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SUBCHAPTER 15. MEDICAL DIAGNOSTIC X-RAY INSTALLATIONS

7:28-15.1 Scope

- (a) This subchapter establishes the requirements for medical radiographic and fluoroscopic installations of certified and uncertified ionizing-radiation-producing machines used in all the healing arts, except where exempted by the rules in N.J.A.C. 7:28-16, Dental Radiographic Installations.
- (b) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless the equipment and installation meet the applicable requirements of this subchapter.
- (c) Provisions of this subchapter are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.
- (d) The registrant shall ensure that all ionizing-radiation-producing machines under his or her jurisdiction are operated only by persons authorized pursuant to the Radiologic Technologist Act, N.J.S.A. 26:2D-24 through 36, and applicable provisions of N.J.A.C. 7:28-19.

7:28-15.2 Definitions

The words and terms listed below, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Accessible surface” means the external surface of the enclosure or housing provided by the manufacturer.

“Acquired date” means the date the unit has been installed and is capable of use on patients.

“Aluminum equivalent” means the thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question.

“Anti-collision device” means either an electronic position sensor combined with a microprocessor or a mechanical touch bar microswitch which will stop all equipment movement and radiation exposures to prevent collision of any part of the radiation therapy simulator system with the patient, or damage to other components of the simulator system.

“Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

“Automatic exposure control” means a device which automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location(s) (for example, phototimer).

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“Beam axis” means a line from the source through the center of the x-ray field.

“Beam-limiting device” means a mechanism which provides a means to restrict the dimensions of the x-ray field.

“C-arm x-ray system” means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

“Cassette holder” means a device, other than a spot-film device, that supports and/or fixes the position of an image receptor during an x-ray exposure.

“Certified components” means components of x-ray systems which are subject to the regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J, Radiological Health, (21 C.F.R. Part 1020 et seq., Performance Standards for Ionizing Radiation Emitting Products).

“Certified system” means any x-ray system which has all certified components. Also known as a certified unit or a certified diagnostic x-ray system.

“Coefficient of variation” means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{\sqrt{\frac{1}{n-1} \sum_{i=1}^n (X_i - \bar{X})^2}}{\bar{X}}$$

where:

s = estimated standard deviation of population

\bar{X} = mean value of observations in sample

X_i = ith observation in sample

n = number of observations in sample

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

“Computed tomography dose index” (CTDI) means the integral of the dose measured along a line perpendicular to and centered at the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{\int_{-T}^{+T} D(z) dz}{nT}$$

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where:

z = position along a line perpendicular to the tomographic plane

$D(z)$ = Dose at position z

T = nominal tomographic section thickness

n = number of tomograms produced in a single scan

This definition assumes that the dose profile is centered around $z=0$ and that, for a multiple tomogram system, the scan increment between adjacent scans is nT .

“Contrast scale” (CS) for computed tomography means the change in the linear attenuation coefficient per CT number relative to water, that is:

$$CS = \frac{u_x - u_w}{(CT)_x - (CT)_w}$$

where:

u_x = linear attenuation coefficient of material of interest

u_w = linear attenuation coefficient of water

$(CT)_x$ = CT number of the material of interest

$(CT)_w$ = CT number of water

“Contrast ratio” for a light field is the ratio of the illumination three millimeters from the edge of the field towards the center of the field to the illumination three millimeters from the edge of the field away from the center of the field.

“Control panel” means the part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

“CT conditions of operation” means all selectable parameters governing the operation of a CT x-ray system, including nominal tomographic section thickness, filtration, and the technique factors.

“CT number” means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

“Dedicated mammography unit” means an x-ray system specifically designed for mammographic procedures.

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“Diagnostic source assembly” means the tube housing assembly with a beam-limiting device attached.

“Diagnostic type protective tube housing” means an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum continuous rated tube potential.

“Diagnostic x-ray system” means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnostic imaging or measurement.

“Emergency off switch” means a switch located near the table or near the console which, when operated, turns off all power to the system.

“Entrance exposure rate” means the exposure per unit time at the point where the center of the useful beam enters the patient.

“Equipment” means x-ray equipment.

“Exposure” means a measure of the quantity of x or gamma radiation based upon its ability to ionize air through which it passes.

“Field emission equipment” means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

“Fluoroscopic imaging assembly” means a subsystem in which x-ray photons produce a fluoroscopic image. The subsystem includes the image intensifier, spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

“General purpose radiographic x-ray system” means any radiographic x-ray system which is not limited by its design to the radiographic examination of a specific anatomical region.

“Half-value layer” (HVL) means the thickness of specified material which attenuates the x-ray beam so that the exposure is reduced to one-half of its original value.

“Image intensifier” means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image.

“Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term “image receptor” shall mean the preselected portion of the device.

“Image receptor support” means that part of the system designed to support the image receptor during a radiographic examination.

“kV” means kilovolts.

“kVp” (see “peak tube potential”).

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“Leakage radiation” means radiation emanating from the diagnostic source assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.

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

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

“Light field” means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to the plane of the image receptor as well as at the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

“mA” means milliamperere.

“mAs” means milliamperere second.

“Mobile x-ray equipment” means completely assembled x-ray equipment, which is mounted on a permanent base with wheels and/or casters and is used in multiple locations.

“Motor vehicle mounted” means an x-ray system permanently mounted and operated in a motor vehicle.

“Multiple-tube installation” means a radiographic installation in which one control panel may energize more than one radiographic x-ray tube.

“Noise” for computed tomography means the standard deviation of the fluctuations in CT number expressed as a percent of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = 100 \times CS \times s$$

uw

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where: CS = contrast scale
uw = linear attenuation coefficient of water
s = estimated standard deviation of the CT
numbers of picture elements in a
specified aread of the CT image

“Nominal tomographic section thickness” means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

“Peak tube potential” means the maximum value of the potential difference across the x-ray tube during an exposure.

“Phantom” means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

“Positive beam-limiting device” (PBL) means a device which automatically restricts the x-ray field to the size of the image receptor.

“Portable x-ray equipment” means x-ray equipment designed to be hand-carried.

“Primary protective barrier” see “protective barrier”

“Protective barrier” means a barrier of radiation-absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:

1. “Primary protective barrier” means the material, excluding filters, intercepting the useful beam for protection purposes to reduce the radiation exposure so that it does not exceed two millirems in any one hour; and
2. “Secondary protective barrier” means a barrier sufficient to attenuate the stray radiation to reduce radiation exposure so that it does not exceed two millirems in any one hour.

“Qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems” as required in this subchapter means an individual who meets at least one of the following criteria:

1. Certification by one of the following agencies in the specialty listed:
 - i. The American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;
 - ii. The American Board of Health Physics in Comprehensive Health Physics;
 - iii. The American Board of Medical Physics in Diagnostic Imaging Physics or Medical Health Physics;

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- iv. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1i or iii above; or
 - v. Certification by other national certifying boards which may be recognized by the Commission on Radiation Protection (Commission) where the person seeking recognition as a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified individual pursuant to this definition;
2. A bachelor's degree from an accredited college in biology, chemistry, radiation sciences, physics, engineering, or mathematics and at least five years of professional technical experience in the field of radiological physics or in the use of medical ionizing-radiation-producing equipment;
 3. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least two years of professional technical experience in the field of radiological physics or in the use of medical ionizing-radiation-producing equipment;
 4. Ten years of professional technical experience in the field of radiological physics or in a radiation protection activity. At least five years of the required health physics experience shall have been with medical ionizing-radiation-producing equipment; or
 5. Any individual who does not meet at least one of the foregoing criteria may petition the Commission for recognition as a "qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems". The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems.

"Qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment" as required in this subchapter means an individual who meets at least one of the following criteria:

1. Certification by one of the following agencies in the specialty listed:

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- i. The American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;
 - ii. The American Board of Medical Physics in Diagnostic Imaging Physics;
 - iii. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1i. or ii. above; or
 - iv. Certification by other national certifying boards which may be recognized by the Commission where the person seeking recognition as a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified medical physicist pursuant to this definition;
2. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least three years of professional, clinical and technical experience in the field of radiological physics obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment; or
 3. Any individual who does not meet at least one of the foregoing criteria may petition the Commission for recognition as a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment. The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment.

“Qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems” means an individual who meets at least one of the criteria listed below:

1. Is certified by the American Board of Radiology in Therapeutic Radiological Physics or by the American Board of Medical Physics with special competency in radiation oncology physics;
2. Is certified by the American Board of Radiology in Radiological Physics which includes all three subspecialties of diagnostic radiological physics, therapeutic radiological physics, and medical nuclear physics;

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3. Is certified by the American Board of Radiology or the American Board of Medical Physics in a specialty other than therapeutic radiological physics or radiation oncology physics and has at least three years of professional, clinical and technical experience obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems;
4. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1, 2, or 3 above;
5. Certification by other national certifying boards which may be recognized by the Commission where the person seeking recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified medical physicist pursuant to this definition;
6. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least three years of professional, clinical and technical experience in the field of radiological physics obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems; or
7. Any individual who does not meet at least one of the foregoing criteria may petition the Commission for recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems. The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems.

“Quality assurance” means an organized effort by the registrant to maintain a level of equipment performance to assure consistent production of diagnostic images without unnecessary radiation exposure. It includes quality control procedures and administrative procedures.

“Quality control” is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of

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radiographs, and the continual adjustment of that performance to an optimal and consistent level.

“Radiation therapy simulation system” means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

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

“Radiographic imaging system” means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

“Reference plane” for computed tomography means a plane which is displaced from and parallel to the tomographic plane.

“Registrant” means a person who is required to register a source of radiation with the Department pursuant to this chapter.

“Scan” for computed tomography means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

“Scan increment” for computed tomography means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

“Scan time” means the period of time between the beginning and end of photon transmission data accumulation for a single scan.

“Scan sequence” for computed tomography means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

“Scattered radiation” means radiation that, during passage through matter, has changed in direction or in energy.

“Sensitivity profile” means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

“Single-purpose x-ray system” means an x-ray system which is limited by its design to the radiological examination of a specific anatomical region.

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

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

“Source-to-skin distance” (SSD) means the distance from the source of radiation to the patient’s skin.

“Spot-film device” means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

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“Stationary equipment” means equipment which is installed in a fixed location.

“Technique factors” means the conditions of operation of a diagnostic x-ray system. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.
2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.
3. For computed tomography x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs.
4. For computed tomography x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time in seconds when the scan time in seconds and the exposure time are equivalent.
5. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“Tomogram” means an image of a planar section of a body part or object.

“Tomographic plane” for computed tomography means that geometric plane which is identified as corresponding to the tomographic image.

“Tomographic section” for computed tomography means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

“Tube housing assembly” means the x-ray tube housing with the x-ray tube insert installed. It includes high-voltage and/or filament transformers and other components that are contained within the tube housing.

“Tube rating chart” means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

“Uncertified unit” means an x-ray system comprised of components that are not subject to the regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J Radiological Health, (21 C.F.R. Part 1020 et seq., Performance Standards for Ionizing Radiation Emitting Products). An “uncertified unit” is also known as a noncertified unit or a noncertified diagnostic x-ray system.

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

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

“Xeromammography” means the recording of an x-ray image of the breast using a uniformly charged photoconductive (selenium alloy) plate held in a light-proof cassette instead of using conventional x-ray film.

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

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

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

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

“X-ray system” means an assembly of components for the controlled production of x-rays. The system includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

“X-ray subsystem” means any combination of two or more components of an x-ray system.

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

7:28-15.3 General requirements for radiographic installations

- (a) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.
- (b) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless a diagnostic type protective tube housing is provided.

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- (c) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless a device is used to collimate the useful beam, and this device provides the same degree of protection as required of the diagnostic type protective tube housing.
1. Any new or used x-ray machine sold or otherwise transferred after July 1, 1969 shall be equipped with an adjustable, rectangular collimator fitted with a light field or laser system for delineating the edges of the collimated x-ray beam. The light field and/or laser system shall be operational. There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters (39.4 inches) shall be equal to or less than five centimeters by five centimeters (two inches by two inches). For equipment that employs a light field to define the x-ray field, the following criteria shall apply:
 - i. The light field shall have an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.
 - ii. The edge of the light field at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four for beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three for beam-limiting devices designed for use on mobile and portable equipment.
 - iii. 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 two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
 - iv. If a laser system is used to delineate the edges of the collimated x-ray beam, this source shall provide illumination levels sufficient to determine the collimated edges under ambient light conditions.
 2. A system not requiring a light-beam collimator shall have an assortment of removable, fixed-aperture, beam-limiting devices (diaphragms) sufficient to meet each combination of image receptor size and SID used. Each fixed-aperture beam-limiting device shall be clearly and permanently marked to indicate the image receptor size and SID for which it is designed. Each fixed-aperture beam-limiting device shall limit the size of the x-ray field to the size

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of the image receptor. It shall be the responsibility of the operator to ensure that the correct combination of diaphragm and image receptor size is used during the radiographic procedure.

3. A single-purpose x-ray system, such as chest x-ray equipment, may use a fixed collimator provided the x-ray field does not exceed the size of the image receptor and the beam is fully intercepted by the image receptor. If such an x-ray system is equipped with a light field system, it shall be exempt from (c) 1 above.
- (d) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the beam alignment and distance measurements meet the following requirements:
1. Certified x-ray systems shall be provided with a means or device to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
 2. The center of the x-ray field shall be aligned with respect to the center of the image receptor to within two percent of the SID when the x-ray beam is perpendicular to the plane of the image receptor; and
 3. A means shall be provided to indicate the SID to within two percent. If it is a fixed SID, the distance shall be indicated on the unit with a permanent marking.
- (e) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the x-ray filtration and beam quality meet the following requirements:
1. The amount of total filtration permanently in the useful beam shall provide the minimum half-value layer specified in the following table:

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TABLE OF HALF VALUE LAYERS OF HALF VALUE LAYERS

Designed Operating Range (kVp)	Measured operating potential (kVp)	Minimum operating half-value layer (HVL) (mm of Al)
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

- (f) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the exposure control and exposure timer meet the following requirements:
1. A device shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses, or preset radiation exposure;
 - i. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure greater than one-half second;
 - ii. Except during serial radiography, termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero;
 - iii. Except during serial radiography, 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;
 - iv. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process;

