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TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.06

Rule Title Medical Diagnostic and Interventional X-Ray and Imaging Systems

XX New XX Amend XX Repeal XX Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? No

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of Certifying Officer P. J. [Signature] Date 10/14/20

REC'D & FILED

OCT 20 2021

LEGISLATIVE SVC AGENCY

**STATE BOARD OF HEALTH**  
**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama Department of Public Health

**RULE NUMBER AND TITLE:** 420-3-26-.06, Medical Diagnostic and Interventional X-Ray and Imaging Systems

**INTENDED ACTION:** To repeal and replace the current rule.

**SUBSTANCE OF PROPOSED ACTION:** This replacement will allow the Department to update the rules to current national standards.

**TIME, PLACE, AND MANNER OF PRESENTING VIEWS:** A public hearing will be held on November 17, 2021, at 2:00 p.m., at the Alabama Department of Public Health Administrative Annex, Training Room B, 208 Legends Court, Prattville, AL 36066.

**FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE:** Written or oral comments will be received until the close of the record at 5:00 p.m. on Friday, December 3, 2021. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

**CONTACT PERSON AT AGENCY:** David Turberville, Office of Radiation Control, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 290-6244.



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P. Brian Hale, Agency Secretary

## **420-3-26-.06 Medical Diagnostic and Interventional X-Ray and Imaging Systems**

(1) **Purpose and Scope.** This rule establishes requirements for which a registrant 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 rule are in addition to, and not in substitution for, other applicable provisions of Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.05, and 420-3-26-.10.

(2) **Definitions.**

(a) As used in this rule, the following definitions apply:

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

2. “Air kerma” means kerma in air.

3. “Air kerma rate (AKR)” means the air kerma per unit time.

4. “Alert value” means a dose index (e.g., of CTDI<sub>vol</sub> (mGy) or DLP (mGy-cm)) that is set by the registrant to trigger an alert to the computed tomography operator prior to scanning within an ongoing examination. The alert value represents a universal dose index value well above the registrant established range for the examination that warrants more stringent review and consideration before proceeding.

5. “Aluminum equivalent” means the thickness of type 1100 aluminum alloy<sup>1</sup> affording the same attenuation, under specified conditions, as the material in question.

6. “Articulated joint” means a joint between two separate sections of a tabletop which the joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.

7. “Attenuation block” means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeter (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

8. “Authorized medical physicist (AMP)” means an individual who:

(i) Is certified by the American Board of Radiology in:

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<sup>1</sup> The nominal chemical composition of type 1100 aluminum is 99.00 percent minimum aluminum, 0.12 percent copper.

- (I) Therapeutic radiological physics; or
- (II) Roentgen-ray and gamma-ray physics; or
- (III) X-ray and radium physics; or
- (IV) Radiological physics; or
- (ii) Is certified by the American Board of Medical Physics in Radiation Oncology Physics; or
- (iii) Is certified by the Canadian College of Medical Physics; or
- (iv) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering or applied mathematics from an accredited college or university, and has completed 1 year of full-time work training in medical physics and an additional year of full-time work experience under the supervision of an Authorized Medical Physicist; or
- (v) Has performed radiation physics work for a period of at least 10 years full-time, prior to the effective date of these rules, in the field of therapeutic radiological physics in radiotherapy facilities where the individual's duties involved calibration and spot checks of a medical use accelerator or a sealed source teletherapy unit.

9. "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.

10. "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.

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

12. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

13. "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.

14. "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.

15. “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.

16. “Cantilevered tabletop” means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

17. “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.

18. “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:

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

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.

19. “Computed radiography (CR; also see DR)” means a digital x-ray imaging method in which a photostimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. CR systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

20. “Computed tomography (CT)” means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

21. “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.

$T$  = 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.

22. “ $CTDI_{100}$ ” means the accumulated multiple scan dose at the center of a 100 millimeter (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  $\pm 50$  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:

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

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.

$T$  = 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.

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

24. “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.

25. “Cradle” means:

- (i) A removable device which supports and may restrain a patient above an x-ray table; or

(ii) 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.

26. "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 420-3-26-.06(8)(a)6.

27. "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.

28. "CT number (CTN)" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image:

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

where:

k = A constant, a normal value of 1,000 when the Hounsfield scale of CT number is used;

$\mu_x$  = Linear attenuation coefficient of the material of interest;

$\mu_w$  = Linear attenuation coefficient of water.

29. "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.

30. "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.

31. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

32. “Diagnostic tube housing” means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of 1 meter in any direction from the target cannot exceed 100 milliroentgens in 1 hour when the tube is operated at any of its specified ratings.

33. “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.

34. “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.

35. “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.

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

37. “Direct supervision” means a licensed 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 qualified practitioner must be present in the room when the procedure is being performed.

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

39. “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-cm<sup>2</sup>, so it does not change with distance from the x-ray tube.

40. “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:

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

41. “Dose profile” means the dose as a function of position along a line.

42. “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).

43. “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.

44. “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.

45. “Filter” means material placed in the useful beam to preferentially absorb selected radiations.

46. “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.

47. “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.

48. “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.

49. “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.

50. “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.

51. “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.

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

53. "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.

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

55. "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.

56. "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e.,  $kVp \times mA \times \text{second}$ .

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

58. "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.

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

60. "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.

61. "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."

62. "kV" means kilovolts.

63. "kW" means kilowatt second.

64. "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.

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

66. “Leakage radiation” means radiation emanating from the diagnostic source assembly except for:

- (i) The useful beam; and
- (ii) Radiation produced when the exposure switch or timer is not activated.

67. “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:

- (i) 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;
- (ii) 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
- (iii) 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.

68. “Licensed practitioner” means a person licensed to practice medicine, chiropractic medicine, podiatry or dentistry in this state with education and specialist training in the medical or dental use of radiation who is deemed competent to independently perform or supervise radiologic imaging or radiation therapy procedures by their respective state licensure boards.

69. “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.

70. “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:

$V_n$  = No-load line potential.

$V_l$  = Load line potential.

71. “mA” means milliamperere.
72. “mAs” means milliamperere second.
73. “Medical event” means one or more of the following criteria have occurred:
  - (i) Unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rad);
  - (ii) 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;
  - (iii) 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  $\geq$  0.05 Sv (5 rem).
74. “Mobile x-ray equipment” means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
75. “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, 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.
76. “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.

77. “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:

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

where:

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

$u_w$  = 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.

78. “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.

79. “Notification value” means a protocol-specific dose index (e.g. CTDI<sub>vol</sub>(mGy) or of DLP (mGy-cm)) that is set by the registrant to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

80. “Patient” means an individual or animal subjected to healing arts examination, diagnosis or treatment.

81. “Picture element” means an elemental area of a tomogram.

82. “Peak tube potential (aka kilovolt peak (kVp))” means the maximum value of the potential difference across the x-ray tube during an exposure.

83. “Personal supervision” means a licensed practitioner must exercise general supervision and be present in the room or adjacent control area during the performance of the procedure.

84. “Personnel monitoring equipment” means devices designed to be worn or carried by an individual for the purpose of measuring the dose received.

85. “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.

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

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

88. "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

89. "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.

90. "Positive beam limitation (PBL)" 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.

91. "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.

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

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

94. "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.

95. "Quality assurance (QA)" 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.

96. "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.

97. "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.

98. "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.

99. "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.

100. "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.

101. "Recording" means producing a retrievable form of an image resulting from x-ray photons.

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

103. "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.

104. "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.

105. "Scan sequence" means a pre-selected set of two or more scans performed consecutively under preselected CT conditions of operation.

106. "Scan time" means the time elapsed during the accumulation of x-ray transmission data for a single scan.

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

108. "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation to the required degree.

109. "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.

