

PART V

X-RAY IN THE HEALING ARTS

64E-5.501 Definitions. As used in this part, the following definitions apply:

- (1) "Accessible surface" means the external surface of any enclosure or housing
- (2) "Added filtration" means any filtration which is in addition to the inherent filtration.
- (3) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same degree of radiation attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.
- (4) "Assembler" means any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.
- (5) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.
- (6) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation. See also "Phototimer".
- (7) "Barrier". See "Protective barrier".
- (8) "Beam axis" means a line from the source through the centers of the x-ray field.
- (9) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field, except for beam-blocking or beam-shaping devices used in radiation therapy.
- (10) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.
- (11) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (12) "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.
- (13) "Certified system" means any x-ray system which has one or more certified components.

- (14) "Changeable filters" means any filter which can be readily removed from the useful beam through any electronic, mechanical or physical process.
- (15) "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.
- (16) "Control panel" means that 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 and operating modes.
- (17) "Cooling curve" means the graphical relationship between the heat units stored and cooling time.
- (18) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- (19) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
- (20) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body as an aid to diagnosis through visualization of anatomical parts.
- (21) "Direct scattered radiation" means that radiation which has been deviated in direction only by materials irradiated by the useful beam. See also "Scattered radiation".
- (22) "Entrance exposure rate" means the roentgens (C per kg) per unit time at the point where the center of the useful beam enters the patient.
- (23) "Equipment". See "X-ray equipment".
- (24) "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.
- (25) "Filter" means material placed in the useful beam to preferentially absorb selected radiation.
- (26) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot film device, equipment housings, electrical interlocks, if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.
- (27) "General purpose radiographic x-ray system" means any diagnostic radiographic x-ray system, except computed tomography systems, which, by design, is not limited to radiographic examination of a specific anatomical region.
- (28) "Gonad shield" means a primary protective barrier for the testes or ovaries.

- (29) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- (30) "Healing arts self-referral" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purposes of diagnosis or medical treatment.
- (31) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, seconds, and a quality factor dependent on the voltage wave form (QF=1 for single phase, 1.35 for three phase) or kVp x mA x seconds x QF.
- (32) "Image intensifier" means a device, when installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
- (33) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further electronic or chemical transformations.
- (34) "Image receptor support" means that part of a mammographic system designed to support the image receptor in a horizontal plane during the mammographic examination.
- (35) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the x-ray tube housing assembly.
- (36) "Irradiation" means the exposure of matter to ionizing radiation.
- (37) "Kilovolts peak(kVp)". See "Peak tube potential".
- (38) "kV" means kilovolts.
- (39) "kWs" means kilowatt second. It is equivalent to kV x mA x seconds x 10⁻³.
- (40) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (41) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly, except for the useful beam and radiation produced when the exposure switch or timer is not activated.
- (42) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

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- (a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being ten milliamperere seconds(10 mAs) or the minimum obtainable from the unit, whichever is larger.
- (b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
- (c) For all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.
- (43) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- (44) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation: $\text{Percent line-voltage regulation} = 100(V_n - V_1)/V_1$ where V_n = no-load line potential and V_1 = load line potential.
- (45) "mAs" means milliamperere second.
- (46) "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
- (47) "Mobile x-ray equipment". See "X-ray equipment".
- (48) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- (49) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- (50) "Photofluorographic" means an x-ray system designed to superimpose a patient's anatomical x-ray image from a fluoroscopic input phosphor onto a film strip through a system of lenses.
- (51) "Phototimer" means a device for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is energized. See also "Automatic exposure control".
- (52) "Portable x-ray equipment". See "X-ray equipment".

- (53) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.
- (54) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.
- (55) "Primary protective barrier". See "Protective barrier".
- (56) "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.
- (57) "Protective barrier" means a barrier containing radiation absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:
- (a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure by a required degree, for protection purposes.
 - (b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation by a required degree, for protection purposes.
- (58) "Protective glove" means a glove made of radiation absorbing material and used to reduce radiation exposure.
- (59) "Qualified person" means an individual who has the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.
- (60) "Radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring single or multiple quantities of incident radiation.
- (61) "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.
- (62) "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.
- (63) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.
- (64) "Radiological physicist" means an individual who meets one of the following criteria:
- (a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x and gamma ray physics; or

- (b) Has a bachelor's degree in a physical science or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - (c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics or engineering; has had one year of full-time training in therapeutic radiological physics; and has had one year of full-time work experience in a radiotherapy facility where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - (d) Has performed radiation physics work for a period of at least ten years full time, prior to the effective date of these rules, in the field of therapeutic radiological physics in radiotherapy facilities where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.
- (65) "Rating" means the operating limits of a component as specified by the component manufacturer.
- (66) "Recording" means producing a permanent form of an image resulting from x-ray photons, such as film or video tape.
- (67) "Registrant", as used in this part and in Parts IV, VI and VIII, means any person who possesses and administratively controls an x-ray system or other radiation producing machine and is required by the provisions in Part I to register with this department.
- (68) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.
- (69) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. See "Direct scattered radiation".
- (70) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system
- (71) "Secondary protective barrier". See "Protective barrier".
- (72) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
- (73) "Source" means the focal spot of the x-ray tube.