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2. The x-ray control panel shall include a means for indicating x-ray tube voltage (kVp), tube current (mA), and time setting or the product of the tube current and time setting in milliamperere-seconds (mAs);
 3. The x-ray control panel shall provide visual indication to the operator whenever x-rays are produced. Certified equipment shall also provide audible indication to the operator while x-rays are produced or on termination of the exposure;
 4. The technique factors to be used during an exposure shall be indicated on the control panel before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. For equipment having fixed technique factors, this requirement shall be met by permanent markings;
 5. The exposure control switch when depressed shall not energize the x-ray tube when the timer is in the “off” or “zero” position;
 6. The exposure control switch shall be arranged so that it can only be operated when the operator is within a shielded area;
 7. For equipment that provides an automatic exposure control, the following requirements shall be met:
 - i. There shall be a device on the control panel that indicates when this mode of operation is selected;
 - ii. For certified equipment only, a signal audible and visible to the operator shall indicate when an exposure has been terminated; or
 - iii. For uncertified equipment only, a signal visible to the operator shall indicate when the exposure has terminated;
- (g) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the accuracy, reproducibility and linearity meet the following requirements:
1. The timer accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer’s specifications, the deviation shall not exceed 10 percent of the indicated value;
 2. The following timer reproducibility requirements shall apply:

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- i. For certified equipment only, the coefficient of variation of the timer reproducibility shall not exceed 0.05 for any specific combination of selected technique factors.
 - ii. For uncertified equipment only, the coefficient of variation of the timer reproducibility shall not exceed 0.07 for any specific combination of selected technique factors;
3. The following exposure reproducibility requirements shall apply:
 - i. For certified equipment only, the coefficient of variation of radiation exposure reproducibility shall not exceed 0.05 for any specific combination of selected technique factors.
 - ii. For uncertified equipment only, the coefficient of variation of radiation exposure reproducibility shall not exceed 0.07 for any specific combination of selected technique factors;
4. The kVp accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value;
5. The kVp reproducibility shall not exceed a coefficient of variation of 0.05; and
6. The following linearity requirements apply to x-ray equipment which allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating.
 - i. For x-ray equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated milliampereseconds product (mR/mAs) or (C/kg/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.
 - ii. For equipment manufactured after May 3, 1994, x-ray equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliampereseconds product (mR/mAs) or (C/kg/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.
 - iii. The average exposure ratio for 15.3(g) 6i and ii above shall be expressed as follows:

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

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where X1 and X2 are the average mR/mAs or C/kg/mAs values obtained at each of two consecutive tube mA or mAs settings.

- (h) No person shall operate or permit the operation of a certified or uncertified multiple-tube installation where a control panel can energize more than one x-ray tube unless the following additional requirements are met: (Interventional biplane radiographic systems shall be exempted from these additional requirements.)
1. Only one radiographic tube shall be capable of activation at any time;
 2. Where two or more radiographic tubes are controlled by one exposure switch, the radiographic tube which has been selected shall be clearly indicated to the operator prior to initiation of the exposure. Certified units only shall be provided with such an indicator on both the x-ray control panel and at or near the radiographic tube housing assembly which has been selected; and
 3. A radiographic tube shall be energized only when that specific radiographic tube is selected.
- (i) No person shall operate or permit the operation of any certified radiographic x-ray equipment that has been provided with positive beam limitation (PBL) unless the following requirements for positive beam limitation are met:
1. When provided, positive beam limitation (PBL) shall function as described in 15.3(i)2 of this section whenever all the following conditions are met:
 - i. The image receptor is inserted into a permanently mounted cassette holder;
 - ii. The image receptor length and width are each less than 50 centimeters (20 inches);
 - iii. The x-ray beam axis is within plus or minus three degrees of vertical and the SID is 90 centimeters (35.5 inches) to 130 centimeters (51 inches) inclusive; or the x-ray beam axis is within plus or minus three degrees of horizontal and the SID is 90 centimeters (35.5 inches) to 205 centimeters (81 inches) inclusive;
 - iv. The x-ray beam is perpendicular to the plane of the image receptor to within plus or minus three degrees; and
 - v. Neither tomographic nor stereoscopic radiography is being performed.
 2. When positive beam limitation (PBL) is provided it shall prevent the production of x-rays whenever:

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- i. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three percent of the SID; or
 - ii. The sum of the differences, without regard to sign, between the length and width of the x-ray field in the plane of the image receptor and the corresponding dimensions of the image receptor exceeds four percent of the SID.
 - iii. The beam-limiting device is at an SID for which PBL is not designed for sizing.
3. Compliance with (i)2 above shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of (i)1 above are met. Determination of compliance shall be no sooner than five seconds after insertion of the image receptor.
4. If a capability for overriding PBL in case of system failure and for servicing the system is provided, it shall comply with the following:
 - i. This override shall be for all SID and image receptor sizes;
 - ii. A key shall be required to defeat the PBL;
 - iii. The key shall remain in place during the entire time the PBL system is overridden; and
 - iv. Each 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 if its location is such that the operator would consider it part of the operational controls.

5. When provided, the positive beam limitation system shall be capable of operation, at the discretion of the operator, in such a manner that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters (39.4 inches) shall be equal to or less than five centimeters by five centimeters (two inches by two inches); and

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6. When provided, the positive beam limitation system shall be so designed that if a change in image receptor does not cause an automatic return to the positive beam limitation function as described in (i)2 above, then any change of image receptor size or SID must cause the automatic return.
- (j) No person shall operate or permit the operation of certified or uncertified mobile or portable radiographic x-ray equipment unless the following requirements are met:
1. These requirements are in addition to and not in substitution for the applicable requirements of this subchapter;
 2. The equipment shall be provided with a collimator and a spacer device to limit the source-to-skin distance to not less than 30 centimeters (12 inches);
 3. If the equipment was manufactured with a device to measure the SID, the device shall be present to measure the SID and the device shall indicate the SID to within two percent;
 4. The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six feet from the patient for all exposures. The exposure control switch when depressed shall not energize the x-ray tube when the timer is in the "off" or "0" position;
 5. A mobile or portable radiographic unit used routinely in one location shall be considered a permanent installation and shall comply with the requirements of N.J.A.C. 7:28-15.10; and
 6. No person shall operate or permit the operation of certified or uncertified mobile or portable equipment unless the person operating the equipment is protected with a lead apron of at least 0.25 mm lead equivalent.
- (k) No person shall operate or permit the operation of certified or uncertified ionizing-radiation-producing podiatric x-ray equipment unless the following requirements are met:
1. These requirements are in addition to and not in substitution for the applicable requirements of this subchapter; and
 2. Certified and uncertified podiatric x-ray equipment shall be provided with an exposure control switch which will allow the operator to stand at least six feet (1.8 meters) from the patient or behind a protective barrier. The requirement set forth in this paragraph shall supersede the requirement in (f)6 above.

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- (l) No person shall operate or permit the operation of medical radiographic x-ray equipment used in the healing arts unless the registrant has developed and continuously implemented a quality assurance program that meets the requirements of N.J.A.C. 7:28-22, Quality Assurance Programs for Medical Diagnostic X-ray Installations.

