12VAC5-481 PART VI USE OF DIAGNOSTIC X-RAYS IN THE HEALING ARTS

12VAC5-481-1581. Purpose and scope.

This part establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with Virginia law to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to and not in substitution for other applicable provisions of this chapter.

12VAC5-481-1591 General and administrative requirements

A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the x-ray system under his administrative control. The registrant or the registrant's agent shall assure that the requirements of this chapter are met in the operation of the x-ray system or systems.

1. An x-ray system that does not meet the provisions of this chapter shall not be operated for diagnostic purposes.

2. Individuals who will be operating the x-ray systems shall meet the qualifications of this part to conduct the practice of radiologic technology.

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel that specifies, for all examinations performed with that system, the following information:

a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

b. Type and size of the image receptor to be used;

c. Type and size of the image receptor combination to be used, if any;

d. Source to image receptor distance to be used (except for dental intraoral radiography);

e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

f. For mammography, indication of kVp/target/filter combination.

4. The registrant of a facility shall create and make available to x-ray operators written safety procedures, including 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.

5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

a. All individuals 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;

b. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material. However, when distances provide sufficient protection from scatter radiation, or for low dose rate devices such as bone densitometry equipment, no protective devices may be necessary; and

c. Human patients who cannot be removed from the room 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 so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. Gonad shielding of not less than 0.5 mm lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. 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:

a. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

b. Exposure of an individual for the purpose of healing arts screening except as authorized by subdivision 11 of this subsection.

8. When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, as required by subdivision 4 of this subsection, shall list individual projections where holding devices cannot be utilized;

b. Written safety procedures, as required by subdivision 4 of this subsection, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 5 of this subsection. Caregivers who stay in the room to assist with imaging of patients shall be positioned and instructed to keep the protective apron between themselves and the patient;

d. No individual shall be used routinely to hold image receptors or patients;

e. 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; and

f. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with x-ray operations and who are otherwise not shielded.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

a. The fastest imaging system consistent with the diagnostic objective of the examinations shall

be used. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

b. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

c. Portable or mobile radiographic (exclude fluoroscopic) x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.

d. X-ray systems subject to 12VAC5-481-1621 shall not be utilized in procedures where the source to patient distance is less than 30 cm, except for veterinary systems.

e. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(1) Be positioned properly, that is, tube side facing the right direction, and grid centered to the central ray; and

(2) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 12VAC5-481-640, 12VAC5-481-700, and 12VAC5-481-710.

11. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

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, that is, type and number of views;

d. Description of the population to be examined in the screening program, that is, age range, sex, physical condition, and other appropriate information;

e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;

f. An evaluation by a qualified medical physicist of the x-ray system or systems to be used in the screening program. The evaluation shall include the following:

(1) Documentation that such systems satisfy all requirements of this chapter; and

(2) Measurement of patient exposures from the x-ray examinations to be performed;

g. A description of the diagnostic x-ray quality control program;

h. A copy of the technique chart for the x-ray examination procedures to be used;

i. The qualifications of each individual who will be operating the x-ray system or systems;

j. The qualifications of the individual who will be supervising the operators of the x-ray system or systems. 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;

l. Procedures to be used in advising the individuals screened and their practitioners of the healing arts or health care providers 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.

12. The registrant shall maintain the following information and maintenance record for each x-ray

system for inspection by the agency:

a. Model and serial numbers of all major components, and user's manuals for those components;

b. Tube rating charts and cooling curves;

c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system or systems; and

d. A copy of all correspondence with the agency regarding that x-ray system.

13. Except for veterinary facilities, each facility shall maintain an x-ray utilization log containing the patient's name, the type of examination, and the date the examination was performed.

14. The registrant shall maintain a list of x-ray operators for each facility. Operators must be licensed by the Department of Health Professions where x-rays are used within the scope of practice or be certified by the American Registry of Radiological Technologists (ARRT), or be an individual enrolled, or was enrolled within the past three months, in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, or if a dental assistant, comply with the Board of Dentistry's radiation certification requirements in 18VAC60-20-195.

B. X-ray film processing facilities and practices.

1. Each installation using a radiographic x-ray system and analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film.