110. "Services" means the installation, calibrating, repairing, maintaining or performing a radiation protection survey of an x-ray producing machine or associated x-ray component.

111. "Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

112. “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.

113. “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.

114. “Source” means the focal spot of the x-ray tube.

115. “Source-image receptor distance (SID)” means the distance from the source to the center of the input surface of the image receptor.

116. “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.

117. “Spot-film”<sup>1</sup> means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

118. “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.

119. “Stationary x-ray equipment” means x-ray equipment which is installed in a fixed location.

120. “Stray radiation” means the sum of leakage and scattered radiation.

121. “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.

122. “Technique factors” means the following conditions of operation:

(i) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

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<sup>1</sup> Digital image receptors used in place of film with spot-film devices should be considered “spot-film”.



(iii) 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;

(iv) 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

(v) 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.

123. "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

124. "Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

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

126. "Tube" means an x-ray tube, unless otherwise specified.

127. "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.

128. "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.

129. "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.

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

131. "Volume computed tomography dose index (CTDIvol)" means a radiation dose parameter derived from the CTDIw (weighted or average CTDI given across the field of view). The formula is:

$$CTDI_{vol} = (N)(T)(CTDI_w)/I$$

where:

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

T = thickness of one axial scan (mm)

I = table increment per axial scan (mm).

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

132. “Weighted computed tomography dose index ( $CTDI_w$ )” means the estimated average  $CTDI_{100}$  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  $CTDI_{100}$  and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

133. “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.

134. “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.

135. “X-ray equipment” means an x-ray system, subsystem, or component thereof.

136. “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.

137. “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.

138. “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.

139. “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.

140. "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

**(3) General and Administrative Requirements.**

(a) Radiation Safety Requirements. The registrant 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 rules are met in the operation of the x-ray system(s).

1. The registrant shall have a radiation safety program. The radiation safety program shall include, but not be limited to, the following:

(i) The use of ionizing radiation within its purview is performed in accordance with Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.05, 420-3-26-.06, and 420-3-26-.10.

(ii) All persons are protected as required by 420-3-26-.03, Standards for Protection Against Radiation.

(iii) Upon discovery of a medical event, the registrant 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 an AMP 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 a record of the medical event as part of the patient's permanent medical record.

2. An x-ray system which does not meet the provisions of these rules shall not be operated for diagnostic purposes unless the Agency or an AMP 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.

3. The AMP, if required in this rule, 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.

4. All x-ray equipment shall be installed and used in accordance with the equipment manufacturer's specifications.

5. The registrant shall assure that all x-ray equipment under his/her control is operated only by individuals adequately instructed in safe operating procedures and competent in the safe use of the equipment.

6. 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.

7. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.

8. Each registrant 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.

9. Nationally recognized DRLs shall be utilized when applicable.

10. The registrant shall use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.

11. 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.

12. 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.

13. The useful x-ray beam shall be limited to the area of clinical interest.

14. Consideration shall be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.

15. 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.

16. 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:

- (i) Patient's (adult and pediatric, if appropriate) body part and anatomical size;
- (ii) Technique factors;

- (iii) Type of image receptor used;
- (iv) Source to image receptor distance used (except for dental intraoral radiography); and
- (v) Type of grid, if any.

17. The registrant 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.

18. The registrant 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:

(i) 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 mm lead equivalent material;

(ii) All persons shall be protected from the secondary radiation by protective garments or whole body protective barriers of not less than 0.25 mm lead equivalent material;

(iii) 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 mm lead equivalent material or shall be positioned so that the 0.02 mSv (2 mR) in any 1 hour limit is met.

19. 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:

(i) Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

(ii) Exposure of an individual for the purpose of healing arts screening except as authorized by the Agency.

20. 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:

(i) Written safety procedures, as required by 420-3-26-.06(3)(a)17, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(ii) The human holder shall be instructed in personal radiation safety and protected as required by 420-3-26-.06(3)(a)18(i)(ii) and (iii);

(iii) No individual shall be used routinely to hold the image receptor or patient during a radiation exposure;

(iv) 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 mm lead equivalent material.

21. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 420-3-26-.03 of these rules.

22. Healing Arts Screening. Any person not exempt under Rule 420-3-26-.06(9)(f) 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 rule. 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.

23. Maintenance of Records. The registrant 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:

(i) 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.

(ii) Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the x-ray system(s); and

(iii) A copy of all correspondence with the Agency regarding the x-ray system.

24. 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.

1. The registrant shall establish and maintain a QA program. In addition to the standards in the modality specific sections, the registrant shall:

- (i) Maintain documentation of minimum qualifications for practitioners, medical physicists, and x-ray equipment operators;
  - (ii) Designate an appropriately trained individual to manage the QA program;
  - (iii) Establish and maintain written QA and quality control (QC) procedures, including evaluation frequencies and tolerances;
  - (iv) Check each study for artifacts. If an artifact is present, the source shall be identified and appropriate action taken;
  - (v) Perform repeat / reject analysis of radiographic images at least quarterly following specifications of a nationally recognized organization;
  - (vi) Complete preventative maintenance on the x-ray systems in accordance with manufacturer specifications at intervals not to exceed 12 months;
  - (vii) Maintain documentation showing the testing instruments used in determining compliance with the provisions of this section are properly calibrated and maintained in accordance with accepted professional standards;
  - (viii) Complete and document an annual review of the QA program; and
  - (ix) Retain QA/QC records of evaluations and reviews for a period of not less than 5 years.
2. X-Ray Film Processing Facilities. A registrant 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:

- (i) Manually developed film:
  - (I) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
  - (II) Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.
  - (III) 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			

(IV) Devices shall be utilized which will indicate the actual temperature of the developer solution and signal the passage of a preset time.

(ii) Automatic processors and other closed processing systems:

(I) Automatic processors shall be operated and maintained following manufacturer specifications.

(II) 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 <sup>a/</sup>
°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
<sup>a/</sup> Immersion time only, no crossover time included.		

(III) Processing deviations from the requirements of 420-3-26-.06(3)(b)2 shall be documented by the registrant 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.

(I) 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.

(II) 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.

(III) 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.

(IV) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary.

(V) Outdated x-ray film shall not be used for diagnostic radiographs.

(VI) The film and intensifying screen shall be spectrally compatible.

(VII) Facilities shall maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every 6 months and after a change that may impact film fog.

(VIII) Facilities other than dental, podiatry and veterinary shall:

I. Have a continuous and documented sensitometric QC program, including QC tests for speed, contrast, and fog. These tests shall be performed according to specifications of the manufacturer, an AMP, or a nationally recognized organization.

II. 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.

III. 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).

(I) 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.

(II) Facilities shall establish and follow an image QC program in accordance with the recommendations of an AMP, the system manufacturer, or a nationally recognized organization.

(III) Facilities other than dental, podiatric, and veterinary, shall quarterly complete phantom image evaluation using a phantom approved by an AMP, system manufacturer, or the Agency. The analysis at a minimum shall include: artifacts, spatial resolution, contrast/noise, workstation monitors, and exposure indicator constancy.

(IV) In addition to 420-3-26-.06(3)(b)2(iv)(I) through (III), CR facilities shall perform erasure of all CR cassettes, at least on a weekly basis.

(c) Exemptions.

1. Dental facilities performing only intra-oral, panoramic, cephalometric, or volumetric dental imaging are exempt from 420-3-26-.06(3)(a)8 (information available to referring physician) and 420-3-26-.06(3)(b)1(v) (repeat analysis).

2. Podiatry facilities are exempt from 420-3-26-.06(3)(a)8 (information available to referring physician) and 420-3-26-.06(3)(b)1(v) (repeat analysis).