Amended by R.2001 d.37, effective January 16, 2001

See: 32 N.J.R. 1459(a), 33 N.J.R. 292(b)

Added (l)

7:28-15.4 Mammography radiographic installations

- (a) This section establishes the requirements for medical diagnostic and screening radiographic mammography procedures. Hereafter, all references to mammography shall mean mammography performed with ionizing-radiation-producing equipment.
- (b) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.
- (c) No person shall operate or permit the operation of x-ray equipment used for mammography unless the equipment and installation meet the applicable requirements of this subchapter.
- (d) The registrant shall ensure that each mammography unit under the registrant's jurisdiction is operated only by a licensed diagnostic x-ray technologist or a licensed practitioner as prescribed in N.J.A.C. 7:28-19.
- (e) Within two years of the effective date of this rule or within two years of the installation of a mammography unit, whichever shall be later, the registrant shall not operate or permit the operation of each mammography unit under the registrant's jurisdiction unless the mammography unit is accredited by the American College of Radiology (ACR) or meets an equivalent standard acceptable to the Commission. Current accreditation by the ACR or its equivalent acceptable to the Commission shall be maintained for each mammography unit under the registrant's jurisdiction.
 - 1. If a mammography unit is accredited or certified by an agency or organization other than ACR, a registrant may petition the Commission in writing for recognition of this agency's or organization's accreditation or certification as equivalent to ACR accreditation. The registrant shall submit sufficient documentation to the Commission related to machine performance standards, quality assurance, operating safety standards, and any additional information that the Commission may request in order to demonstrate equivalence to ACR accreditation.

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2. The Commission may approve the registrant's petition based on the information contained in the petition and the Commission's determination that the alternative agency's or organization's accreditation or certification is equivalent to ACR accreditation.
 3. A mammography unit that is used exclusively for stereotactic biopsies is exempt from the requirements of 15.4(e) 1 and 2 above but shall meet the other requirements of this subchapter.
- (f) No person shall operate or permit the operation of any radiographic equipment for mammography unless the equipment meets the following requirements:
1. It shall be a dedicated mammography unit;
 2. The tube housing assembly shall be provided with a beam-limiting device. When a light localizer used to define the x-ray field is provided on the mammography unit, the light localizer shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based upon measurements made in the approximate center of each quadrant of the light field.
 3. The tube housing assembly shall be so constructed that the leakage radiation measured at a distance of one meter (39 inches) from the source does not exceed 26 microcoulombs per kilogram (0.1 Roentgen) in any one hour when the source is operated at its leakage technique factors;
 4. A mark shall be provided on the visible exterior of the source assembly which indicates the location of the focal spot;
 5. An x-ray beam-limiting device shall be used to restrict the size of the x-ray beam to the size of the image receptor. Types of beam-limiting devices include, but are not limited to, diaphragms, cones, and adjustable collimators. The beam-limiting device shall provide the same primary beam attenuation as the tube housing.
 - i. The misalignment between the edges of the light field and the x-ray field shall be less than two percent of the SID.
 - ii. The x-ray beam shall be totally intercepted by the image-receptor support, except for the edge of the image-receptor support designed to be adjacent to the chest wall. The x-ray field at the edge of the image-receptor support designed to be adjacent to the chest wall shall not extend beyond

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the edge of the image-receptor support by more than two percent of the SID;

6. The image-receptor support shall transmit less than 0.026 microcoulombs (0.1 milliroentgens) per exposure at 5 centimeters (2 inches) beyond the support with no breast present for maximum kV and mAs values clinically used;
7. The requirements for the control panel on the mammography system are as follows:
 - i. The mammography system shall have the capability of automatic exposure control;
 - ii. The control panel shall provide visual display of the x-ray tube voltage (kVp) and either the tube current (mA) and time setting (sec) or the product of the tube current and time setting in millampere-seconds (mAs); and
 - iii. The control panel shall have a device or means for emitting a signal audible to the operator which indicates when the exposure has terminated and a device such as a light or milliammeter to give a visual indication when the beam is on;
8. The radiation exposure reproducibility shall not exceed a coefficient of variation of 0.05. For manual mode this shall be for any selected technique factors. For automatic exposure control this shall be for any selected absorber or phantom;
9. The timer shall meet the following requirements:
 - i. The timer reproducibility shall not exceed a coefficient of variation of 0.05 for any specific combination of selected technique factors; and
 - ii. The timer accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value;
10. The kVp shall meet the following requirements:
 - i. The kVp accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed five percent from the nominal kVp setting;
 - ii. The kVp reproducibility shall not exceed a coefficient of variation of 0.02;
 - iii. The kVp shall be capable of being selected in increments of no greater than three kVp whether kVp is selected manually or automatically; and

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iv. The kVp shall be selected either manually or automatically;

11. The following linearity requirements apply to mammography x-ray equipment which allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating:

i. For x-ray equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated milliamperere-seconds product (mR/mAs) or (C/kg/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

ii. For equipment manufactured after May 3, 1994, x-ray equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliamperere-seconds product (mR/mAs) or (C/kg/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.

iii. The average exposure ratio for (f) 11 i and 11 ii above shall be expressed as follows:

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

where X1 and X2 are the average mR/mAs or C/kg/mAs values obtained at each of two consecutive tube mA or mAs settings.

12. The measured HVL shall be equal to or greater than the value:

$$\text{HVL} \geq \frac{\text{kVp}}{100} \quad (\text{in units of mm of aluminum})$$

For film-screen mammography units only, the maximum measured HVL shall be equal to or less than the value:

$$\text{HVL} \leq \frac{\text{kVp}}{100} + 0.1 \quad (\text{mm of aluminum})$$

13. There shall be a device to maintain parallel breast compression. The degree of compression shall be adjustable and shall remain at the set level during the exposure. A device, scale or other means shall indicate the thickness of the compressed breast. The compression plate shall attenuate the beam by no more than the attenuation provided by two mm of polymethylacrylate;

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14. There shall be a means or a device on the mammography unit to indicate the SID, if this is variable. The actual SID shall be posted on the mammography unit if this distance is fixed. Accuracy of the SID indicator shall be within \pm two percent of the indicated value;
 15. There shall be a means of determining the angulation on the mammography unit. This determination shall be displayed on the unit.
 - i. There shall be a means to lock the position and angulation of the source assembly.
 - ii. Such lock shall be deemed to have been provided if the position or angulation can only be changed by activation of a motor; and
 16. The exposure switch shall be a dead-man type and shall be arranged so that it can only be operated when the operator is within a shielded area. The exposure control when depressed shall not energize the x-ray tube when the timer is in the "off" or "zero" position.
- (g) A radiation-protection barrier for the operator shall be provided in the room for a mammography unit that requires the operator to remain in the room during the exposure. The operator shall stand behind the protective barrier provided and shall observe the patient during each mammographic exposure.
- (h) No person shall operate or permit the operation of a mammography unit unless the registrant has developed and maintains a quality assurance program that meets the requirements listed in (j) below.
- (i) The registrant shall ensure that no person operates the mammography unit until he or she has reviewed the quality assurance manual and has documented that such review has been completed.
- (j) The requirements for the quality assurance program shall be as follows:
1. The registrant shall develop and maintain a quality assurance manual that identifies and assigns over-all quality control responsibilities. The following items shall be in the quality assurance manual:
 - i. A list of the individuals responsible for testing, supervising, repairing or servicing the equipment. This list shall include the specific responsibilities for the radiologist, the qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment (the medical physicist), the diagnostic x-ray technologist (radiologic technologist), and repair or service personnel;