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) 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:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2-1/2
25.0	77	2-1/2
24.4	76	3
23.9	75	3
23.3	74	3-1/2
22.8	73	3-1/2
22.2	72	4
21.7	71	4
21.1	70	4-1/2
20.6	69	4-1/2
20.0	68	5
19.4	67	5-1/2
18.9	66	5-1/2
18.3	65	6
17.8	64	6-1/2
17.2	63	7
16.7	62	8
16.1	61	8-1/2
15.6	60	9-1/2

(3) Devices shall be utilized that will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

b. Automatic processors and other closed processing systems. 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*
°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

*Immersion time only, no crossover time included.

Processing deviations from the requirements of this subdivision 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).

2. Other requirements.

a. 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.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-ray radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used,

daylight film handling boxes shall preclude fogging of the film.

c. 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.

d. 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.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

h. Living and deceased patients' diagnostic images shall be maintained for a minimum of five years. Diagnostic images for minors shall be maintained for a minimum of five years beyond their 18th birthday.

C. The registrant shall submit to the agency a copy of all surveys, calibrations, and inspections performed by a private inspector within 30 days of completion of the survey, calibration, or inspection.

D. The private inspector shall provide the inspection report to the registrant within 14 days of the completion of the inspection. A summary or recommendation shall be included with this report. The inspector shall notify the registrant of any noncompliances that need corrective action.

E. Violations identified as "serious" must be corrected within 30 days. Certification of the unit will not be issued until the violation is corrected. Violations identified as "non-serious" shall be corrected before the next inspection cycle. Uncorrected "non-serious" violations will become "serious" and require immediate correction.

12VAC5-481-1601. General requirements for all diagnostic x-ray systems.

In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

1. Warning label. 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."

2. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (100 milliroentgen (mR) exposure) in one 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.

3. 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 (two milliroentgens exposure) in one hour at five 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.

4. Beam quality half-value layer (HVL).

a. The HVL of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1 (i) under the heading "Specified Dental Systems" for any dental x-ray system

designed for use with intraoral image receptors and manufactured after December 1, 1980; (ii) under the heading "I-Other X-Ray Systems" for any dental x-ray system 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; and (iii) under the heading "II-Other X-Ray Systems" for 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. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 1, 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 that 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]	I-Other X-Ray Systems[2]	II-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.

b. Optional filtration. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube or tubes with a continuous output of one kilowatt or more and an anode heat storage capacity of one 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 in Table 1. 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.

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

5. 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, which are used between the patient and the image receptor, shall 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 for the potential. This requirement applies to front panel or panels of cassette holders 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)
Front panel(s) of cassette holders (total of all)	1.2
Film panel(s) of film changer (total of all)	1.2
Cradle	2.3
Tabletop, stationary, without articulated joints	1.2
Tabletop, movable, without articulated joints (including stationary subtop)	1.7
Tabletop, with radiolucent panel having one articulated joint	1.7
Tabletop, with radiolucent panel having two or more articulated joints	2.3
Tabletop, cantilevered	2.3
Tabletop, radiation therapy simulator	5.0

6. 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.

7. Modification of certified diagnostic x-ray components and systems.

a. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this part.

b. 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 a component to comply with the applicable requirements of this part. The owner who causes such modification need not submit the reports required by this part, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with this part.

8. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch,

the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

9. 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.

10. Technique indicators.

a. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set prior to the exposure shall be indicated.

b. The requirement of subdivision 10 a of this subsection 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.

11. 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.

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

13. Mechanical timers. The use of mechanical timers is prohibited.

12VAC5-481-1611. Fluoroscopic equipment.

A. The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

B. Primary protective barrier.

1. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier that 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 $3.34x10^{-3}$% 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 subsection E of this section. 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 subdivisions 4 and 5 of this subsection 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 subdivisions 4 and 5 of this subsection. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or capability of a visible area of greater than 300 square cm, 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 square cm 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 square cm 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 five cm by five cm. This paragraph does not apply to non-image-intensified fluoroscopy.

3. Non-image-intensified fluoroscopy. The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

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

a. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

(2) 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 that pass through the center of the visible area of the image receptor.

b. 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:

(1) 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% of the area of the x-ray field overlaps the visible area of the image receptor; or

(2) 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 two cm.