- (74) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
- (75) "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.
- (76) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- (77) "Spot-film device" means a device intended to transport 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.
- (78) "SSD" means the distance between the source and the skin of the patient.
- (79) "Stationary x-ray equipment". See "X-ray equipment".
- (80) "Stray radiation" means the sum of leakage and scattered radiation.
- (81) "Technique factors" means the conditions of operation. They are specified as follows:
- (a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
 - (b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
 - (c) 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.
- (82) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
- (83) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- (84) "Tube" means an x-ray tube, unless otherwise specified. See "X-ray tube".
- (85) "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.
- (86) "Tube rating chart" means the set of curves provided by the manufacturer which specify the rated limits of operation of the tube in terms of the technique factors.

- (87) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.
- (88) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.
- (89) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- (90) "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
- (91) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.
- (92) "X-ray equipment" means an x-ray system, subsystem or component thereof.
- (a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
 - (b) "Portable" means x-ray equipment designed to be hand-carried.
 - (c) "Stationary" means x-ray equipment which is installed in a fixed location.
 - (d) "Special Purpose" means x-ray equipment or a system designed for radiographic examinations of a specific anatomical area of the human body utilizing image receptors of more than one size; for example, the head or the spinal column.
- (93) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- (94) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube, high-voltage switches, electrical protective devices and other appropriate elements.
- (95) "X-ray system" means an assemblage of components for the controlled production of x-rays. It minimally 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.

- (96) "X-ray subsystem" means any combination of two or more components of an x-ray system.
- (97) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.
- (98) "Medical physicist" means a person who practices the branch of physics that is associated with the practice of medicine.
- (99) "Clinical image" means a radiograph.
- (100) "Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Specific Authority: 404.051, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), F.S.

History: New July 17, 1985, amended April 4, 1989.,

Amended November 20, 1994, Amended January 5, 1995, Amended , May 15, 1996, Formerly 10D-91.602

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64E-5.502 General Requirements.

(1) Administrative Controls.

- (a) Registrant. The registrant shall be responsible for directing the operation of the x-ray systems which are subject to registration as described in 64E-5.511. The registrant or the registrant's agent shall assure that the following requirements are met in the operation of the x-ray system.
1. Any x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes unless the department determines that such operation will not endanger the public health, safety and welfare.
 2. Individuals who will be operating any x-ray system shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. Nonphysician operators of medical x-ray systems shall be certified in accordance with 64E-3, FAC.
 3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel, which specifies techniques and procedures to be used for all examinations performed by that system.
 4. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
 - b. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
 - c. Other patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the useful beam.
 - d. When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one-fourth of the maximum permissible dose as defined in Part III, additional protective devices may be required by the department.

5. Gonad shields of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
6. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits the following:
 - a. Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and a proper prescription has been provided.
 - b. Exposure of an individual for the purpose of healing arts self-referral program except when authorized by 64E-5.502(1)(a)10.
 - c. Advertisement of free x-ray examinations unless the advertisement states that a determination of need will be made prior to the x-ray examination.
7. When a patient or film must be provided with auxiliary support during a radiation exposure:
 - a. Mechanical holding devices shall be used when the technique permits;
 - b. Written safety procedures shall be available to indicate the requirements for selecting a holder, list the individual projections where holding devices cannot be used and describe the procedure the holder shall follow;
 - c. The human holder shall be protected as required by (1)(a)4., above; and,
 - d. No individual shall be used routinely to hold film or patients.
8. Exposure Procedures Designed to Minimize Patient and Personal Exposure
 - a. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.
 - b. The radiation exposure to the patient shall be the minimum required to produce images of good diagnostic quality.

- c. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.
- d. X-ray systems subject to 64E-5.505 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

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- e. A person shall not perform fluoroscopic imaging or otherwise expose a human to x-rays from a fluoroscopic system unless the person is a:
 - (I) Licensed practitioner as that term is defined in section 468.301, Florida Statutes; or
 - (II) Certified radiologist assistant practicing in accordance with the requirements of Chapter 468, Part IV, Florida Statutes; or
 - (III) Certified general radiographer practicing in accordance with the requirements of Chapter 468, Part IV, Florida Statutes; and
 - (A) The general radiographer has been trained and authorized in writing by the licensed practitioner in charge to perform the specified imaging; and
 - (B) The specified imaging does not rely upon the general radiographer to provide any diagnostic interpretation, or to determine suspicious areas for additional imaging, or to otherwise modify the scope of authorization for the imaging; and
 - (C) The specified imaging is designed to prevent or reduce exposure to patients by facilitating proper location and positioning for the authorized radiographic imaging.

- 9. Personnel Monitoring. All individuals who are associated with the operation of an x-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses stated in 64E-5.304 and 64E-5.308, FAC. In addition, when protective clothing or devices are worn on portions of the body and a personnel monitoring device is required, at least one such device shall be utilized as follows:
 - a. When a protective apron is worn, the monitoring device shall be worn at the collar outside of the apron
 - b. The dose to the whole body shall be recorded in the records required by 64E-5.339, FAC. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

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- 10. Healing arts self-referral. Only healing arts self-referral programs for mammography screening will be authorized by the department.