3. Veterinary facilities are exempt from 420-3-26-.06(3)(a)8 (information available to referring physician), 420-3-26-.06(3)(a)9 (use of reference levels), 420-3-26-.06(3)(a)12 (use of dose reduction techniques), 420-3-26-.06(3)(a)15 (patient identification), 420-3-26-.06(3)(a)13 (protocol control), 420-3-26-.06(3)(a)18 (routine holding of patient), 420-3-26-.06(3)(a)20 (healing arts screening), 420-3-26-.06(3)(b)1(v) (repeat analysis), and 420-3-26-.06(3)(b)2(i) through (iii) (use of sensitometric equipment).

**(4) General Requirements for All Diagnostic and Interventional X-Ray Systems.**

In addition to other requirements of this rule, 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 420-3-26-.06(7).

**(a) Warning Label.**

1. 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 420-3-26-.06(4)(a)2, 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."

2. 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 mGy air kerma (vice 100 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 cm with no linear dimension greater than 20 cm.

(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 cm 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 cm with no linear dimension greater than 20 cm.

(d) Technique Indicators.

1. 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 AECs are used, the technique factors which are set prior to the exposure shall be indicated.

2. The requirement of 420-3-26-.06(4)(d)1 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.

3. The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within  $\pm 10$  percent.

(e) Beam Quality.

1. 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.

TABLE 1

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.				

2. 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 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 section. 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.

3. 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 (mm)
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.**

1. 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 rule.

2. 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 rule. The owner who causes such modification need not submit the reports required by this rule, 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 rule.

(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.

**(5) Fluoroscopic Equipment.**

The provisions of this rule apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor.

(a) Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

**(b) Primary Protective Barrier.**

1. **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  $3.34 \times 10^{-3}$  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.

2. **Measuring compliance.** The AKR shall be measured in accordance with 420-3-26-.06(5)(e). 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.

**(c) Field Limitation.**

1. **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 420-3-26-.06(5)3(v) and (vi) shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of 420-3-26-.06(5)3(v) and (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 cm<sup>2</sup>, 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 cm<sup>2</sup> 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 cm<sup>2</sup> 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.

3. Spot-film devices. In addition to applicable regulations in 420-3-26-.06(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:

(i) 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.

(ii) 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.

(iii) 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.

(iv) 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:

(I) 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.



(II) 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.

4. 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”

5. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

(i) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(I) 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.

(II) 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.

(ii) 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:

(I) 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.

(II) 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.

6. 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:

(i) 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.

(ii) 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.

7. **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”**

(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.

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

1. Fluoroscopic equipment manufactured before May 19, 1995.

(i) 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 420-3-26-.06(5)(e)4 except as specified in 420-3-26-.06(5)(e)1(v).

(ii) 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 420-3-26-.06(5)(e)4 except as specified in 420-3-26-.06(5)(e)1(v).

(iii) 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 420-3-26-.06(5)(e)4 except as specified in 420-3-26-.06(5)(e)1(v).

(iv) Equipment may be modified in accordance with this Rule to comply with 420-3-26-.06(5)(e)2. 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)”

(v) Exceptions:

(I) During recording of fluoroscopic images, or

(II) When a mode of operation has an optional high-level control, that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in 420-3-26-.06(5)(e)1(i), (ii) or (iii) at the measurement point specified in 420-3-26-.06(5)(e)4, unless the high-level control is activated. 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.

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

(i) 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 420-3-26-.06(5)(e)4. Provision for manual selection of technique factors may be provided.

(ii) 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 420-3-26-.06(5)(e)4, except as specified in 420-3-26-.06(5)(e)2(iii).

(iii) Exceptions:

(I) 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.

(II) 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.

3. Fluoroscopy equipment with optional high-level control.

(i) 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 420-3-26-.06(5)(e)4. 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.

4. Measuring compliance. Compliance with this section shall be determined as follows:

(i) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.

(ii) 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.

(iii) 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.

(iv) In a C-arm type of fluoroscope having a SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(v) In a lateral type of fluoroscope, the AKR 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.

5. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in 420-3-26-.06(5)(e) when used for therapy simulation purposes.

(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.

(g) Source-skin distance.

1. Means shall be provided to limit the SSD 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 SSDs specified in this paragraph, provisions may be made for operating at shorter source skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum SID of less than 45 cm, means shall be provided to limit the SSD to

not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical or interventional applications that would be prohibited at the SSD 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.

1. Fluoroscopic equipment manufactured before June 10, 2006:

(i) 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)”

(ii) 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.

2. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

(i) 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 section. The following requirements apply:

(I) 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.

(II) The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.

(III) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(ii) 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.

(i) Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display a LIH image following termination of the fluoroscopic exposure.

1. For a LIH image obtained by retaining pre-termination 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.

2. For a 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.

3. 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.

(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:

1. 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.

2. 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.

3. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

4. 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.

(i) 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 420-3-26 .06(5)(e)1, 2, and 5.

(ii) 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.

5. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than  $\pm 35$  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.

(k) Protection From Scatter Radiation.

1. 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.

2. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.

(i) Shielding required under 420-3-26-.06(5)(k)1 shall be maintained to the degree possible under the clinical conditions.

(ii) 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.

(iii) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest).

(iv) 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.

1. In addition to the applicable sections of these rules, the operation of a fluoroscopic x-ray system for clinical purposes shall be limited to:

(i) A licensed practitioner working within his or her scope of practice; or

(ii) 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 420-3-26-.06(5)(l)1(i); or

(iii) A medical resident or radiologic technology student, in training, and only under the personal supervision of the licensed practitioner meeting the conditions of 420-3-26-.06(5)(l)1(i).

2. The operator of the fluoroscopic unit shall meet the minimum operator requirements of these rules and be specifically trained on the operational features of the unit by the manufacturer's application specialist, AMP, or someone deemed qualified by the Agency.

3. Documentation pertaining to the requirements of 420-3-26-.06(5) shall be maintained for review for 3 years.

(m) Equipment Operation.

1. All fluoroscopic images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

3. 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.

4. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.

5. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

6. The registrant shall use all methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.

7. 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) Authorized Medical Physicist Evaluations.

1. Fluoroscopic equipment shall be evaluated by an AMP within 30 days of installation and of any maintenance of the system that may affect the exposure rate. Thereafter, the measurements shall be made at intervals not to exceed 12 months from the date of the prior measurement by or under the direction of an AMP. At a minimum these evaluations shall include:



(i) 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:

(I) For systems without AEC, be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

(II) For systems with AEC, 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;

(ii) A measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with 420-3-26-.06(5)(o).

(iii) An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes.

(iv) An evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors.

(v) An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes.

(vi) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(vii) An evaluation of any changes that may impact patient and personnel protection devices.

2. Measurements required in 420-3-26-.06(5)(n)1 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 FGI procedures.

1. A registrant utilizing FGI procedures shall establish a RPC in accordance with the following:

(i) The registrant may establish a system-wide committee if the registrant has more than one site.

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

(iii) If the registrant has already established a radiation safety committee, the requirements of this section may be delegated to that committee if the members meet the requirements of 420-3-26-.06(5)(o)5.

2. A quorum of the RPC shall meet as often as necessary, but at intervals not to exceed 12 months.

3. 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 shall maintain the record for inspection by the Agency.

4. Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,

5. RPC Members. Members shall include but not be limited to the following individuals:

(i) A supervising physician of the healing arts who meets the requirements in 420-3-26-.06(5)(l);

(ii) An AMP;

(iii) The lead technologist; and

(iv) Other individuals as deemed necessary by the registrant.

6. Establish and implement FGI procedure protocols.

(i) 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:

(I) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes;

(II) A method to be used to monitor patient radiation dose during FGI;

(III) Dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety;

(IV) Substantial radiation dose levels (SRDL) values following nationally recognized standards;

(V) Actions to be taken for cases when a SRDL is exceeded which may include patient follow-up; and

(VI) A review of the established protocols at an interval not to exceed 12 months.