5. 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:

a. Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

b. The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

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 that 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 or exposures 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.

a. 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 (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

b. 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 (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

c. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

d. Equipment may be modified in accordance with this part to comply with subdivision 2 of this subsection. 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)"

e. Exceptions:

(1) During recording of fluoroscopic images; or

(2) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of any of the rates specified in subdivisions 1 a, b, and c of this subsection at the

measurement point specified in subdivision 3 of this subsection, 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 being employed.

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

a. Equipment 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 (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Provision or manual selection of technique factors may be provided.

b. Equipment 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 (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 2 c of this subsection.

c. Exceptions:

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from the fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(2) 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 or images after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(3) When a mode of operation has an optional high-level control 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 (20 R/min exposure rate) at

the measurement point specified in subdivision 3 of this subsection. 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.

3. Measuring compliance. Compliance with this subsection shall be determined as follows:

a. If the source is below the x-ray table, the AKR shall be measured at one cm above the tabletop or cradle.

b. 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.

c. 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.

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

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

4. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

F. (Reserved.)

G. 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.

H. Source-skin distance.

1. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subsection, 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 source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this subsection, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

I. Fluoroscopic irradiation time, display, and signal.

1. Fluoroscopic equipment manufactured before June 10, 2006.

a. Equipment 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 five 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 subdivision. When the equipment is modified, it shall bear a label indicating the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

b. As an alternative to the requirements of this subsection, 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:

a. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

(1) 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 six seconds.

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

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

b. A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

J. Mobile and portable fluoroscopes. In addition to the other requirements of this subsection, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

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

1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination

of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

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.

L. 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 five seconds of termination of an exposure or displayed continuously and updated at least once every five 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.

a. 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 subdivision E 3 a or E 3 e of this section.

b. 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 ±35% over the range of six 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 three seconds.

M. Control of scattered radiation.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 centimeters from the center of the useful beam; or

b. The radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12VAC5-481-1591 A 5.

3. The agency may grant exemptions to subdivision 2 of this subsection where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

N. Operator qualifications. The facility shall ensure that only a licensed practitioner of the healing arts or a radiologic technologist or equivalent be allowed to operate fluoroscopic x-ray systems.

O. Equipment operation.

1. All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. The operation of fluoroscopic x-ray systems by radiologic technologists or equivalent shall be performed under the direct supervision of a licensed practitioner of the healing arts.

3. Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or radiologic technologist as specified in subsection N of this section.

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

5. Facilities shall maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

P. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic x-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1621. Radiographic equipment.

A. Control and indication of technique factors.

1. Visual indication. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the

fluoroscopist.

2. 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.

a. 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.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

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

a. Indication shall be made on the control panel when this mode of operation is selected;

b. 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 five milliampere-seconds (mAs), whichever is greater;

c. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) 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

d. A visible signal shall indicate when an exposure has been terminated at the limits described

in subdivision 3 c of this subsection, and manual resetting shall be required before further automatically timed exposures can be made.

4. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer. In the absence of manufacturer's limits, the deviation shall not exceed 10% of the indicated value for kVp and time.

B. Reproducibility. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

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 0.10.

2. Measuring compliance. Determination of compliance shall be based on four consecutive measurements taken within a time period of one hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

C. Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated.

1. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliampere-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:

$|X1 – X2| \leq 0.10(X1 + X2)$

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 milliampere-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:

$$|X1 - X2| \leq 0.10(X1 + X2)$$

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 shall be based on four exposures, made within one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

D. 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 an SID of 100 cm shall be equal to or less than five cm.

2. Visual definition.

a. 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 2.0% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

b. When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 10 foot-candles 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.

c. 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 four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three 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 three mm from the edge of the light field toward the center of the field, and I_2 is the illuminance three mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one mm.

E. 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 subsection D of this section:

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 2.0% of the SID and to indicate the SID to within 2.0%;

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 centimeters or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2.0% 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 or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm 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.

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

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

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

b. If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six cm.

For dental intraoral uses, an open ended shielded positioning device shall be used.

2. 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 2.0% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

3. Systems designed for mammography.

a. Radiographic systems designed only for mammography and general purpose radiography

systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

b. Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. For systems that allow changes in SID, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

c. Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

4. Other x-ray systems. Radiographic systems not specifically covered in subsections D, E, and H of this section, 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 2.0% 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 2.0% 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:

a. A system that performs in accordance with subsections D and E of this section; or when alignment means are also provided, may be met with either;

b. 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

c. 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.

G. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems that contain PBL.

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

a. 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 3.0% of the SID; or

b. The sum of the length and width differences stated in subdivision 1 a of this subsection without regard to sign exceeds 4.0% of the SID.

c. The beam-limiting device is at an SID for which PBL is not designed for sizing.

2. Conditions for PBL. When provided, the PBL system shall function as described in subdivision 1 of this subsection whenever all the following conditions are met:

a. The image receptor is inserted into a permanently mounted cassette holder;

b. The image receptor length and width are less than 50 cm;

c. The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

d. The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

e. Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance. Compliance with the requirements of subdivision 1 of this subsection shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of subdivision 2 of this subsection are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

4. Operator initiated undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm. Return to PBL function as described in subdivision 1 of this subsection 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 System Failure"

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

H. Field limitation and alignment for spot-film devices. 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:

1. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the 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.

2. Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3.0% 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 4.0% 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.

3. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2.0% of the SID.

4. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

a. For spot-film devices used on fixed-SID fluoroscopic systems that are not required to and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

b. For spot-film devices used on fluoroscopic systems that have a variable SID or stepless

adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

5. 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"

I. Source-skin distance.

1. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

a. 18 cm if operable above 50 kVp; or

b. 10 cm if not operable above 50 kVp.

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

J. 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.

K. (Reserved.)

L. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed:

1. An air kerma of 0.26 microGy (0.03 mR exposure) in one minute at five 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 (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 one hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

M. Primary protective barrier for mammography x-ray systems.

1. For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

2. For mammographic x-ray systems manufactured on or after September 30, 1999:

a. At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

b. The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in subdivision 2 a of this subdivision.

c. The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

3. Compliance with the requirements of subdivisions 1 and 2 c of this subsection for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged

over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

N. (Reserved.)

O. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of subsection G of this section have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.

P. 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.

a. Stationary systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator may remain in that protected area during the entire exposure. For dental intraoral systems installed prior to September 20, 2006, if the x-ray control is not permanently mounted behind a protected barrier, then dosimetry is required by all operators of the system.

b. Mobile and portable systems. Mobile and portable x-ray systems that are:

(1) Used continuously for greater than one week in the same location, that is, a room or suite,

shall meet the requirements of subdivision 3 a of this subsection;

(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two 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 (nine feet) from the tube housing assembly during the exposure.

4. Operator protection for veterinary systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a two 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 2.7 meters (nine feet) from the tube housing assembly during exposures.

Q. Tube stands for portable x-ray systems. 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 exposures.

R. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all x-ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers, hand-held units, and x-ray machines other than head CT or cone beam units used in the practice of podiatry, dentistry, or veterinary medicine shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.

12VAC5-481-1631. Intraoral dental radiographic equipment.

In addition to the applicable provisions of 12VAC5-481-1591, 12VAC5-481-1601, and 12VAC5-481-1621, the requirements of this section apply to x-ray equipment and associated facilities used for dental intraoral radiography. Requirements for extraoral dental radiographic systems are in 12VAC5-481-1621.

1. 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.

2. Exposure control location and operator protection.

a. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

b. Mobile and portable x-ray systems that are:

(1) Used for greater than one week in the same location that is, a room or suite, shall meet the requirements of subdivision 2 a of this section.

(2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

3. kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4. Administrative controls.

a. Patient and film holding devices shall be used when the techniques permit.

b. The tube housing and the PID for a permanently mounted intraoral dental system shall not be hand-held during an exposure.

c. Dental fluoroscopy without image intensification shall not be used.

12VAC5-481-1641. Computed tomography equipment.

A. (Reserved.)

B. Requirements for equipment.

1. Termination of exposure.

a. 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% of its preset value through the use of either a backup timer or devices that monitor equipment function.

b. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by subdivision 1 a of this subsection.

c. 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.

2. Tomographic plane indication and alignment.

a. 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.

b. 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.

c. If a device using a light source is used to satisfy the requirements of subdivision 2 a or b of this subsection, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and shutter status indicators and control switches.

a. 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.

b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT conditions of operation. 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.

5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subdivision 3 of 12VAC5-481-1601.

6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985.

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five mm.

b. 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.

c. The deviation of indicated scan increment versus actual increment shall not exceed one millimeter with any mass from 0 to 100 kg 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.

d. 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.