- (b) Information and Maintenance Records and Associated Information. The registrant shall maintain at least the following information for each x-ray system:
 - 1. Tube rating charts and cooling curves.
 - 2. Record of surveys, calibrations, maintenance, modifications from the original schematics and drawings performed on the x-ray machine along with the names of persons who performed the service.
 - 3. A copy of all correspondence with the department regarding each x-ray system.
 - 4. An x-ray log containing the patient's name, the type of examination and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
 - (c) Maintenance of x-ray Equipment. X-ray systems and accessory devices shall be maintained in good working condition, both mechanically and electrically, so that the clinical objectives may be fulfilled without risk of unproductive exposure due to equipment failure or malfunction.
- (2) Shielding.
- (a) Each x-ray facility shall have primary and secondary protective barriers as needed to assure that an individual will not receive a radiation dose in excess of the limits specified in Part III of these regulations.
 - (b) Structural shielding in walls and other vertical barriers required for personnel protection shall extend without breach from the floor to a height of at least seven feet (2.1 m).
 - (c) Doors, door frames, windows and window frames shall have the same lead equivalent shielding as that required in the wall or other barrier in which they are installed.
 - (d) In computation of protective barrier requirements, the maximum anticipated workload, use factors, occupancy factors and the potential for radiation exposure from other sources shall be taken into consideration.

- (e) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-ray energies of 200 keV and above for diagnostic or therapeutic purposes shall be submitted to the department for review and approval.
1. The plans shall show, as a minimum, the following:
 - a. The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
 - b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room concerned.
 - c. The dimensions of the room concerned.
 - d. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest area where it is likely that individuals may be present.
 - e. The make and model of the x-ray equipment and the maximum technique factors.
 - f. The type of examinations or treatments which will be performed with the equipment.
 2. Information on the anticipated maximum workload of the x-ray system.
 3. If the services of a qualified person have been utilized to determine the shielding requirements, a copy of the report, including all basic assumptions used, shall be submitted with the plans.
- (3) X-ray Film Processing Facilities and Practices.
- (a) Processing Facilities. Each installation using a radiographic x-ray system shall provide suitable equipment for handling and processing radiographic film in accordance with the following provisions:
 1. The area in which undeveloped films are handled for processing shall be devoid of light with the exception of light in the wave lengths having no significant effect on the radiographic film.
 2. Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

3. Darkrooms used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.
4. Where film is developed manually,
 - a. At least one tri-sectional tank made of mechanically rigid, corrosion resistant material shall be utilized; and
 - b. The temperature of each solution shall be maintained within the range of 60 °F to 80 °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships specified by the film manufacturer, or, in the absence of such recommendations by the film manufacturer, with the following time temperature chart:

TIME-TEMPERATURE CHART		
Thermometer Reading		Minimum Developing Time (minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½
20.6	69	4 ½
20.0	68	5
19.4	67	5 ½
18.9	66	5 ½
18.3	65	6
17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

- c. Devices shall be utilized which will:
 - (I) Indicate the actual temperature of the developer; and
 - (II) Signal the passage of a preset time as short as two minutes.

(b) Precautionary Practices.

1. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
2. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.
3. Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.
4. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.
5. Safe light and darkroom fog shall be such that, when a radiographic film is exposed to radiation to achieve a density of 1.0 and is exposed for one minute on any darkroom working surface, the film shall not have a density change greater than 0.1.

(c) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of nonuse, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good diagnostic film quality.

(d) Radiographic Film Quality.

1. Developed radiographs of patients or phantoms shall have an optical density of 0.5 to 2.0 in the area of clinical interest to allow for diagnostic interpretation of the image, unless justified due to special circumstances. Radiographs which provide the necessary diagnostic information shall not be repeated for the sole purpose of meeting the stated density range.
2. Radiographic film used for diagnostic purposes shall be free from light fog and artifacts.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

R7 Law Implemented: 404.051, 404.081, 404.141, 404.22, F.S.

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R7 Amended January 1, 1995, Formerly 10D-91.603, Amended May 18, 1998, Amended August 16, 2007.

64E-5.503 General Requirements for All Diagnostic X-ray Systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

- (1) Warning label. The main control panel and all auxiliary control panels of the x-ray system shall bear the equivalent warning statement, legible and accessible to view, "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
- (2) Battery Charge Indicator. Visual means shall be provided on the control panel of battery-powered x-ray generators to indicate whether the battery is in a state of charge adequate for proper operation.
- (3) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC per kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (4) Radiation from Components Other than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens (0.516 μC per kg) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (5) Beam Quality.
 - (a) Half-value Layer. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown below. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed below, linear interpolation or extrapolation may be made.