(ii) 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.

7. Procedures for maintaining record.

(i) 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:

(I) Patient identification;

(II) Type and date of examination;

(III) Identification of the fluoroscopic system used; and

(IV) Peak skin dose, cumulative air kerma, or DAP used if the information is available on the fluoroscopic system.

(V) If the peak skin dose, cumulative air kerma, or DAP 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.

(ii) The registrant shall maintain records required by this subparagraph for inspection by the Agency.

(6) **Radiographic Equipment.** The following regulations apply to all non-dental registrants using diagnostic x-ray equipment. Requirements specific to using dental intra-oral, hand held, panoramic, and cephalometric equipment are in 420-3-26-.06(7).

(a) Digital radiographic systems shall be evaluated by an AMP within 30 days of clinical use and by or under the direction of an AMP 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 rule, dental, podiatric, and veterinary systems are exempt from this requirement.

(b) Control and indication of technique factors.

1. 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.

(i) 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.

(ii) 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.

2. Automatic exposure controls. When an AEC is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) 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 milliamperes-seconds (mAs), whichever is greater;

(iii) 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

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in 420-3-26-.06(6)(b)2(iii), and manual resetting shall be required before further automatically timed exposures can be made.

3. Accuracy. Deviation of technique factors under 420-3-26-.06(6)(b) from indicated values shall not exceed the limits given by the manufacturer.

(c) Reproducibility.

1. 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.

2. **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  $\pm 1$  of the mean value for all measurements. For equipment having AECs, 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.

(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.

1. 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.

2. 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.

3. **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  $\pm 1$  of the mean value for all measurements at these technique factors.

(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:

1. **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 a SID of 100 cm shall be equal to or less than 5 cm.

2. Visual definition.

(i) 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.

(ii) 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.

(iii) 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.

(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 420-3-26-.06(6)(e):

1. 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;

2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in cm 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

4. 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.

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

1. 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 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.

2. Other x-ray systems. Radiographic systems not specifically covered in 420-3-26-.06(6)(e), (f), (g)1, (g)2, and systems covered in (g)2(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 align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with 420-3-26-.06(6)(e) and (f); or when alignment means are also provided, may be met with either:

(I) 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

(II) 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.

(h) Positive beam limitation. The requirements of this section shall apply to radiographic systems which contain PBL.

1. Field size. When a PBL system is provided, it shall prevent x-ray production when:

(i) 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

(ii) The sum of the length and width differences stated in 420-3-26-.06(6)(h)1(i) without regard to sign exceeds 4 percent of the SID.

- (iii) The beam-limiting device is at a SID for which PBL is not designed for sizing.

2. Conditions for PBL. When provided, the PBL system shall function as described in 420-3-26-.06(6)(h)1 whenever all the following conditions are met:

- (i) The image receptor is inserted into a permanently mounted cassette holder;
- (ii) The image receptor length and width are less than 50 cm;
- (iii) The x-ray beam axis is within  $\pm 3$  degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within  $\pm 3$  degrees of horizontal and the SID is 90 cm to 205 cm inclusive;
- (iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within  $\pm 3$  degrees; and
- (v) Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance. Compliance with the requirements of 420-3-26-.06(6)(h)1 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 420-3-26-.06(6)(h)2 are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

4. Operator initiated under sizing. 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 420-3-26-.06(6)(h)1 shall occur automatically upon any change of image receptor size or SID.

5. 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 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.

6. Disabling of PBL. A facility has the option to permanently and functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.



(i) **Source-skin distance.** The minimum SSD shall not be less than 30 cm, except intraoral dental equipment covered under 420-3-26-.06(7)(p)2(i) and veterinary equipment.

(j) **Radiation from capacitor energy storage equipment.** Radiation emitted from the x-ray tube shall not exceed:

1. 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

2. 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.

(k) **Radiation Exposure Control.**

1. **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.

2. **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.

3. **Operator Protection, Except Veterinary Systems.**

(i) **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.

(ii) **Mobile and Portable Systems.** Mobile and portable x-ray systems which are:

(I) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 420-3-26-.06(6)(k)3(i);

(II) Used for less than 1 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.

(iii) Podiatry Systems. Podiatry facilities shall meet the protection requirements in 420-3-26-.06(6)(k)3(ii)(II).

4. 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 420-3-26-.06(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 rule.

**(7) Dental Facilities.**

In addition to the applicable provisions of Rule 420-3-26-.06(3), the requirements of 420-3-26-.06(7) apply to dental facilities using intraoral, panoramic, and cephalometric x-ray equipment. Dental facilities using CBCT technology shall follow applicable provisions of 420-3-26-.06(8)(h).

(a) Quality Assurance. In addition to the general QA provisions in 420-3-26-.06(3), the following requirements apply to a dental facility:

1. If using film, maintain a light-tight darkroom, use proper safe lighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every 6 months and after a change that may impact film fog.

2. If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications.

3. Registrant 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.

1. 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 420-3-26-.06(7)(b)2, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. 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 handheld, the exposure control shall allow the operator to be:

1. Behind a protective barrier at least 2 meters (6.5 feet) tall; or
2. 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.

1. Patient and image receptor holding devices shall be used when the techniques permit.
2. Except for units designed to be hand-held, the tube housing and PID shall not be hand-held during an exposure.
3. Dental fluoroscopy without image intensification shall not be used.

(f) **Hand-Held Intraoral Equipment.** In addition to the standards in this rule, the following applies specifically to hand-held devices:

1. 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.

2. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer and approved by the Agency.

3. The facility shall adopt and follow protocols provided by the manufacturer, and approved by the agency, regarding the safe operation of the device.

4. 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 authorized medical physicist.

5. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

6. The registrant 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.

(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.

(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.

(k) **Locks.** All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

(l) **Technique Indicators.**

1. 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 AECs are used, the technique factors which are set prior to the exposure shall be indicated.

2. The requirement of 420-3-26-.06(7)(l)1 may be met by permanent markings on equipment having fixed technique factors.

(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.

(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.

(o) Kilovolt Peak. Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer. 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.

1. The useful x-ray beam shall be limited to the area of clinical interest.

2. Intraoral Dental Units.

(i) 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.

(ii) The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm.

3. Extraoral, Panoramic and Cephalometric Units

(i) 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 size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(I) 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

(II) 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.

(q) **Beam Quality.** 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 the HVL 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.

Table 1

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.

1. 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 rule.

2. 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 rule. The owner who causes such modification need not submit the reports required by this rule, 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 rule.

(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 mGy air kerma (vice 100 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 cm with no linear dimension greater than 20 cm.

(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 cm 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 cm with no linear dimension greater than 20 cm.

(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.

(8) Computed Tomography Equipment.

(a) Requirements for CT Equipment.

1.     **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.

2.     **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.

3.     **Termination of Exposure.**

(i)     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.

(ii)    A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 420-3-26-.06(8)(a)3(i).

(iii)   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.

4.     **Tomographic Plane Indication and Alignment.**

(i)     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.

(ii)    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.

(iii)   If a mechanism using a light source is used to satisfy the requirements of 420-3-26.06(8)(a)4(i) or (ii), 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.

5.     **Beam-On and Shutter Status Indicators and Control Switches.**

(i)     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.

(ii)    Each emergency button or switch shall be clearly labeled as to its function.

6.     **Indication of CT Conditions of Operation.**



(i) 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.

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

(i) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 mm.

(ii) 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.

(iii) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 mm 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 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(iv) 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.

(b) CT Facility Design Requirements.

1. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing Systems.

(i) 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.

(ii) 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.