C. 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.

a. 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.

b. 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.

D. Surveys, calibrations, spot checks, and operating procedures.

1. Surveys.

a. All CT x-ray systems installed after September 19, 2006, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

b. The registrant shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the agency upon request.

2. Radiation calibrations.

a. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified medical physicist who is physically present at the facility during such calibration.

b. The calibration of a CT x-ray system shall be performed (i) after initial installation and before use on human patients, (ii) annually or at intervals specified by a qualified medical physicist, and (iii) after any change or replacement of components that in the opinion of the qualified medical physicist could cause a change in the radiation output.

c. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

d. CT dosimetry phantom shall be used in determining the radiation output of a CT x-ray

system. Such phantom shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic cm. The phantom shall be at least 14 cm in length and shall have diameters of 32.0 cm for testing CT x-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(2) CT dosimetry phantom shall provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(2) The CTDI along the two axes specified in subdivision 2 d (2) of this subsection shall be

measured. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and

(3) The spot checks specified in subdivision 3 of this subsection shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

3. Spot checks.

a. The spot-check procedures shall be in writing and shall have been developed by a qualified medical physicist.

b. The spot-check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of (i) providing an indication of contrast scale, noise, nominal tomographic section thickness, and the resolution capability of the system for low and high contrast objects; and (ii) measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by subdivision 2 of this subsection and at time intervals and under system conditions specified by a qualified medical physicist.

d. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom or phantoms using the same processing mode and CT conditions of operation as are used to perform calibrations required by subdivision 2 of this subsection.

e. The results of each spot check shall be maintained for two years.

4. Operating procedures.

a. The CT x-ray system shall not be operated except by an individual who has been specifically

trained in its operation.

b. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(2) Instructions on the use of the CT dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.

12VAC5-481-1651. Mammography requirements.

A. Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 (Pub.L. 105-248) and 21 CFR Part 900, shall be used for screening and diagnostic mammography.

B. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

C. A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever

performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

D. The operator of the mammography machine shall be certified by the American Registry of Radiologic Technologists (ARRT) and shall have had specialized training in mammography meeting the requirements set forth by the U.S. Food and Drug Administration under the Mammography Quality Standards Reauthorization Act of 1998.

E. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality.

F. Agency inspectors may conduct unannounced inspections during normal business hours.

12VAC5-481-1653. Hand-held radiographic unit.

In addition to the applicable provisions found elsewhere in this chapter, the following provisions apply to a hand-held radiographic unit.

1. A hand-held radiograph unit shall be:

   a. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

   b. Registered with the agency in accordance with applicable parts of this chapter.

   c. Maintained and operated in accordance with the manufacturer's specifications.

2. For all uses:

   a. Operators of a hand-held radiographic unit shall be specifically trained to operate such

equipment.

b. When operating a hand-held radiographic unit, operators shall wear dosimetry unless otherwise authorized by the agency.

c. A hand-held radiographic unit shall have the backscatter radiation shield in place to protect the operator during operation.

d. The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held radiograph unit.

e. A hand-held radiographic unit shall not be used in hallways or waiting rooms.

12VAC5-481-1655. Bone densitometry.

A. A bone densitometry system shall be:

1. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

2. Registered with the agency in accordance with applicable parts of this chapter.

3. Maintained and operated in accordance with the manufacturer's specifications.

B. Equipment requirements. A system with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2.0% of the SID.

C. Operators of a bone densitometry system shall meet one of the following:

1. Be certified by the American Registry of Radiologic Technologists (ARRT);

2. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a radiologic technologist or a limited radiologic technologist for bone density operation;

3. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

4. Be in an accredited program for radiologic technology and under the supervision of an individual who meets one of the criteria listed in subdivision 1, 2, or 3 of this subsection.

D. During the operation of any bone densitometry system:

1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

E. The registrant shall keep maintenance records for bone densitometry systems as prescribed by subdivision A 3 of this section. These records shall be maintained for inspection by the agency.

F. Bone densitometry on human patients shall be conducted only:

1. Under a prescription of an individual licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

2. Under a screening program approved by the agency.

12VAC5-481-1657. Quality assurance program.

All registrants of diagnostic x-ray imaging equipment may be required by the agency to establish and maintain a quality assurance program consisting of quality control assessments.