Design Operating Range (kVp)	Measured Potential (kVp)	Half-value Layer (mm of Al)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	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

- The above HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown below:

Filtration Required vs. Operation Voltage	
Operating Voltage (kVp)	Total Filtration (inherent plus added)
Below 50	0.5 mm Al equivalent
50 to 70	1.5 mm Al equivalent
Above 70	2.5 mm Al equivalent

- Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.
- For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure
- The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient.
- In addition to the requirements of (5)(a)1., above, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

- (b) Filtration Controls. For x-ray systems which have variable kVp and changeable filters, and which are used for low filtration techniques, a positive means shall be provided that will prevent an exposure unless the minimum required amount of filtration is in the useful beam for the selected kVp.
- (6) Aluminum equivalent of material between patient and image receptor. The aluminum equivalent of each of the items listed below, which are used between the patient and image receptor, shall not exceed the indicated limits. This requirement is applicable to the front panel of cassette holders and film changers provided by the manufacturer for purposes of patient support or to prevent foreign object intrusions. It does not apply to such items as a screen and its associated mechanical support panel or grids.

Item	Maximum Aluminum Equivalent
Front panel of cassette holder (total of all)	1.0 mm
Front panel of film changer (total of all)	1.0 mm
Stationary tabletop	1.0 mm
Movable tabletop (including stationary subtop)	1.5 mm
Cradle Above 70	2.0 mm

- (7) Multiple Tube Heads. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the selected tube housing assembly.
- (8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.
- (9) Technique Indicators.
- (a) Each x-ray system shall be equipped with devices, such as labeled control settings or meters, correctly indicating the physical factors and modes of operation used for exposures. x-ray systems utilizing arbitrary number or letter designators for kVp, time and milliamperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.
- (b) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

- (c) On equipment having fixed technique factors, the requirement in (9)(a), above, may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of fluoroscopy or spot films made by the fluoroscopist.
- (d) Reproducible technique factor indicators may be relabeled to meet the accuracy requirements of this part. Such relabeling shall be conspicuous and clearly legible and shall be utilized by the registrant in setting technique factors.
- (10) Accuracy of Technique Factors. Meters, labeled control settings, exposure time selectors and other physical factor indicators shall be accurate within the following tolerances:
- (a) Milliamperage (mA) for Radiographic: $\pm 10\%$
- (b) Milliamperage (mA) for Fluoroscopic: ± 0.2 mA
- (c) Kilovolt peak (kVp): $\pm 5\%$
- (d) Timer at settings
1. Greater than ten seconds: \pm one second
 2. Ten seconds or less: $\pm 10\%$
- (11) Timer Reproducibility. When four timer tests are performed at the same timer settings, the average time period (T_{mean}) shall be greater than or equal to 12 times the maximum time period (T_{max}) less the minimum time period (T_{min}). Expressed mathematically, $T_{\text{mean}} \geq 12 (T_{\text{max}} - T_{\text{min}})$.
- (12) Exposure Reproducibility. The x-ray exposure produced by radiographic systems shall be reproducible to within the following criteria: When all technique factors are held constant and four or more exposures at the same technique factors are made, the value of the average exposure (E_{mean}) shall be greater than or equal to 12 times the quantity of maximum exposure (E_{max}) minus the minimum exposure (E_{min}). Expressed mathematically, $E_{\text{mean}} \geq 12 (E_{\text{max}} - E_{\text{min}})$.
- (13) Exposure Linearity. The x-ray output produced by radiographic systems utilizing means other than automatic exposure controls shall be linear to within the following criteria:
- (a) When a choice of two or more current settings (mA) or current-time product settings (mAs) may be selected and where $X_{1\text{mean}}$ and $X_{2\text{mean}}$ are the average mR per mAs values obtained from four exposures on each of two mA or mAs settings at a fixed tube potential (kVp) setting, within the range of 40 to 100 percent of the maximum tube rating, the average of four exposures (mR) for a given milliamperere-second (mAs) product in mR per mAs shall not differ by more than:

1. Five hundredths times the sum of any two consecutive mA or mAs averaged settings; expressed mathematically,
$$|X_{1\text{mean}} - X_{2\text{mean}}| \leq 0.05 (X_{1\text{mean}} + X_{2\text{mean}});$$
 and
 2. One tenth times the sum of any other two mA or mAs averaged settings; expressed mathematically,
$$|X_{1\text{mean}} - X_{2\text{mean}}| \leq 0.10 (X_{1\text{mean}} + X_{2\text{mean}});$$
- (b) Equipment, which after calibration cannot be made to meet the requirements of (13)(a) above, may be relabeled to indicate the effective mA or mAs, providing that use of such relabeled stations will meet the requirements of (13)(a), above.
- (c) Equipment, which after calibration cannot be made to meet the requirements of (13)(a) or (b) above, shall not be used unless written approval is obtained from the department. Approval shall not be granted when the linearity determination exceeds the federal standard for certified systems.
- (14) Automatic Exposure Controls. When automatic exposure control is provided
- (a) Indication shall be made on the control panel when this mode of operation is selected.
 - (b) When the x-ray tube potential is greater than or equal to 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be less than or equal to a time interval equivalent to two pulses.
 - (c) The minimum exposure time for all equipment other than that specified in (14)(b), above, shall be less than or equal to 1/60 second or a time interval required to deliver five mAs, whichever is greater.
 - (d) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure.
 - (e) A visible signal shall indicate when an exposure has been terminated at the limits described in (14)(d), above, and manual resetting shall be required before further automatically timed exposures can be made.