**1. Radiation Protection Surveys.**

(i) All CT x-ray systems installed after the effective date of these rules shall have a radiation protection survey completed by, or under the direct supervision of, the AMP within 30 days of installation. Existing systems not previously surveyed shall have a survey made by, or under the direct supervision of, an AMP 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.

(ii) The registrant shall obtain a written report of the survey from the AMP, and a copy of the report shall be made available to the Agency upon request.

**2. System Performance Evaluations.**

(i) The annual testing of the CT x-ray system shall be performed by, or under the personal supervision of, an AMP who assumes the responsibility and signs the final performance evaluation report.

(ii) Evaluation standards and tolerances shall be established by the AMP and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT x-ray system.

(iii) 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 AMP 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 AMP, could cause a change in the radiation output or image quality.

(iv) The evaluation shall include but not be limited to:

(I) Geometric factors and alignment including:

I. Alignment light accuracy;

II. Table increment accuracy.

(II) Image localization from scanned projection radiograph (localization image);

(III) Radiation beam width;

(IV) Image quality including:

- I. High-contrast (spatial) resolution;
- II. Low-contrast resolution;
- III. Image uniformity;
- IV. Noise;
- V. Artifact evaluation.
- (V) CT number accuracy;
- (VI) Image quality for acquisition workstation display devices;
- (VII) A review of the results of the routine QC required under 420-3-26-.06(8)(a)3;
- (VIII) A safety evaluation of audible and visual signals, posting requirements; and
- (IX) Dosimetry.

(v) The measurement of the radiation output of a CT x-ray system shall be performed with 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.

3. Routine Quality Control. A routine QC program on the CT system shall:

- (i) Be developed by an AMP and include acceptable tolerances for points evaluated;
- (ii) Incorporate the use of a water equivalent phantom and at a minimum, noise, CT number, and artifacts shall be evaluated:
- (iii) Be completed at time intervals that shall not exceed 1 week, and under system conditions specified by the AMP; and
- (iv) Be documented and maintained for inspection by the Agency.

4. Operating Procedures.

- (i) The operator of the CT x-ray system shall meet the minimum operator requirements of these rules and be specifically trained on the operational features of the unit by a manufacturer's applications specialist, an AMP, or someone deemed qualified by the Agency.
- (ii) The following information shall be readily available to the CT operator:

(I) 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 AMP for the indicated parameters, and the results of at least the most recent routine QC completed on the system; and

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

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

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

1. Members of the RPC.

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

(I) Lead CT radiologist;

(II) Lead CT technologist;

(III) AMP; and

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

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

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

(iv) If the registrant has already established a radiation safety committee, the requirements of this section may be delegated to that committee if the members meet the requirements of 420-3-26-.06(8)(d)1.

2. Responsibilities of the RPC. The RPC shall:

(i) 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.

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

(iii) 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:

(I) Pediatric Head;

(II) Pediatric Abdomen;

(III) Adult Head;

(IV) Adult Abdomen;

(V) Adult Chest;

(VI) Brain Perfusion.

(iv) Establish and implement written protocols, or protocols documented in an electronic reporting system, that include, but are not limited to, the following:

(I) A method to be used to monitor the CT radiation output.

(II) A standardized protocol naming policy.

(III) A DRL, notification value, and alert value for CT procedures reviewed in 420-3-26-.06(8)(d)2(iii). 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 AMP.

(IV) Actions to be taken for cases when the dose alert value was exceeded which may include patient follow-up.

(V) 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.

(v) If CT fluoroscopy is performed, the RPC shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.

(vi) Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,

(vii) At a minimum, the RPC members in 420-3-26-.06(8)(d)1(i) through (iii) shall meet as often as necessary to conduct business at intervals not to exceed 12 months.

3. Records.

(i) 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.

(ii) The registrant shall maintain a record of RPC policies and procedures.

(iii) The registrant 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:

(I) Patient identification;

(II) Type and date of examination;

(III) Identification of the CT system used; and

(IV) 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 following QA requirements:

1. QA shall include acceptance testing and periodic verification of system performance;  
and

2. Be performed in accordance with “Comprehensive QA for Radiation Oncology; Report of AAPM Radiation Therapy Committee Task Group No. 40: AAPM Report No. 46” for a conventional simulator; or

3. Be performed in accordance with “Quality assurance for computed tomography simulators and the computed-simulated process; Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83” for a virtual simulator.

(f) PET CT and SPECT CT Systems. CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in Rule 420-3-26-.06(8)(a) through (d) unless otherwise exempted below:

1. 420-3-26-.06(8)(a)1 (Accreditation).

2. In lieu of Rule 420-3-26-.06(8)(a)1, an AMP 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.

3. In lieu of Rule 420-3-26-.06(8)(c)3, routine QC checks shall be completed at intervals not to exceed 1 week. These checks shall be established and documented by an AMP following nationally recognized guidelines or those approved by the Agency.

4. 420-3-26-.06(8)(c)4(ii)(II) (RPC).

(g) Veterinary CT Systems. CT systems, including CBCT systems, solely used in non-human imaging shall meet the requirements of 420-3-26-.06(8)(c)1 (radiation protection surveys) and are otherwise exempt from the standards of 420-3-26-.06(8).

(h) Cone Beam Computed Tomography Systems.

1. CBCT facilities shall meet 420-3-26-.06(4), 420-3-26-.06(6)(i) and (k), and 420-3-26-.06(8)(a)2 through (a)7, as applicable.

2. 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.

3. A performance evaluation shall be performed by, or under the direct supervision of, an AMP. 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 AMP, 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.

4. The registrant shall follow the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer provided QC recommendations, the registrant shall implement and document QC guidelines established by an AMP in accordance with nationally recognized guidelines or those recognized by the Agency.

5. The registrant or RPC, if established, shall implement and document a policy addressing deviations from established protocols.

6. The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.

7. The following information shall be readily available to the CBCT operator:

(i) 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 AMP, if required, for the indicated parameters, and the results of at least the most recent routine QC completed on the system.

8. Exemption. An AMP 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.

9. Exemption. The registrant using fluoroscopy systems capable of CBCT shall meet 420-3-26-.06(8)(h), except 420-3-26-.06(8)(a)2 through (8)(a)7 referenced in 420-3-26-.06(8)(h)1.

**(9) Dual-Energy X-Ray Absorptiometry (DXA) (Bone Densitometry).**

(a) DXA systems shall be:

1. 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;

2. Registered in accordance with Rule 420-3-26-.05; and

3. At a minimum, maintained and operated in accordance with the manufacturer's specifications.

(b) Operator Requirements. In addition to the manufacturer's recommended training, operators shall complete training specific to patient positioning and the operation of the DXA system.

(c) During the operation of any DXA system:

1. In the absence of a survey performed by or under the supervision of, an AMP 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.

(d) Quality Assurance. In addition to the applicable requirements in 420-3-26-.06(3)(b)1, a facility performing DXA shall:

1. 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;

(e) Records. The registrant shall keep the following records for a minimum of 3 years:



1. The maintenance and QC tests as prescribed by 420-3-26-.06(9)(a)3 and (d).

(f) Exemptions.

1. Accredited institutions of higher education using DXA systems for bone densitometry for research protocols are exempt from Rule 420-3-26-.06(3)(a)19 provided:

- (i) The research protocols are reviewed and approved by the Institutional Review Board and Radiation Safety Committee of the institution, and a licensed practitioner of the healing arts; and

- (ii) The calculated exposure to each human subject does not exceed 0.1 millisieverts (10 millirem) total effective dose equivalent for the entire research study.