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- ii. A list of the equipment to be tested;
 - iii. A list of the tests to be performed. For each test, the following items shall be included:
 - (1) The frequency of performance of each test in accordance with (j)4, 6, 7, 8, 9, 10, and 11 below;
 - (2) The acceptability limits for each test; and
 - (3) A brief description of the procedures to be used for each test;
 - iv. The protocol for corrective action which shall be taken if the test results do not lie within the acceptability limits.
 - v. Sample forms to be used for each test; and
 - vi. Reference materials and their location;
2. The registrant shall present the quality assurance manual, records of all testing, test data, equipment maintenance and other required procedures to the department for review during any inspection;
3. For each mammography unit, the registrant shall ensure that tests are performed and records are maintained as listed below:
- i. The initial test results shall be maintained for as long as the mammography unit is registered plus one year; and
 - ii. A record of each service to the mammography unit shall be kept for 36 months from the date of such service;
4. For each mammography unit, the registrant shall perform or have performed at least annually the test procedures listed below and shall maintain the records for as long as the mammography unit remains registered plus one year.
- i. Measurement of breast entrance exposure and average glandular dose;
 - ii. Measurement of half-value layer;
 - iii. Measurement of accuracy and reproducibility of kVp settings;
 - iv. Measurement of linearity of exposure at various mA stations or mAs settings;

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- v. Measurement of accuracy and reproducibility of timer settings where these are adjustable;
 - vi. Measurement of exposure reproducibility at techniques representative of clinical use;
 - vii. Measurement of focal spot size;
 - viii. Assessment of performance of automatic exposure control system, including short-term reproducibility, kilovoltage and thickness compensation, density control selector function and back-up timer function;
 - ix. Assessment of mammography unit assembly, including accuracy of source-to-film distance indicator, physical integrity of breast thickness indicator, functioning of all locks, detents, angulation indicators and mechanical support for the x-ray tube and image-receptor-holder assembly; and x. Assessment of collimation, including alignment of light field and x-ray field;
5. For each processor used for mammography, the registrant shall ensure that the records of maintenance and quality control tests are maintained in a processor maintenance log. Processor maintenance logs shall include preventive maintenance, cleaning performed and corrective actions taken. A record of each such measure taken shall be maintained in the log for at least 36 months;
 6. For each processor used for film-screen mammography, the registrant shall perform or have performed quality control tests for each processor on each day the processor is used for mammography. For motor vehicle and mobile mammographic units with processing capability, quality control tests for each processor shall be performed at each new location.
 - i. Quality control tests shall include measurement of developer temperature, film sensitometry to indicate film speed, film contrast and base-plus-fog density.
 - ii. Logs, charts, or graphs of these measurements shall be maintained for 36 months from the dates of such measurements. The registrant may discard such records after 36 months, except that at least one representative set of quality control records from each year shall be maintained for an additional five years;
 7. For each darkroom used for loading, storing or processing film used for mammography, the registrant shall ensure that:

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- i. Measurement of film fog is performed at least semiannually and test results are maintained for the current year and the preceding year; and
 - ii. Darkroom cleanliness is maintained and checked daily;
8. For each radiographic cassette used for film-screen mammography, the registrant shall ensure that:
 - i. The intensifying screen is cleaned and inspected at least weekly;
 - ii. The film-screen contact is tested at least semiannually and the record of each test is maintained for at least 36 months from the date of the test; and
 - iii. Uniformity of screen speed is assessed annually and the record of each test is maintained for at least 36 months from the date of the test;
9. For each component used for xeromammography, the registrant shall perform or have performed the quality control tests listed below:
 - i. For the conditioner, tests for light leaks, temperature of relaxation oven, charging of the plate, and optimization for the kVp used shall be performed on each day the conditioner is used for mammography.
 - ii. For the processor, tests for light leaks, toner supply, back bias setting, and optimization for the kVp used shall be performed on each day the processor is used for mammography;
 - iii. Each cassette shall be cleaned and checked for dust particles and pressure artifacts every week; and
 - iv. Each selenium plate shall be examined for powder deficiency spots, powder efficiency spots, dark dusting, scratches, and artifacts on a monthly basis;
10. For each mammography unit, the registrant shall ensure that the following image quality assessments are performed:
 - i. A phantom is used whose image can be quantitatively scored;
 - ii. For fixed units, mammographic phantom image quality is tested monthly;
 - iii. For mobile units and motor vehicle mounted units, mammographic phantom image quality is tested after each relocation and at least monthly.

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Equipment must be recalibrated prior to use to maintain quality of the phantom image; and

- iv. At least one test phantom image for each mammography unit is maintained for each month of the current calendar year and for the preceding year. The registrant shall also maintain at least one phantom image a year for each mammography unit beginning from the year of installation;
11. Repeat analysis shall be performed at least quarterly for film-screen mammography and xeromammography; and
 12. Technique charts or standard settings of factors such as density, kVp, focal spot selection, listing of all factors appropriate to the design of the mammography unit shall be posted either next to or on each mammography unit.

7:28-15.5 Medical fluoroscopic x-ray systems

- (a) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.
- (b) No person shall operate or permit the operation of certified or uncertified fluoroscopic x-ray equipment used in the healing arts unless the equipment meets the following requirements:
 1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-to-image receptor distance.
 - i. The x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam. Radiation therapy simulator systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required to be in the manufacturer's specifications manual and provides the registrant with precautions concerning the importance of remote control operation.
 - ii. The exposure rate due to transmission through the primary protective barrier with an attenuation block in the useful beam combined with the radiation from the image intensifier, if provided, shall not exceed 5.2 E-6 Coulombs per kilogram (two milliroentgens per hour) at 10 centimeters (four inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per

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minute of entrance exposure rate. The attenuation block shall be a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters (eight inches by eight inches by 1.5 inches), of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation. Radiation therapy simulator systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required to be in the manufacturer's specifications manual and provides the registrant with precautions concerning the importance of remote control operation.

- iii. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier, if provided, shall be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (eight inches). If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (12 inches) 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 centimeters (12 inches). 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 centimeters (four inches) from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly. For C-arm fluoroscopy equipment, the measurement shall be made with the end of the beam-limiting device at the minimum SID and the attenuation block not closer than 30 centimeters (12 inches) from the imaging assembly.
 - iv. For uncertified fluoroscopic equipment only, the fluoroscopic screen shall be covered with a transparent protective material such that under normal operating conditions the dose rate measured five centimeters from the viewer's side of the screen shall not be more than 20 milliroentgens per hour (5.2 E-6 Coulombs per kilogram) without a patient and with the screen 20 centimeters (eight inches) from the tabletop or panel;
2. For fluoroscopic equipment that does not have image intensification the following field limitation requirements shall be met:
 - i. The x-ray field shall not extend beyond the visible area of the image receptor;
 - ii. Means shall be provided for stepless adjustment of the field size;

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- iii. The minimum field size at the greatest SID shall be equal to or less than five centimeters by five centimeters (two inches by two inches); and
 - iv. Equipment manufactured after February 25, 1978, which permits a variable angle between the image receptor and the axis of the x-ray beam shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
3. Except for fluoroscopic systems used for radiation therapy simulation, image-intensified fluoroscopic equipment shall meet the following field limitation requirements:
- i. Neither the length nor the 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 three percent of the SID;
 - ii. The sum of the excess length and the excess width shall be no greater than four percent of the SID.
Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor;
 - iii. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined by comparison of the length and width of the x-ray field with the diameter of the visible area of the image receptor which parallels each;
 - iv. Equipment manufactured after February 25, 1978, in which the angle between the image receptor and beam axis is variable, shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
 - v. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters (46.5 square inches) shall be provided with a means for stepless adjustment of the x-ray field;
 - vi. Equipment with a fixed SID and a visible area of 300 square centimeters (46.5 square inches) or less shall be provided with either stepless adjustment of the x-ray field or with some other means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters (19.4 square inches) or less;