- (f) Exposure Linearity. When a choice of two or more tube current settings (mA) may be selected, the average of four consecutive exposures ($E_{1\text{mean}}$) made at any one tube current setting minus the average of four consecutive exposures ($E_{2\text{mean}}$) made at any other tube current setting shall be less than or equal to 0.05 times the sum of the two averages. Expressed mathematically, $|E_{1\text{mean}} - E_{2\text{mean}}| \leq 0.05 (E_{1\text{mean}} + E_{2\text{mean}})$. Measuring compliance for the above shall be based on the following criteria:
1. An attenuation block as described in 64E-5.501(5) shall be in the useful beam.
 2. Exposure (mR) shall be measured on the exit side of the attenuation block.
 3. The tube potential (kVp) shall be maintained at a fixed setting within the range of 40 to 100 percent of the maximum tube rating.
- (15) Beam Limiting Devices.
- (a) Beam limiting devices capable of restricting the useful beam to the area of clinical interest shall be used during exposures.
 - (b) Beam limiting devices shall provide a degree of attenuation not less than that required for the tube housing.
- (16) Remote Exposure Switches. Where an x-ray control is equipped with two or more remote exposure switches, each remote switch shall serve a single x-ray tube, and exposures with any tube shall be possible only by the remote switch with which that particular tube is associated.
- (17) Electrical Power Supply. The electrical power supply and service lines to x-ray systems shall be of sufficient capacity to permit operation without significant variation in voltage or machine output.

Specific Authority: 404.051, 404.151, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, Formerly 10D-91.604

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64E-5.504 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

- (1) Limitation of the Useful Beam.
 - (a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire cross section of the useful beam.
 - (b) A means shall be provided between the x-ray source and the patient for stepless adjustment of the size of the x-ray field.
 - (c) With the collimating shutters adjusted to the closed position, the minimum field size at the maximum SID shall not be greater than five by five centimeters when measured at the point where the beam enters the patient.
 - (d) Limitation to the Imaging Surface.
 1. The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the useable area of the largest image receptor at any SID.
 2. The longitudinal and transverse dimensions of the x-ray field produced by image-intensified fluoroscopic equipment shall not extend beyond the corresponding dimensions of the image receptor by more than three percent of the SID in either dimension in the plane of the image receptor and the sum of the excess shall be no greater than four percent of the SID. If the collimation is automatically accomplished, the x-ray field dimension criteria above shall apply to all film sizes and portions thereof that the spot film device accommodates and to the dimensions of the input phosphor, as appropriate. If collimation is not automatic, the x-ray field dimension criteria shall apply to the **useful area of the** input phosphor.
 3. Compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which passes through the center of the visible area of the image receptor.
 4. 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.
 5. Adjustable automatic and manual collimators shall operate smoothly throughout the entire range of use.

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6. For fluoroscopic systems with spot film capability, means shall be provided for adjustment of the x-ray field size in the plane of the film to a size smaller than the selected portion of the film.
- (e) The requirements of (1)(b) and (c), above, are not applicable to mobile fluoroscopic systems.
- (2) Activation of the Fluoroscopic Tube. A control of the dead-man type shall be incorporated into each fluoroscopic system such that x-ray production will be terminated at any time pressure is released from the switch except during the recording of serial fluoroscopic images with equipment in which means have been provided to permit completion of any single exposure of the series in progress.
- R1 (3) Allowable Entrance Exposure Rate Limits for Fluoroscopic Equipment.
- R1 (a) Fluoroscopic equipment manufactured after June, 1995, operable at any combination of tube potential and current that results in an exposure rate greater than five roentgens (1.29×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure control. Provision for manual selection of technique factors can be provided.
- (b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ten roentgens (2.58×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient except:
1. During the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.
 2. When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 roentgens (5.16×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient. Special means to activate high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.
- (c) Special means to activate high level controls such as additional pressure applied continuously by the operator shall be required to avoid accidental use.
- (d) A continuous signal audible to the fluoroscopist shall indicate when the high level control is being employed.
- (e) Measuring Compliance of Entrance Exposure Rate Limits. Compliance with this subsection shall be determined as follows:

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1. Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - R7 2. If the source **can be operated** below the **patient support device**, the exposure rate shall be measured at least one centimeter above the **patient support device** and corrected for distance to show the actual entrance exposure rate.
 - R7 3. If the source **can be operated** above the **patient support device**, the exposure rate shall be measured at 30 centimeters above the **patient support device** with the end of the beam-limiting device or spacer assembly positioned as closely as possible to the point of measurement.
 - R7 4. In a **mobile** C-arm type of fluoroscope, **not associated with a specific patient support device**, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
 - R7 5. **If the source can be operated laterally to the patient support device**, the exposure rate shall be measured at a point 15 centimeters 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 to the centerline of the x-ray table.
 6. X-ray systems that incorporate automatic exposure controls such as automatic brightness control shall have sufficient lead or lead equivalent placed in the useful beam to produce the maximum output of the x-ray system.
 7. X-ray systems that do not incorporate automatic exposure control shall use the maximum combination of current and potential to produce the highest output. Attenuating materials shall be placed in the useful beam to protect the imaging system.
- R1 (f) Periodic Measurement of Entrance Exposure Rates. The entrance exposure rate shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system that might affect the exposure rate.
- R1 (g) For cinefluoroscopy, the maximum exposure at the face of the input phosphor with the grid removed and with an attenuation block in the beam shall not exceed 40 microroentgens (0.01 μC per kg) per frame. The maximum exposure shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system which might affect the maximum exposure.