**Authors:** Aubrey V. Godwin, Greg Locklier, James McNees

**Statutory Authority:** §§ 22-14-4, 22-14-7, 22-14-8, Code of Alabama, 1975.

**History:** New 6-15-66; Revised 6-17-68, 3-18-70, Repromulgated 8-21-74, Revised 15-76, 1-18-78; Recodified 6-11-78; Revised 11-21-79; Revised and Repromulgated 10-21-81; Revised and Repromulgated effective 12-31-83. Revised effective 12-31-86. Revised and Repromulgated effective 1-31-90. Revised effective 9-30-90. Amended: Filed 5-20-10; effective 6-24-10. Repeal and Replace: Filed XX-XX-XXXX, effective XX-XX-XXXX.

## **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 an AMP 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.

**Authors:** Aubrey V. Godwin, Greg Locklier, James McNees

**Statutory Authority:** §§ 22-14-4, 22-14-7, 22-14-8, Code of Alabama, 1975.

**History:** New 6-15-66; Revised 6-17-68, 3-18-70, Repromulgated 8-21-74, Revised 15-76, 1-18-78; Recodified 6-11-78; Revised 11-21-79; Revised and Repromulgated 10-21-81; Revised and Repromulgated effective 12-31-83. Revised effective 12-31-86. Revised and Repromulgated effective 1-31-90. Revised effective 9-30-90. Amended: Filed 5-20-10; effective 6-24-10. Repeal and Replace: Filed XX-XX-XXXX, effective XX-XX-XXXX.

**420-3-26-.06**

**RADIATION SAFETY REQUIREMENTS FOR USERS OF  
X-RAY IN HEALING ARTS OR SERVICERS OF X-RAY  
EQUIPMENT**

- (1) **Scope.** Rule 420-3-26-.03 establishes standards for use of x-rays in the healing arts including but not limited to medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine or servicers of x-ray equipment. The provisions of this Rule 420-3-26-.06 are written in addition to, and not in substitution for, other applicable provisions of these regulations. Periodic inspections will be performed of all registrants. The inspection frequency will depend upon available personnel and workload, but every x-ray unit ideally should be inspected not less than once every two years.
- (2) **Definitions.**
  - (a) "Agency" means the State Board of Health.
  - (b) "ARCR" means the Alabama Regulations for Control of Radiation.
  - (c) "Aluminum Equivalent" means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.
  - (d) "Dead Man Switch" means a switch so constructed that a circuit closing contact can only be maintained by continuous pressure by the operator.
  - (e) "Diagnostic Tube Housing" means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of one (1) meter in any direction from the target cannot exceed one hundred (100) milliroentgens in one (1) hour when the tube is operated at any of its specified ratings.
  - (f) "Filter" means material placed in the useful beam to absorb preferentially the less penetrating radiations.
  - (g) "Half-Value Layer (hvl)" means the thickness of absorber required to reduce a beam of radiation to one-half ( $\frac{1}{2}$ ) its incident exposure rate.

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- (h) "High Radiation Area" means any area in which there exists radiation or such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 100 millirems.
- (i) "Inherent Filtration" means the filtration in the useful beam due to the window of the x-ray tube and any permanent tube enclosure.
- (j) "Interlock" means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.
- (k) "Kilovolts Peak (kVp)" means the crest value in kilovolts of the potential of a pulsating potential generator.
- (l) "Lead Equivalent" means the thickness of lead affording the same attenuation under specified conditions as the material in question.
- (m) "Leakage Radiation" means all radiation coming from within the tube housing except the useful beam.
- (n) "Mobile X-Ray Unit" means a unit that is not permanently fixed to a definite location in a building or vehicle.
- (o) "Personnel Monitoring Equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (film badges, pocket dosimeters).
- (p) "Primary Protective Barrier" means a barrier sufficient to attenuate the useful beam to the required degree.
- (q) "Protective Apron" means a barrier of attenuating materials, used to reduce radiation exposure.
- (r) "Protective Barrier" means a barrier of attenuating materials, used to reduce radiation exposure.
- (s) "Protective Glove" means a glove made of attenuating materials used to reduce radiation exposure.
- (t) "Radiation." The word radiation shall mean ionizing radiation, that is any electromagnetic or particulate radiation capable of producing ions directly

- or indirectly in its passage through matter.
- (u) "Radiation Area" means any area in which there exists radiation at such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 5 millirems, or in any five (5) consecutive days a dose in excess of 100 millirems.
  - (v) "Restricted Area" means any area to which access is controlled by the registrant for purposes of protection of individuals from exposure to radiation. "Restricted area" shall not include any areas used for residential quarters, although upon authorization by the Agency a separate room or rooms in a residential building may be set apart as a restricted area.
  - (w) "Scatter Radiation" means secondary radiation or radiation that, during passage through matter has been deviated in direction.
  - (x) "Secondary Protective Barrier" means a barrier sufficient to attenuate stray radiation to the required degree.
  - (y) "Shutter" means a device, generally of lead, fixed to an x-ray housing to intercept the useful beam.
  - (z) "Stray Radiation" means radiation not serving any useful purpose. It includes leakage and scattered radiation.
  - (aa) "Therapeutic Type Tube Housing" means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of one (1) meter in any direction from the target cannot exceed one (1) roentgen in one (1) hour and at a distance of five (5) centimeters from any point of the surface of the housing accessible to the patient, cannot exceed thirty (30) roentgens in one (1) hour when the tube is operated at any of its specified ratings.
  - (bb) "Useful Beam" means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing.
  - (cc) "Services" means the installation, calibrating, repairing, maintaining or performing a radiation protection survey of an x-ray producing machine or associated x-ray component.
  - (dd) "Healing Arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for non-humans, veterinary medicine.
  - (ee) "Portable" means x-ray equipment designed to be hand-held.

- (ff) "Stationary" means x-ray equipment which is installed in a fixed location.
- (gg) "Gonad shield" means a primary protective barrier for the testes or ovaries.
- (hh) "Image receptor" means any device, such as a fluorescent screen or radiographic film, 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 electronic or chemical transformations.

**(3) General Safety Provisions.**

- (a) The Agency may waive compliance with the specific requirements of this Rule 420-3-26-.06 by an existing machine or installation if (1) such compliance would require replacement or substantial modification of the machine or installation and (2) the registrant demonstrates, to the Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules.
- (b) Persons shall not be exposed to the useful beam except for healing arts purposes, each exposure of which shall be authorized by:
  - 1. A licensed practitioner of the healing arts; or
  - 2. A licensed physician's assistant, a certified registered nurse practitioner, or a certified nurse midwife subject to the rules of his/her licensure board.
- (c) A written order for each exposure shall be prepared by the licensed practitioner of the healing arts, certified registered nurse practitioner or certified nurse midwife and provided to the individual administering the radiation. This order shall, at a minimum, include the following information:
  - 1. Patient's name;
  - 2. Date of birth;
  - 3. Examination(s) requested;
  - 4. Related diagnosis;

5. Name of the individual ordering the exposure; and

6. Date of the order.

(d) These rules specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other purposes unless (a) there are also healing arts requirements and proper prescription has been provided, (b) the radiographs are made for the student's own training, (c) the radiographs are made only once with no more than two retakes and if only a small tissue volume (e.g. less than a skull) is exposed per radiograph, and (d) the images are properly interpreted and are made a part of the dental or medical record.
2. Exposure of an individual for the purpose of healing arts screening without prior written approval of the Agency. (Screening means an exposure of a person without prior examination or a determination of a specific individual need by a licensed practitioner).

(e) **Personnel Monitoring.** Each registrant shall provide personnel monitoring devices which shall be used by:

1. Each individual who receives, or is likely to receive, whole body dose in excess of 25 milliroentgens per week;
2. Each individual who enters a high radiation area;
3. Each individual who operates mobile x-ray equipment;
4. Each individual who operates fluoroscopic equipment;
5. Each individual while he services an operable x-ray producing machine.

