipment. In the revised Part F draft this is applicable to both radiographic and fluoroscopic equipment. The requirement is similar to a requirement made in the present SSRCR which is applicable to radiographic installations in Subparagraph F.5(a)(6). The question of whether this requirement should be made applicable to both radiographic and fluoroscopic equipment was discussed at length. The conclusion was that it was not unreasonable to require rheostat or switch settings on fluoroscope consoles to be labeled.

Sec. F.5 Fluoroscopic X-Ray Systems

- (a) **Limitation of the Useful Beam.** The requirements made in this paragraph are also made in 1020.32(a) and (b). The coding and arrangement has been changed allowing the coding to refer to a specific requirement.

- (1) The wording used is found within 1020.32(a)(1). A similar requirement is found in SSRCR Subparagraph F.4(a)(4).
 - (2) The wording used is found within 1020.32(a)(1). The requirement is also found in SSRCR Subparagraph F.4(a)(4).
 - (3) ~~Minimum Field Size.~~ The BRH is considering this as a possible amendment to existing Federal regulations. However, it was requested that this not be included within the revised Part F at this time. The subparagraph was placed in the Concepts for Resolution.
 - (4) Limitation to the Imaging Surface
 - (i) ~~Nonimage-Intensified Fluoroscopy and Spot Filming.~~ The wording is made in SSRCR Subdivision F.4(a)(4)(ii). As stated it applies to both the x-ray field used during fluoroscopy and the x-ray field used during spot film procedures. Note that this is a different requirement than is made for the x-ray field during spot filming procedures in the Federal x-ray regulations. (See (iii) below.)
 - (ii) ~~Image-Intensified Fluoroscopy and Spot Filming~~
 - (a) This is identical to a rewritten Federal provision under consideration as a future amendment. Numerous comments had been submitted regarding the previous version and the difficulty of interpretation.
 - (b) States the standard for compliance.
 - (iii) ~~Spot Film Device Certified Equipment Only.~~ The wording utilized here is the wording found in 1020.31(g) and includes subparagraphs (1), (3), and (4). Subparagraph (2) of 1020.31(g) is covered in (ii) above.
- (b) ~~Activation of the Fluoroscopic Tube.~~ The wording used for this requirement is found in 1020.32(c). A similar requirement is found in the existing SSRCR Subparagraph F.4(a)(5).
- (c) Exposure Rate Limits
 - (1) ~~Entrance Exposure Rate Allowable Limits.~~ This subparagraph generated a lengthy discussion involving the Federal requirements regarding this subject, the requirement made in the SSRCR, and the lack of any upper limit for the exposure rate within the Federal regulations. The need for exposure rates which would exceed 10 R per minute for special procedure units was also discussed. As a result of these discussions, the BRH did agree to undertake studies of the

need to set upper limit exposure rate limits on fluoroscopes and also to develop manufacturing standards for special procedures units. The wording used for entrance exposure rate allowable limits in the draft comes from 1020.32(d). For this subparagraph in Part F, the wording has been rearranged such that there is a requirement stated for all fluoroscopic units and a special requirement for certified equipment which does not incorporate automatic brightness control. Subdivision (v) requires that the entrance exposure rate be periodically monitored and would allow the user to use a commercially available dosimeter to perform this measurement. Since the user is permitted to make the measurement, conditions of measurements are stated within this section.

- (d) ~~Barrier Transmitted Radiation Rate Limits.~~ The wording used in this paragraph is found in 1020.32(a)(1) and (2). A similar requirement is found in SSRCR Subdivision F.4(a)(4)(i).
- (e) ~~Indication of Potential and Current.~~ The wording utilized is found in 1020.32(e).
- (f) ~~Source-Skin Distance.~~ This paragraph uses two standards for source to panel top spacing. Units newly installed would be required to have a 15-inch source to panel top distance. Units which are presently in operation would be permitted to have a 14-inch target to panel top distance. The task force felt that the majority of presently existing fluoroscopes could meet the 14-inch requirement. Units which could not meet the 14-inch requirement and that a state felt should continue in operation should be handled under a special exemption. The requirement of a 12-inch source-skin distance on mobile fluoroscopes is found both in the Federal regulations and the existing SSRCR regulation. The requirement for surgical fluoroscopes comes from the Federal regulations.
- (g) ~~Fluoroscopic Timer.~~ The wording used is found in 1020.32(g). The format was changed to allow reference to specific requirements. This requirement parallels a similar requirement in the SSRCR Subparagraph F.4(a)(6).
- (h) ~~Mobile Fluoroscopes.~~ The requirement for image intensification is made in both the Federal regulations in 1020.32(h) and in the SSRCR Subdivision F.5(a)(11)(ii).
- (i) ~~Control of Scattered Radiation.~~ Because of the varied equipment configurations (over the table tubes, under the table tubes), the task force has incorporated requirements which do differ from previous existing requirements contained in the SSRCR which were designed to control exposure of personnel to scatter radiation. Rather than stating requirements for individual items such as Bucky slot covers, protective drapes, or sliding panels, a generalized performance standard for exposure to scatter radiation is stated.