- R1 (4) Barrier Transmitted Radiation Limits.
- R1 (a) The exposure rate due to transmission through the primary protective
R1 barrier and frame assembly with the attenuation block in the useful beam
R1 combined with radiation from the image intensifier if provided shall not
R1 exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from
R1 any accessible surface of the fluoroscopic image assembly beyond the
R1 plane of the image receptor for each roentgen per minute of entrance
R1 exposure rate.
- R1 (b) Measuring Compliance with Barrier Transmission Limits
- R1 1. The exposure rate due to transmission through the primary
R1 protective barrier combined with radiation from the image intensifier
R1 shall be determined by measurements averaged over an area no
R1 greater than 100 square centimeters with no linear dimension
R1 greater than 20 centimeters.
- R1 2. If the source is below the tabletop, the measurement shall be made
R1 with the input surface of the fluoroscopic imaging assembly position
R1 30 centimeters above the tabletop.
- R1 3. If the source is above the tabletop and the SID is variable, the
R1 measurement shall be made with the end of the beam limiting
R1 device or spacer assembly as close to the table top as it can be
R1 placed but not closer than 30 centimeters.
- R1 4. Movable grids and compression devices shall be removed from the
R1 useful beam during the measurements.
- R1 5. The attenuation block shall be positioned in the useful beam 10
R1 centimeters toward the input surface of the imaging assembly from
the point at which the entrance exposure rate was measured.
- R1 6. The maximum beam size shall be used during measurements.
- R1 (5) Indication of Potential and Current. During fluoroscopy and cinefluorography,
x-ray tube potential and current shall be continuously indicated.
- R1 (6) Source-to-Skin Distance. Positive means shall be provided to assure the source-
to-skin distance shall not be less than:
- R1 (a) Thirty-eight centimeters on stationary fluoroscopes installed after
January 1, 1977,
- R1 (b) Thirty-five and one-half centimeters on stationary fluoroscopes installed
prior to January 1, 1977,
- R1 (c) Thirty centimeters on all mobile fluoroscopes,

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- (d) Twenty centimeters for image intensified fluoroscopes used for specific surgical applications. Written safety procedures must be provided and precautionary measures followed during the use of this device.
- R1 (7) Fluoroscopic Timer. A cumulative timing device activated by the fluoroscopic exposure switch shall be provided, the maximum cumulative time of which shall not exceed five minutes without resetting. The timer shall indicate the passage of the predetermined period of exposure by an audible signal or termination of the exposure. If such a signal is utilized, it shall continue while x-rays are produced until the timing device is reset.
- R1 (8) Mobile Fluoroscopes. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.
- R1 (9) Control of Scatter Radiation.
- (a) Fluoroscopic table designs shall be such that scattered radiation which originates beneath the tabletop is attenuated by not less than 0.25 mm lead equivalent, and that no unprotected part of any staff or ancillary person's body shall be exposed to unattenuated scattered radiation.
- (b) Fluoroscopic equipment configuration shall be such that no portion of any staff or ancillary person's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless:
1. Such person is at least 120 centimeters from the center of the useful beam, or
 2. The radiation has passed through not less than 0.25 millimeter lead equivalent material.
- (c) Exceptions to (10)(b), above, may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.
- R1 (10) Photofluorographic Medical x-ray Systems.
- (a) In addition to other applicable sections of these regulations, photofluorographic x-ray systems shall conform with the following requirements:
1. Usage shall be limited to diagnostic radiography of the lungs and other soft tissues of the thoracic region.
 2. Personnel monitoring shall be provided for all individuals who operate photofluorographic apparatus.
 3. The average exposure, including backscatter, for chests measuring 25 centimeters in thickness shall not exceed 100 millirems (1.0 mSv) at the point where the x-ray beam enters the patient.

(b) Photofluorographic x-ray systems shall not be installed unless specifically approved by the department.

R1 (11) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of (1), (3), (4), (5) and (8), above, provided that:

(a) Such systems are designed and used in such a manner that no person other than the patient is in an unprotected area during periods of time when the system is producing x-rays; and

(b) Systems that do not meet the requirements of (8), above, are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, the timer shall be reset between examinations

(c) The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 20 roentgens (5.16 mC per kg) per minute, except during the recording of fluoroscopic images.

R7 (12) For remotely operated fluoroscopic systems:

R7 (a). The control panel shall be arranged or configured to allow the operator to
R7 have both auditory and visual communication with the patient during
R7 exposures.

R7 (b). The operator's protective barrier shall have a window or mirror system
R7 arranged so that the operator can keep the patient under constant visual
R7 surveillance during exposures.

R7 (c). Windows shall have lead equivalent shielding equal to that required in the
R7 operator's protective barrier.

Specific Authority: 404.051, 404.22, F.S.