(f) **Use.**

1. The registrant shall be responsible for assuring that all requirements of Rule 420-3-26-.03 are met.



2. The registrant shall assure that all x-ray equipment under his control is operated only by individuals adequately instructed in safe operating procedures and competent in safe use of the equipment.
3. After October 1, 1974, no registrant who services x-ray producing equipment shall permit any person to service such equipment, when operable, until such person has been appropriately instructed in the subjects outlined in Appendix A of Rule 420-3-26-.05 of these rules and shall have demonstrated an understanding thereof.
4. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.
5. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

**(g) Shielding.**

1. Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with 420-3-26-.03(2), 420-3-26-.03(5), and 420-3-26-.03(6). This requirement shall be deemed to be met if the thickness of such barriers is equivalent to those as computed in accordance with National Council on Radiation Protection and Measurements Report No. 49.<sup>1</sup>

**(h) Darkroom Requirements.** To reduce unnecessary re-exposures of patients resulting from film processing problems:

1. The darkroom shall be light-proof.
2. The area in which undeveloped films are handled for processing shall be devoid of light, during handling and processing, with the exception of light in the wave lengths having no specific effects on the radiographic film.

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<sup>1</sup> Available from NCRP Publications, 7910 Woodmont Avenue, Suite 1016 Bethesda, Md. 20814

3. A thermometer and timer operable and appropriate to the type of film processing shall be in use in the darkroom. The use of properly maintained automatic film processing equipment shall meet this requirement for all film so processed.

**(4) Fluoroscopic Installations.**

**(a) Equipment.**

1. The tube housing shall be of diagnostic type.
2. The target-to-panel or target-to-table top distance of equipment installed before the effective date of these rules shall not be less than twelve (12) inches, and shall not be less than fifteen (15) inches in equipment installed thereafter.
3. The total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 millimeters aluminum at normal operating voltages.
4. The equipment shall be so constructed that the entire cross section of

the useful beam is attenuated by a primary barrier. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.

- (i) For equipment installed before the effective date of the rules,<sup>2</sup> the required lead equivalent of the barrier shall not be less than 1.5 millimeters for 100 kVp, shall not be less than 1.8 millimeters for 125 kVp or shall not be less than 2.0 millimeters for 150 kVp.

For equipment installed or re-installed after the effective date of these rules, the required lead equivalent of the barrier shall not be less than 2.0 millimeters for 125 kVp, or shall not be less than 2.7 millimeters for 150 kVp.

For conventional fluoroscopes the requirements of

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<sup>2</sup> June 15, 1966

paragraph (i) may be assumed to have been met if the exposure rate measured at the viewing surface of the fluorescent screen does not exceed fifty (50) milliroentgens per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.

- (ii) Collimators shall be provided to restrict the size of the useful beam to less than the area of the barrier. For conventional fluoroscopes this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left on the fluorescent screen with the screen centered in the beam at a distance of fourteen (14) inches from the panel or table top. The margin requirement does not apply to installations where image intensifiers are used, but a protective shield shall be provided in these installations so that the useful beam does not produce a radiation hazard; however, the useful beam may not exceed the viewing area by more than 2% of the source to image receptor distance for any dimension.
  - (iii) The tube mounting and the barrier shall be so linked together that under conditions of fluoroscopic use, the barrier always intercepts the useful beam.
  - (iv) Collimators and adjustable diaphragms or shutters to restrict the size of the useful beam to the area of clinical interest and shall provide a minimum of 2.0 millimeters lead-equivalent protection for 100 kVp, 2.4 millimeters for 125 kVp, or 2.7 millimeters for 150 kVp.
- 5. The exposure switch shall be of the dead-man type.
  - 6. A manual-reset, cumulative timing device shall be used which will either indicate elapsed time by an audible signal or turn off the apparatus when the total exposure exceeds a predetermined limit in one or a series of exposures. The device shall have a maximum time range of five minutes.
  - 7. For fluoroscopy, the exposure rate measured at the panel or table top shall not exceed ten (10) roentgens per minute. This does not apply during cinegraphic procedures.

8. Unless measurements indicate otherwise, protective aprons of at least a quarter millimeter lead equivalent shall be worn by all persons in the fluoroscopic room except the patient.
  9. Protective gloves of at least a quarter millimeter lead equivalent shall be worn by the fluoroscopist during every examination.
  10. Mobile fluoroscopic equipment shall meet the requirements of this Rule where applicable, except that:
    - (i) In the absence of a table top, a cone or spacer frame shall limit the target-to-skin distance to not less than 20 centimeters.
    - (ii) Image intensification shall always be provided. Conventional fluoroscopic screens shall not be used.
    - (iii) It shall be impossible to operate a machine when the collimating cone or diaphragm is not in place.
    - (iv) The exposure rate measured at the 30 cm from image receptor shall not exceed ten (10) roentgens per minute.
  - (b) **Structural Shielding.** Ordinarily, only secondary barriers are necessary except for combined fluoroscopic-radiographic installations.
- (5) **Radiographic Installations Other than Dental and Veterinary Medicine.**
- (a) **Equipment.**
    1. The tube housing shall be of a diagnostic type.
    2.
      - (i) Diaphragms or cones shall be provided for collimating the useful beam. When round collimators are used, the diameter of the beam at the film location shall be no greater than the diagonal dimension of the film plus three percent of the source to image receptor distance. For rectangular collimators, the beam size shall be no greater than the film dimension plus three percent of the source to

image receptor distance. The diaphragms or cones shall provide the same degree of protection as the tube housing.

- (ii) Adjustable collimators installed after the effective date of this rule<sup>3</sup> shall incorporate light beams to define the projected dimensions of the useful beam.

- 3. (i) Except when contraindicated for a particular purpose, for equipment operation at seventy (70) kVp, and below, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 1.5 mm aluminum at normal operating voltages.

- (ii) Except when contraindicated for a particular medical purpose, for equipment capable of operating above seventy (70) kVp the total filtration permanently in the useful beam shall be equivalent to at least 2.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 mm aluminum at normal operating voltages.

- 4. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. 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.

- 5. A dead-man type of exposure switch shall be so arranged that it cannot be conveniently operated out of a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic tables are exempted from this shielding requirement.

(b) **Structural Shielding.**

- 1. All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four (84) inches above the floor of the area being shielded.

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<sup>3</sup> March 18, 1970

2. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier's requirements are lower than the secondary barrier's requirements.
3. The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.
4. A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure, and shall meet the requirements of 420-3-26-.05, Appendix C.3.

**(c) Operating Procedures.**

1. No individual exposed to occupational radiation shall hold patients during exposures except during emergencies, nor shall any individual be regularly used for this service. If the patient must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and apron and he shall be so positioned that no part of his body will be struck by the useful beam.
2. Only the operators of radiographic equipment, other required individuals, and the patient shall be present during exposures. No unprotected parts of the operator's body shall be in the useful beam.
3. The useful beam shall be restricted to the area of clinical interest.

**(6) Mobile Diagnostic Radiographic Equipment.**

**(a) Equipment.**

1. All requirements of 420-3-26-.06(5)(a) apply except 420-3-26-.06(5)(a)5.
2. The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six (6) feet

from the patient and well away from the useful beam.

**(b) Structural Shielding.**

1. When a mobile unit is used routinely in one location, it shall be considered a fixed installation subject to shielding requirements specified in 420-3-26-.06(3)(d) and 420-3-26-.06(5)(b).

**(c) Operating Procedures.**

1. All provisions of 420-3-26-.06(5)(c) apply, except 420-3-26-.06(5)(c)2.
2. The target-to-skin distance shall not be less than twelve (12) inches.

**(7) Chest Photofluorographic Installations.**

**(a) Equipment.**

1. All provisions of 420-3-26-.06(5)(a) apply.
2. A collimator shall restrict the useful beam to the area of the photofluorographic screen.