~~Sec. F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Veterinary Systems~~

- (a) **Beam Limitation.** The generalized statement here, which is also contained in the present version of the SSRCC, is probably not enforceable. Consideration was given to generally requiring evidence of collimation to appear on each x-ray film. The Concepts for Resolution section contains the task force's thoughts on the subject.
- (1) **General Purpose X-Ray Systems.** This subparagraph does require that a variable aperture collimator or the equivalent be provided on every general purpose x-ray unit. No phase-in period is stated. Individual states may wish to further tailor this requirement to their own needs. The language found in 1020.31(d)(1) and (2) was used in writing this requirement. The further requirement for light field intensities found in the Federal regulations was not included in this subparagraph, which is applicable to all x-ray units.
 - (2) **Additional Requirements for Stationary General Purpose X-Ray Systems.** It was deemed feasible to make these Federal requirements for indication of alignment and x-ray field size applicable to all stationary x-ray units.
 - (3) **X-Ray Systems Designed for One Image Receptor Size.** The wording of 1020.31(f)(2) was utilized for this requirement. Photofluorographic x-ray units would be subject to this provision.
 - (4) **Special Purpose X-Ray Systems.** The requirement and wording closely follows 1020.31(f)(3).
- (b) **Radiation Exposure Control Devices**
- (1) **Timers.** The wording utilized may be found in 1020.31(a)(2) and (3). However, the Federal regulations cover both timers and exposure switches. In the draft, requirements which are applicable to timers are stated in this subparagraph.
 - (2) **X-Ray Control (Exposure Switch).** This subparagraph contains the requirements from the Federal regulations for x-ray control switches contained in the 1020.31(a)(2). It was questioned whether this exposure switch should not be a dead-man type switch; a paragraph to this effect is found in the concepts section. Requirements for the placement of exposure switches for mobile and portable systems are also contained in this subparagraph. The requirements made represent the task force's thoughts on this subject. These would be difficult to enforce rigorously but are far better than saying "routinely" as in the current SSRCC. The requirement for a control which would permit the operator to be 12 feet from the tube head assembly was made to permit the operator to be outside a room during an exposure.
 - (4) **Accuracy.** A paragraph was placed in the concepts section regarding timer accuracy.
 - (5) **Reproducibility.** The criteria stated allow a coefficient of variation of around 10

percent.

(c) ~~Source-to-Skin or Receptor Distance~~

(1) ~~Limitation.~~ The requirement here of a 12-inch source-to-skin distance spacing is made for all units where previously it was stated only for mobile x-ray equipment. There is no equivalent Federal requirement.

(d) ~~Exposure Reproducibility.~~ This requirement is applicable to all units. The formula stated will allow a fairly rapid determination of whether an x-ray system could meet the required reproducibility. It was recognized that at times the monitoring instrument may not accurately record the true exposure. Where a system does not meet the stated criteria for compliance a more complete determination of the coefficient of variation is going to be necessary. This requirement is also related to the power supply capabilities. Although discussed at length, no power supply requirements were stated in the task force's draft.

(e) ~~Standby Radiation from Capacitor Energy Storage Equipment.~~ The language utilized here can be found in 1020.31(k). The Federal statement regarding compliance was not incorporated in this requirement.

(f) ~~Additional Requirements Applicable to Certified Systems Only.~~ Requirements stated in 1020.30, .31, and .32 which are not requirements applicable to all x-ray systems are stated in this paragraph as requirements for certified components or certified systems except as otherwise noted in this rationale.

~~Special Note:~~

The task force discussed at length whether all x-ray units should meet one standard at a future date (1984 was proposed). Good arguments were presented on both sides of the question. The provision was not included in the final draft.

~~Sec. F.7 Intraoral Dental Radiographic Systems.~~ This section is intended to cover x-ray equipment designed and used for intraoral dental radiography. All dental x-ray systems used for extraoral examinations should be required to meet the provisions for radiographic systems in Section F.6.

(a) ~~Source-to-Skin Distance.~~ These source-to-skin distances are approximately the same as in the SSRCR Subparagraph F.7(a)(3).

(b) ~~Field Limitation~~

(1) Even though the beam shall be containable within a circle of 7 cm diameter or 6 cm diameter, it may be rectangular or other acceptable geometric configuration.

(2) Any state implementing this concept of open-ended shielded position indicating

device (See F.2 Definitions (au)) as a requirement, should allow an adequate time span for compliance with the requirement.

- (c) ~~Timers.~~ The words in the introductory sentence of paragraph (c) and in subparagraphs (1) and (2) are identical to the Federal standard. In subparagraph (4), the presumptive test on reproducibility of the timer is the same requirement as stated for radiographic systems in Section F.6.
- (d) ~~X-Ray Control (Exposure Switch)~~
 - (1) This is similar to the general requirement in Section F.6, except for deletion of the provision relating to serial radiography (Subdivision F.6(b)(2)(i)).
 - (2) This is similar to the switch placement requirements in Section F.6, although more latitude is intended in implementation of this requirement as indicated by the example and deletion of the reference to Appendix B (see rationale for Subparagraph F.6(b)(2)).
 - (3) This subparagraph is identical to the provision in Subdivision F.6(b)(2)(ii)(c).
- (e) ~~Exposure Reproducibility.~~ This is identical to the requirement in Section F.6 (see rationale for Paragraph F.6(d)).
- (f) ~~Operating Controls~~
 - (1) Film holding devices should be available and used when possible rather than the patient holding the film. This subparagraph is also intended to cover the provision in SSR CR Subdivision F.7(c)(1)(i) regarding the dentist, assistant, etc., holding the film or patient. The requirement to list individual projections where holding devices cannot be utilized should be of benefit in both the compliance and educational aspects of the radiation control program.
 - (2) This subparagraph is similar to the provision in SSR CR Subparagraph F.7(c)(4).
 - (3) This is a further delineation of the beam restriction requirements in Subparagraph F.7(b)(1).
 - (4) This subparagraph relates to the SSR CR Subparagraph F.7(c)(5); however, the SSR CR prohibits the use of fluoroscopy in dental examinations, whereas this draft prohibits dental fluoroscopy without image intensification.
- (g) ~~Additional Requirements Applicable to Certified Systems Only.~~ These are provisions of the Federal standard applicable to certified radiographic systems, including dental, that have not been stated as requirements applicable to all dental x-ray systems earlier in this Section F.7. These provisions are identical to those in Paragraph F.6(g).