R7 Law Implemented: 404.05, 404.22, F.S.

R1 History: New July 17, 1985, amended April 4, 1989., March 17, 1992,

R7 Amended January 5, 1995, Formerly 10D-91.605, Amended May 18, 1998, Amended August 16, 2007.

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64E-5.505 Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems.

- (1) Beam Limitation. The useful beam shall be limited to the area of clinical interest.
 - (a) General Purpose Stationary and Mobile X-ray Systems.
 1. A means for stepless adjustment of the size of the x-ray field shall be provided.
 2. Means shall be provided for visually defining the perimeter of the x-ray field. 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.
 3. Mobile x-ray systems shall be equipped with an attached rule to accurately measure the SID at any distance up to 72 in (183 cm).
 - (b) Stationary general purpose diagnostic x-ray systems shall be equipped with the following additional features:
 1. Positive means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; to align the center of the x-ray field with the center of the image receptor to within two percent of the SID; and to indicate the SID to within two percent.
 2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
 3. Indication of field size dimensions and SID's shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam limiting device to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.
 - (c) X-ray Systems Used for One Image Receptor Size. Radiographic equipment used for only one image receptor size shall have a fixed SID and shall be provided with positive means to limit the x-ray field at the plane of the image receptor to the area of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(d) Special Purpose x-ray Systems.

1. **For x-ray systems with more than one image receptor size,**
 - a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
2. The requirements in this paragraph are met by a system that meets the requirements for a general purpose x-ray system as specified in (1)(a), above, or, when positive alignment means are also provided, may be met with either:
 - a. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed; each such device shall have clear markings to indicate the image receptor size and SID for which it is designed; or
 - b. A beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(2) Radiation Exposure Control Devices.

- (a) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor.
 1. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to 0.
 2. It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.

- (b) X-ray Exposure Control Switch Type and Location.
1. A control of the dead-man type shall be incorporated into each x-ray system such that an exposure will be terminated at any time pressure is released from the switch, except during serial radiography, when means have been provided to permit completion of any single exposure of the series in progress.
 2. Each x-ray control shall be located in such a way as to meet the following requirements:
 - a. The operator's station at the control panel shall be behind a protective barrier so positioned that leakage radiation and once scattered radiation will be intercepted.
 - b. For panoramic dental units with intensifying screens and a beam stop, the operator shall stand at least four feet (1.25 m) from the patient and the tube head or behind a protective barrier during exposures.
 - c. The operator's protective barrier shall be equipped with a window or mirror system so arranged that the operator may keep the patient under constant visual surveillance during exposures. The window shall have lead equivalent shielding equal to that required in the operator's protective barrier.
 - d. Each exposure switch, except those used in conjunction with fluoroscopic spot film devices and movable protective barriers, shall be securely fixed so that the operator cannot conveniently make exposures from an unshielded position.
 - e. Provision shall be made for aural communication with the patient from the control panel.
 - f. Mobile and portable x-ray systems which are:
 - (I) Used continually in a single location for a period greater than one week shall be considered a stationary radiographic system and shall meet the requirements for such an installation.
 - (II) Used at multiple locations shall be provided either with an adequate protective barrier or protective apron for the operator and with a method of control which will permit the operator to be at least 12 feet (3.75 m) from the tube head and the nearest edge of the useful beam during exposures.
 3. The x-ray control shall provide a visual indication observable from the operator's protected position whenever x-rays are produced.

4. A sound audible to the operator shall indicate that the exposure has terminated or is in progress.
- (3) Source-to-Skin Distance Limitations. All mobile or portable radiographic systems shall be provided with a positive means to limit the source-to-skin distance to not less than 30 centimeters.
- (4) Standby Radiation from Capacitor Energy Storage Equipment. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens (0.516 mC per kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
- (5) Intracavitary x-ray Systems. Use of intracavitary x-ray systems on humans is prohibited unless specific approval has been granted by the department. Application for such use must include evidence attesting to the exclusive advantages to be gained in the use of intracavitary radiographic techniques as opposed to conventional radiographic procedures.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended March 17, 1993, Amended January 5, 1995, Formerly 10D-91.606

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64E-5.506 Intraoral Dental Radiographic Systems.

- (1) Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:
 - (a) 18 centimeters if operable at or above 50 kVp, or
 - (b) Ten centimeters if not operable above 50 kVp.
- (2) Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
 - (a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters; and
 - (b) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six centimeters.
 - (c) An open-ended position indicating device shall be used on machines procured after September 19, 1972. The attenuation shall be equivalent to that required for the diagnostic source assembly as described in 64E-5.503(3).
- (3) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:
 - (a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero; and
 - (b) 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.
- (4) X-ray Exposure Control Switch.
 - (a) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time. This switch shall be of the dead-man type.
 - (b) Each x-ray control shall be located in such a way as to meet the following criteria:
 1. The operator shall observe the patient during an exposure.
 2. The operator shall stand as far as practicable and at least six feet (1.8 m) from the patient and tube head and outside the useful beam or behind a protective barrier during exposures.