**(b) Structural Shielding.**

1. All provisions of 420-3-26-.06(3)(d) and 420-3-26-.05(5)(b) apply.

**(c) Operating Procedures.**

1. All provisions of 420-3-26-.06(5)(c) apply.
2. All individuals except the patient being examined shall be in shielded positions during exposures.

**(8) Dental Radiographic Installations.**

**(a) Equipment.**

1. The tube housing shall be of diagnostic type.
2. Diaphragms or cones shall be used for collimating the useful beam and shall provide the same degree of protection as the housing. The diameter of the useful beam at the cone tip shall not be more than three (3) inches.
3. A cone or spacer frame shall provide a target-to-skin distance of not less than seven (7) inches with apparatus operating above fifty (50) kVp or four (4) inches with apparatus operating at fifty (50) kVp or below.
4.
  - (i) For equipment operating up to seventy (70) kVp, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 1.5 mm aluminum at normal operating voltages.
  - (ii) For equipment operating above seventy (70) kVp, the total filtration permanently in the useful beam shall be equivalent to at least 2.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 mm of aluminum at the normal operating voltages.
5. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set at a zero or off position, if either position is provided. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the time to its initial setting or to zero.
6. The exposure control switch shall be of the dead-man type.
7. Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.

(b) **Structural Shielding.**



1. Dental rooms containing x-ray machines shall be provided with primary barriers for all areas struck by the useful beam.
2. When dental x-ray units are installed, the rooms adjacent will be adequately protected.

NOTE: In most cases structural materials or ordinary walls suffice as a protective barrier without addition of special shielding material.

**(c) Operating Procedures.**

1. Neither the dentist nor his assistant shall be permitted to hold patients or films during exposure, nor shall any individual be regularly used for this service.
2. During each exposure, the operator shall stand at six (6) feet from the patient or behind a protective barrier.
3. Only the patient shall be in the useful beam.
4. Neither the tube housing nor the pointer cone shall be hand-held during exposure.
5. Fluoroscopy shall not be used in dental examinations.

**(9) Therapeutic X-ray Installations.**

**(a) Equipment.**

1. The tube housing shall be of therapeutic type.
2. Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the tube housing. Adjustable or removable beam-defining diaphragms or cones shall transmit not more than five (5) percent of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter.
3. Filters shall be secured in place to prevent them from dropping out during treatment. The filter slot shall be so constructed that the radiation escaping through it does not exceed one (1) roentgen per

hour at one (1) meter, or if the radiation from the slot is accessible to the patient, thirty (30) roentgens per hour at five (5) centimeters from the external opening.

4. The x-ray tube shall be so mounted that it cannot turn or slide with respect to the aperture.
5. Means shall be provided to immobilize the tube housing during stationary portal treatment.
6. A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present.
7. Equipment utilizing shutters to control the useful shall have a shutter position indicator on the control.
8. There shall be on the control panel an easily discernible indicator which will give positive information as to whether or not the x-ray tube is energized.

**(b) Structural Shielding.**

1. All wall, floor, and ceiling areas that can be struck by the useful beam, plus a border of one foot, shall be provided with primary protective barriers.
2. All wall, floor, and ceiling areas that cannot be struck by the useful beam shall be provided with secondary barriers.
3. With equipment operating above one hundred and twenty-five (125) kVp, the required barriers shall be an integral part of the building.
4. With equipment operating above one hundred and fifty (150) kVp, the control panel shall be within a protective booth equipped with an interlocked door, or outside the treatment room.
5. Interlocks shall be provided for x-ray therapy equipment capable of operating above 150 kVp so that, when any door of the treatment room is opened, either the machine will shut off

automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens per hour and a maximum of ten milliroentgens per hour at a distance of one (1) meter in any direction from the target. After such shut off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

6. Provisions shall be made to permit continuous observation of patients during irradiation.
7. Windows, mirror systems, or closed-circuit television viewing screens used for observing the patient shall be so located that the operator may see the patient and the control panel from the same position.

**(c) Operating Procedures.**

1. All new installations shall have a protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the installation which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the installation and to the Agency (State Board of Health).

NOTE: Paragraph (c)1. of 420-3-26-.06(9), Rule 420-3-26-.06 was revised by the State Board of Health on March 19, 1979.

2. The installation shall be operated in compliance with any limitations indicated by the protection survey.
3. No individual who works with radiation, unless he is the patient, shall be in the treatment room during exposure. No other individual shall be there except when it is clinically necessary. If any individual is required to be in the treatment room with the patient during exposure, he shall be protected as much as possible from scattered radiation, and shall not be in the useful beam.
4. Records of surveys required by subparagraph (4) of this paragraph shall be maintained for two years after the facility has ceased to be used as described in the survey. If the survey was used to determine an individual's exposure, the record must be maintained

until disposal is authorized by the Agency.

- (d) All provisions of this Section apply to therapeutic veterinary installations.
  - (e) The output of each therapeutic x-ray machine shall be calibrated by, or under the direction of, a qualified expert. The calibration shall be repeated after any change in or replacement of components of the x-ray generating equipment which could cause a change in x-ray output. Check calibrations shall be made at least one a year thereafter. Records of calibration shall be maintained by the registrant.
- (10) **X-ray Therapy Equipment Operated at Potentials of Sixty (60) KV and Below.**
- (a) **Equipment.**
    - 1. All provisions of 420-3-26-.06(9)(a) apply, except for equipment used for "contact therapy", 420-3- 26-.06(9)(a) in which instance the leakage radiation at the surface of the tube housing shall not exceed 0.1 roentgen per hour.
    - 2. There shall be on the control panel some easily discernible device which will give positive indication as to whether or not the tube is energized.
  - (b) **Operating Procedures.**
    - 1. Automatic timers shall be provided which will permit accurate presetting and determination of exposures as short as one second.
    - 2. In the therapeutic application of apparatus constructed with beryllium or other low-filtration windows, the registrant shall insure that the unfiltered radiation reaches only the part intended and that the useful beam is blocked at all times except when actually being used.
    - 3. Machines having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the primary disconnecting means.
    - 4. If the tube is hand-held during irradiation, the operator shall wear protective gloves and apron.

**(11) Veterinary Medicine Radiographic Installations.**

**(a) Equipment.**

1. The tube housing shall be of diagnostic type.
2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as required of the housing, as indicated in 420-3-26-.06(5)(a)2.(i) and (ii).
3. Except when contraindicated for a particular radiographic purpose, the total filtration permanently in the useful beam shall not be less than 1.5 millimeters aluminum-equivalent for equipment operating up to seventy (70) kVp and 2.0 millimeters aluminum-equivalent for machines operated in excess of seventy (70) kVp.
4. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set at a zero or off position, if either position is provided.
5. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam at least six (6) feet from the animal during all x-ray exposures.

**(b) Structural Shielding.**

1. All wall, floor, and ceiling areas shall be provided with applicable protective barriers as required in 420-3-26-.06(5)(b).

**(c) Operating Procedures.**

1. The operator shall stand well away from the tube housing and the animal during radiographic exposures. Provisions shall be made so that it will not be necessary for the operator to stand in the useful beam. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individual other than the persons involved in the operation shall be in the x-ray room

while exposures are being made.

2. In any application in which the operator or an assistant is not located behind a protective barrier, a protective apron having a lead- equivalent of not less than 0.5 millimeter shall be worn
3. No individual shall be regularly employed to hold or support animals or hold film during radiation exposures. Occupationally exposed individuals shall not perform this service except in cases in which no other method is available. Any individual holding or supporting an animal during radiation exposure shall wear protective gloves and apron having a lead-equivalent of not less than 0.5 millimeter.

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