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- vii. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters (two inches by two inches) or less; and
 - viii. Fluoroscopic x-ray equipment that automatically adjusts the field size as the SID is changed may be provided with a capability 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 "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE";
4. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in progress;
 5. Fluoroscopic equipment which is provided with automatic exposure rate control or with both automatic exposure rate control and manual mode (dual mode units) shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of 10 Roentgens per minute (2.6 E-3 Coulombs per kilogram per minute) at the point where the center of the useful beam enters the patient except:
 - i. During the recording of fluoroscopic images; or
 - ii. When an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of 5 Roentgens (1.3 E-4 Coulombs/kilogram/minute) at the point where the center of the useful beam enters the patient unless the high-level control is activated;
 6. Fluoroscopic equipment which is not provided with automatic exposure rate control (manual mode) shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of five Roentgens per minute (1.3 E-4 Coulombs/kilogram/minute) at the point where the center of the useful beam enters the patient, except:
 - i. During recording of fluoroscopic images; or
 - ii. When an optional high-level control is activated;

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7. For equipment provided with high-level control, the following requirements shall be met:
 - i. Special means of activation of high-level controls shall be required (for example, two-step foot pedal);
 - ii. Continuous manual activation of the high-level control shall be provided by the operator; and
 - iii. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed;
8. Measuring compliance of entrance exposure rates shall be determined as follows:
 - i. When the source is below the table, the entrance exposure rate shall be measured one centimeter (0.4 inch) above the tabletop or cradle.
 - ii. When the source is above the table, the entrance exposure rate shall be measured at 30 centimeters (12 inches) above the tabletop with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.
 - iii. For stationary and mobile c-arm types of fluoroscopes, the entrance exposure rate shall be measured 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly.
 - iv. In a lateral type of fluoroscope, the entrance exposure rate shall be measured 15 centimeters (5.9 inches) 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 centimeters (5.9 inches) to the centerline of the x-ray table;
9. Fluoroscopic radiation therapy simulation systems are exempt from the entrance exposure rate requirements of (b)5 and (b)6 above;
10. The x-ray tube potential and current shall be continuously indicated to the operator and/or at the control panel during fluoroscopy and cinefluorography. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer;

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11. A means shall be provided to limit the source-to-skin distance to not less than 38 centimeters (15 inches) on stationary fluoroscopes and to not less than 30 centimeters (12 inches) on mobile and portable fluoroscopes.
 - i. Image-intensified fluoroscopes intended for specific surgical applications that would be impossible to perform at the source-to-skin distances specified above, may be operated at shorter source-to-skin distances but in no case less than 20 centimeters (eight inches);
12. The following requirements shall apply to a fluoroscopic timer:
 - i. A means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timer shall not exceed five minutes without resetting;
 - ii. The timer shall either terminate the exposure or emit a signal audible to the fluoroscopist when the exposure time reaches five minutes. Such signal shall continue to sound while x-rays are produced until the timer is reset; and
 - iii. As an alternative to the requirements of (b)12ii above, 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;
13. Mobile and portable fluoroscopes shall be provided with image intensification;
14. The fluoroscopy table that is provided with an undertable tube and a bucky shall have a bucky slot cover that provides protection equivalent to at least 0.5 millimeters of lead. Radiation therapy simulation systems are exempt from the requirements of this paragraph.
15. Protective shielding, such as a drape, shall be in place between the patient and fluoroscopist and shall provide protection equivalent to at least 0.5 millimeters of lead;
16. When a sterile field will not permit the use of the normal protective barriers, the requirements of (b)15 above may be omitted.
17. A mobile fluoroscopic unit used routinely in one location shall be considered a permanent installation and shall comply with the shielding and survey requirements in N.J.A.C. 7:28-15.10; and

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18. The following requirements shall apply to spot-film devices except when the spot-film device is provided for use with a radiation therapy simulator system:
 - i. A means shall be provided between the source and the patient which will automatically limit the x-ray field at the time the exposure is initiated to no more than that portion of the image receptor chosen by the operator on the spot-film selector. 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 such a mode of operation;
 - ii. Neither the length nor the 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 three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum of the differences in length and width, without regard to the sign, shall not exceed four percent of the SID. Spot-film devices manufactured after February 25, 1978, which permit a variable angle between the plane of the image receptor and beam axis, shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
 - iii. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent of the SID;
 - iv. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:
 - (1) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to provide, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, shall not exceed five by five centimeters (two by two inches); or
 - (2) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, each dimension of the minimum field size, and the greatest SID, shall not exceed five centimeters (two inches); and
 - v. 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

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shall be clearly labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

- (c) No person shall operate or permit the operation of medical fluoroscopic x-ray equipment used in the healing arts unless the registrant has developed and continuously implemented a quality assurance program that meets the requirements of N.J.A.C. 7:28-22, Quality Assurance Programs for Medical Diagnostic X-ray Installations.

Amended by R.2001 d.37, effective January 16, 2001

See: 32 N.J.R. 1459(a), 33 N.J.R. 292(b)

Added (l)

7:28-15.6 Radiation therapy simulators

- (a) No person shall operate or permit the operation of a radiation therapy simulator system unless it meets the requirements of this section and complies with all applicable requirements of this subchapter, unless otherwise exempted.
- (b) Operation of a radiation therapy simulator system on a patient shall be performed only by a licensed practitioner, a licensed radiation therapy technologist, or a licensed diagnostic x-ray technologist, as prescribed in N.J.A.C. 7:28-19.
- (c) No person shall operate or permit the operation of a radiation therapy simulator system unless it meets the following requirements:
 - 1. A quality assurance program has been established in collaboration with a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems, and implemented by the registrant to ensure congruence of the position and size of the simulated field with the position and size of the irradiation field.
 - i. The quality assurance program is consistent with, but not limited to, the guidelines established by the American Association of Physicists in Medicine, (AAPM) Report Number 13;
 - ii. The quality assurance program is documented by the registrant; and
 - iii. The quality assurance program records are maintained by the registrant for at least 36 months, and are available for review at the facility by the department during any inspection;
 - 2. Any radiation therapy simulator system, which uses a gantry rotation system when performing radiographic examinations, shall be equipped with a sensor

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mechanism that shall stop the gantry motion if necessary to prevent collision. This requirement shall take effect one year after the effective date of this subchapter.

- i. Restarting the unit shall only be possible when the cause of the termination has been determined and corrected and the sensor mechanism is satisfied that a collision reoccurrence is not possible.
 - ii. Tests of the operation of the anti-collision sensor mechanism are performed and results are documented by those individuals listed in (b) above or by a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems at intervals not to exceed 12 months. The records shall be maintained for at least 36 months, and shall be available at the facility for review by the department during any inspection. A true copy of these records shall be sent to the department upon request;
3. A dead-man switch and/or an emergency “off” control shall be located on the remote control console and also at all places in the simulator room from which motions are controlled;
4. A radiation therapy simulator system attached to a megavoltage radiation therapy x-ray system shall meet the following requirements:
 - i. Exposure controls shall be located outside the therapy room;
 - ii. The operator shall be able to view the patient from the control panel at all times during the procedure. The viewing system may consist of, but is not limited to, a window, mirror, or closed circuit television; and
 - iii. A method for two-way aural communication between the patient and the operator shall be provided at the control panel and shall be operable at all times when the system is in operation;
5. A superficial or orthovoltage therapy x-ray system shall not be used for radiation therapy simulation except for treatments given on this system; and
6. Protective aprons of at least 0.25 millimeters lead equivalent shall be worn by the operator or therapy physician during every instance in which entry into the simulator room is necessary while the patient exposure is in progress. Protective gloves of at least 0.25 millimeters lead equivalent shall be worn by the operator or therapy physician during every instance when the hands must be in the primary beam while the patient exposure is in progress. The exposure of such individuals shall be controlled by the use of shielding and

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protective clothing as necessary to ensure that they are not exposed to radiation doses in excess of those permitted by N.J.A.C. 7:28-6.

7:28-15.7 Computed tomography equipment

- (a) The provisions of this section are in addition to and not in substitution for the applicable sections of this subchapter.
- (b) No person shall operate or permit the operation of computed tomography equipment used in the healing arts unless the equipment meets the following requirements:
 1. The registrant shall maintain the technical and safety information supplied by the manufacturer as required by the Code of Federal Regulations at 21 C.F.R. 1020.33(c) near the control panel and produce it to the department during any inspection;
 2. The registrant shall ensure that a CT quality assurance phantom is available for testing the CT system. The use of the phantom and the physical properties of the phantom shall meet the following requirements:
 - i. Instructions on the use of the phantom shall be provided. The instructions shall include a schedule of tests appropriate for the CT system, the allowable variations for the test parameters, and a method to store the test results;
 - ii. Images of the phantom that demonstrate compliance with the CT's performance specifications shall be obtained on both film and digital archive media. These images shall be maintained and used to compare with current test results; and
 - iii. The phantom shall be capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measurement of the mean CT number of water or a reference material;
 3. The registrant shall ensure that a CT dosimetry phantom is available for testing the CT system. The use of the phantom and the physical properties of the phantom shall meet the following requirements:
 - i. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19 ± 0.01 grams per cubic centimeter;

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- ii. The phantom shall be at least 14 centimeters in length and shall have a diameter of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners);
 - iii. The phantom shall be at least 16.0 centimeters in diameter for any system designed to image the head (head scanner) or for any whole body scanner operated in the head scanning mode;
 - iv. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom; and
 - v. Any effect 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;
4. A visual indication of the conditions of operation to be used during a scan or scan sequence shall be indicated prior to initiation of a scan or 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 shall be visible from any position from which the scan can be initiated;
5. A means shall be provided to terminate the 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. A visible signal shall indicate when the x-ray exposure has been terminated by this means. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of the preset value through the use of either a backup timer or devices which monitor equipment function. Means shall be provided such that the exposure from the system does not exceed 100 mR/scan except when x-ray transmission data are being collected for use in image production or technique factor selection;
6. The operator shall be able to terminate the x-ray exposure at any time during a scan or during a series of scans under the x-ray system control of greater than one-half second exposure. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan;
7. A means shall be provided to permit visual determination of the location of the tomographic plane or a reference plane offset from the tomographic plane;

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8. If a device using a light source, including a laser source, is used to determine the location of the tomographic plane, this 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;
 9. The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for one-half second. Indicators at or near the housing of the scanning mechanism 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;
 10. For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-rays with a shutter, the radiation emitted shall not exceed 100 milliroentgens (2.6×10^{-2} Coulombs per kilogram) in one hour at any point five centimeters (two inches) outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimensions greater than 20 centimeters (eight inches);
 11. The deviation of indicated scan increment from actual scan increment shall not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass of 100 kilograms or less on the patient support. The patient support shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters (12 inches), whichever is less, and then returned to the starting position;
 12. The distance between the indicated location of the tomographic plane or reference plane and its actual location may not exceed five millimeters; and
 13. An emergency off switch shall be available at the control panel and in the CT room.
- (c) No person shall operate or permit the operation of computed tomographic equipment unless the facility meets the following:
1. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; and
 2. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be

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so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means, such as a closed-circuit television, an alternate viewing system, which may also be electronic, shall be provided to permit continuous observation of the patient during irradiation in the event of failure of the primary viewing system.

- (d) No person shall operate or permit the operation of computed tomography x-ray equipment used in the healing arts unless the following operating conditions are met:
1. The CT system shall not be operated except by a licensed individual who has been specifically trained in its operation;
 2. Information shall be available near the control panel regarding the operation and calibration of the system. That information shall contain:
 - i. Dates of the latest calibration and spot checks and the location within the facility where the results of these tests may be obtained;
 - ii. Instructions on the use of the phantom(s), including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent tests conducted on the system; and
 - iii. A technique chart for each predetermined scan protocol shall be available at the control panel; and
 - iv. No person shall operate or permit the operation of computed tomography equipment used in the healing arts unless the registrant has developed and continuously implemented a quality assurance program that meets the requirements of N.J.A.C. 7:28-22, Quality Assurance Programs for Medical Diagnostic X-ray Installations.

Amended by R.2001 d.37, effective January 16, 2001

See: 32 N.J.R. 1459(a), 33 N.J.R. 292(b)

Rewrote this section

7:28-15.8 Medical cabinet x-ray systems

- (a) The requirements of this section are in addition to and not in substitution for the applicable requirements in N.J.A.C. 7:28.
- (b) No person shall operate or permit the operation of a medical cabinet x-ray system used in the healing arts unless it meets the following requirements:

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1. The registrant shall ensure and document that the operator has received a copy of the operator's manual, has been trained in the operating procedures for the system, and has demonstrated competence in operating the system to the registrant. This documentation shall be available to the department for review during any inspection. The registrant shall maintain a copy of the operator's manual in the proximity of the system;
2. Radiation emitted from the medical cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgens in one hour at any point five centimeters outside the external surface;
3. No medical cabinet x-ray system shall be placed into operation until the registrant demonstrates that a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment has determined that the exposure level in (b)2 above is not exceeded. Where an operating system is subsequently modified, repaired, or moved to a new location, the unit shall not be used until a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment has determined compliance with this limit. The registrant shall maintain the original report(s) at the facility, and make the report(s) available to the Department during any inspection. The registrant shall submit a copy of the report(s) to the department within 30 days of the date the determination has been completed.
4. Safety interlocks shall be provided on medical cabinet x-ray systems as follows:
 - i. Each door of a cabinet x-ray system shall have a minimum of two safety interlocks installed in such a manner that the opening of any door would disconnect the energy supply circuit to the high-voltage generator;
 - ii. Each access panel on a cabinet x-ray system shall have at least one safety interlock;
 - iii. Following interruption of the energy supply circuit by the functioning of any safety interlock, a manually reset control switch shall be activated before x-ray production can resume;
 - iv. Failure of any single component of the medical cabinet x-ray system shall not cause failure of more than one required safety interlock; and
 - v. Safety interlocks shall be tested for operation at intervals not to exceed six months. A record of these tests shall be maintained for review by the department during any inspection;

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5. A medical cabinet x-ray system shall have a permanent floor, which means the underside external surface of the cabinet;
6. There shall be permanently affixed or inscribed on the medical cabinet x-ray system at the location of any controls which can be used to initiate x-ray production a clearly legible and visible label bearing the statement or words having a similar meaning: “CAUTION: X-RAYS PRODUCED WHEN ENERGIZED”; and
7. All medical cabinet systems shall be provided with the following controls and indicators:
 - i. A key-activated control to insure that x-ray production is not possible with the key removed;
 - ii. A control button or control switch to initiate and terminate the production of x-rays other than by the functioning of a safety interlock or the main power control;
 - iii. A warning light at the control button or control switch that indicates when and only when x-rays are being produced. This light shall be clearly labeled with the words: “X-RAY ON”;
 - iv. A warning light which indicates when and only when x-rays are being produced. This warning light shall be visible from each door, access panel, and port, and shall be clearly labeled with the words: “X-RAY ON”; and
 - v. A means to indicate the kilovoltage, current and time during the production of x-rays at each x-ray control button or control switch unless the x-ray tube current is preset.

7:28-15.9 Individual radiation safety

- (a) No person shall operate or permit the operation of certified or uncertified medical radiographic and fluoroscopic equipment or therapy simulation systems unless the following conditions are met:
 1. Only individuals required for the medical procedure, for training, or for equipment maintenance shall be in the radiographic or fluoroscopic or therapy simulator room during an exposure.
 - i. Individuals who are present in a radiographic or fluoroscopic or therapy simulator room during any exposure shall wear protective aprons of at least 0.25 mm lead equivalent during every exposure.

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- ii. Protective gloves of at least 0.25 mm lead equivalent shall be worn by the fluoroscopist and assistant(s) during every examination when it is required that their hands be placed in the useful beam;
2. When a patient must be provided with auxiliary support during a radiation exposure and mechanical holding devices are insufficient, the following procedures shall be followed:
 - i. The person holding the patient shall be protected with a lead apron of at least 0.25 mm lead equivalent;
 - ii. The person holding the patient shall be protected with lead gloves of at least 0.25 mm lead equivalent if the hands must be placed in the useful beam;
 - iii. No licensed practitioner shall order or otherwise cause an individual who is licensed pursuant to N.J.S.A. 26:2D and this chapter to hold a patient during a radiation exposure, except in a life-threatening situation;
 - iv. No person shall be employed, routinely assigned, or required to hold a patient during radiographic and fluoroscopic procedures;
 - v. If a patient must be held during the x-ray exposure, non-radiation workers such as aides, orderlies, nurses, or members of the patient's family may be asked to perform this duty; and
 - vi. No person other than the patient shall hold the film during the exposure;
3. Gonadal shielding of not less than 0.5 mm lead equivalent shall be used on a patient during radiographic and fluoroscopic procedures, except for cases in which this would interfere with the diagnostic procedure. If the patient is sterile, the use of gonadal shielding may be omitted;
4. The operator shall collimate x-ray units that do not have positive beam limitation to ensure that the x-ray field does not extend beyond the image receptor;
5. The radiographic field shall be restricted to the area of clinical interest as far as practical;
6. A method to observe the patient during the x-ray exposure shall be provided for all units. Observation of the patient shall be made from the shielded area;

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7. During radiographic exposures, the operator shall stand behind the protective barrier;
8. The registrant shall provide written safety rules to each individual operating x-ray equipment including any restrictions as to the operating technique required for the safe operation of the particular x-ray apparatus, and require that the operator sign a form acknowledging that the safety manual was read. These safety rules and restrictions shall be made available for review by the Department during any inspection;
9. No person shall permit or arrange for the intentional irradiation of a human being except for the purpose of medical diagnosis or treatment;
10. No person shall deliberately expose an individual to the useful beam for the sole purpose of training or demonstration; and
11. No person shall operate an ionizing-radiation-producing machine unless that person understands and uses the principles of radiation safety to keep radiation exposure as low as reasonably achievable.

7:28-15.10 Structural shielding and radiation safety surveys

- (a) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless permanent structural shielding and/or protective barriers are used as necessary to ensure that no person other than the patient being examined receives a dose in excess of the limits specified in N.J.A.C. 7:28-6.
- (b) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless the survey requirements listed below are met. To the extent that this section imposes more stringent requirements than the survey requirements in N.J.A.C. 7:28-7 and recordkeeping requirements in N.J.A.C. 7:28-8, the requirements of this section shall be followed.
 1. The registrant of a medical ionizing-radiation-producing machine shall ensure that a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulators performs or supervises the performance of a radiation safety survey of the environs and submits a copy of the radiation safety survey report to the Department within 60 days of the date the machine is acquired. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available to the Department during any inspection.
 2. The registrant of a medical ionizing-radiation-producing machine shall ensure that a qualified individual for the performance of surveys for diagnostic x-ray equipment and therapy simulator systems performs or supervises the

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performance of a radiation safety survey of the environs when changes have been made to shielding, equipment, or equipment location which affect the radiation levels of the environs. A copy of the survey report shall be submitted to the Department within 60 days of the date of such change. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available to the Department during any inspection.

3. The minimum requirements for the information to be included in the radiation safety survey report are as follows:
 - i. The name of the registrant of the installation as listed on form VRH-001, address, telephone number, and room location of the unit;
 - ii. The New Jersey Registration Number, if available;
 - iii. The manufacturer, model number, generator serial number, control panel serial number, tube manufacturer, tube serial number, and tube housing number;
 - iv. The name and address of the qualified individual performing the survey;
 - v. The date of survey;
 - vi. The survey instrument manufacturer, model number, and date calibrated;
 - vii. A diagram or floor plan of the area indicating the x-ray tube location, exposure switch location, normal operator position, lead shielding if present, wall, floor, and ceiling construction, labeling all areas adjacent to the exposure room including those above and below, and labeling of all areas as to occupancy and use;
 - viii. Records of the measurement of radiation exposure with a suitable phantom in the average patient position.
 - x. Measurements shall be taken at the operator's position and at all nearby locations which are normally occupied. For each measurement, the kVp, mA, exposure time, instrument reading, and correction made to the instrument reading (such as energy response, calibration, etc.) shall be recorded; and
 - ix. Exposure rates at each measured location shall be converted into Coulombs/kilogram/week or mR/week. Records shall include all assumptions of workload, use and occupancy factors used in the calculations.

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7:28-15.11 Prohibited installations

- (a) No person shall operate, permit to be operated, maintain or display in working condition any of the following:
1. Shoe-fitting fluoroscopic devices.
 2. Chest photofluorographic machine after one year from the effective date of these rules.
 3. Fixed vertical systems designed for non-image intensified fluoroscopy used for radiography after October 18, 1994;
 4. Uncertified fluoroscopic equipment that does not have image intensification after October 18, 1994; or
 5. Hand-held fluoroscopic screens.

7:28-15.12

- (a) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.
- (b) No person shall operate or permit the operation of any x-ray bone densitometer equipment used in the healing arts unless the registrant ensures that the equipment is operated in such a manner as to meet the manufacturer's specifications.
- (c) The registrant shall maintain a copy of the manufacturer's specifications and the operator's manual at the facility.
- (d) The registrant shall ensure that the operator is trained in the operating procedures for the x-ray bone densitometer equipment.
- (e) No person shall operate or permit the operation of x-ray bone densitometer equipment used in the healing arts unless the registrant has developed and continuously implemented a quality assurance program that meets the requirements of N.J.A.C. 7:28-22, Quality Assurance Programs for Medical Diagnostic X-ray Installations.

Amended by R.2001 d.37, effective January 16, 2001

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See: 32 N.J.R. 1459(a), 33 N.J.R. 292(b)
Former N.J.A.C. 7:28-15.12, Severability, recodified to N.J.A.C. 7:28-15.13

7:28-15.13 Severability

If any provision of this subchapter or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the subchapter, which can be given effect without the invalid provision or application, and to this end, the provisions of this subchapter are declared to be severable.

Recodified from N.J.A.C 7:28-15.12 by R.2001 d.37, effective January 16, 2001.
See: 32 N.J.R. 1459(a), 33 N.J.R. 292(b).