- (c) The x-ray control shall provide visual indication observable at or from the operator's position whenever x-rays are produced.
- (d) A sound audible to the operator shall indicate that the exposure has terminated or is in progress.
- (5) Operating Controls.
- (a) The dentist, operator or assistant shall not hold the film in place for the patient during the exposure. Patient and film holding devices shall be used when the techniques permit.
- (b) No person other than the patient shall be exposed to the useful beam.
- (c) Neither the tube housing nor the position indicating device shall be held during an exposure.
- (d) The x-ray system shall be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in (2)(a), above.
- (e) Dental fluoroscopy without image intensification is prohibited.
- (f) Each user of intraoral units that are specifically designed to be handheld shall:
1. Have and use individual monitoring devices to document safe use practices; and
 2. Successfully complete training provided by the manufacturer using electronic media such as CD/DVD or a website. Training on the safe use of the unit shall be documented and include at a minimum:
 - a. Proper positioning of the unit to ensure an adequate protected position;
 - b. Limitations on the use of position indicating devices that require longer distances to the patients face;
 - c. Diagrams (ie: drawings, illustrations, schematics, etc.) of protected position and location in relationship to the unit;
 - d. Diagrams (ie, drawings, illustrations, schematics, etc.) of the effect of improper distance or removal of shielding device; and
 - e. Diagrams (ie. drawings, illustrations, schematics, etc.) of common examples of improper positioning of the unit and or location of the operator.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051, 404.22, F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.607, Amended August 16, 2007

64E-5.507 Therapeutic X-Ray Systems of Less Than 1 MeV.

- (1) Equipment Requirements.
- (a) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the following classification of that x-ray system:
1. Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at five centimeters from the surface of the tube housing assembly.
 2. Zero to 150 kVp Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at one meter from the source.
 3. 151 to 999 kVp Systems. The leakage radiation shall not exceed 0.1 percent of the useful beam one meter from the source, for any of its operating conditions.
- (b) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.
- (c) Removable and Adjustable Beam Limiting Devices.
1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
 2. Adjustable beam limiting devices shall transmit not more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter in the useful beam.
- (d) Filter System. The filter system shall be so designed that:
1. The filters cannot be accidentally displaced at any possible tube orientation;
 2. The radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.7 mC per kg) per hour under any operating conditions;
 3. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and

4. A filter indication system shall be used on all therapy machines using changeable filters. It shall be designed to permit easy recognition of any added filter in place. The presence or absence of any filter shall be discernible at the control panel.
- (e) Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.
 - (f) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
 - (g) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
 - (h) Beam Monitor System. Systems of greater than 150 kVp manufactured after January 1, 1985, shall be provided with a beam monitor system which:
 1. Shall have the detector of the monitor system interlocked to prevent incorrect positioning;
 2. Shall not allow irradiation until a pre-selected value of exposure has been made at the treatment control panel;
 3. Shall independently terminate irradiation when the preselected exposure has been reached;
 4. Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
 5. Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;
 6. Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and
 7. Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
 - (i) Timer.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 3. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
 4. The timer shall permit accurate presetting and determination of exposure times as short as one second.
 5. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- (j) Control Panel Functions. The control panel, in addition to the displays required in other provisions of this section, shall have:
1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 2. An indication of whether x-rays are being produced;
 3. Means for indicating x-ray tube potential and current;
 4. Means for terminating an exposure at any time; and
 5. A locking device which will prevent unauthorized use of the x-ray system.
- (k) Multiple Tubes. When a control panel may energize more than one x-ray tube
1. It shall be possible to activate only one x-ray tube at any time;
 2. There shall be an indication at the control panel identifying which x-ray tube is energized; and
 3. There shall be an indication at the tube housing assembly when that tube is energized.
- (l) Source-to-Skin Distance (SSD). There shall be means of determining the SSD to within one centimeter.
- (m) Low Filtration x-ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

- (2) Facility Design Requirements for x-ray Systems Operable Above 50 kVp.
- (a) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (b) Viewing Systems. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
 - (c) Additional Requirements for x-ray Systems Operable Above 150 kVp:
 - 1. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - 2. The control panel shall be located outside the treatment room.
 - 3. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening:
 - a. The exposure at a distance of one meter from the source shall be reduced to less than ten milliroentgens (2.58 $\mu\text{C}/\text{kg}$) per hour; and
 - b. It shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
 - 4. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights located in a readily observable position near the outside of all access doors to indicate when the useful beam is on.
- (3) Surveys, Calibrations, Spot Checks and Operating Procedures.
- (a) Surveys.
 - 1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 - 2. The registrant shall transmit a copy of the survey report to the department within 30 days of the receipt of the report.

3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.
- (b) Calibrations.
1. The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
 2. The calibration of the radiation output of an x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.
 3. Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding two years.
 4. The calibration shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty not to exceed five percent.
 5. The calibration of the x-ray system shall include, but not be limited to, the following determinations:
 - a. Verification that the x-ray system is operating in compliance with the design specifications;
 - b. The exposure rates as a function of field size, technique factors, filter and treatment distance used;
 - c. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
 - d. An evaluation of the uniformity of the largest radiation field used.
 6. Records of calibration shall be maintained by the registrant for five years after completion of the calibration.
 7. A copy of the most recent x-ray system calibration shall be available at the facility for inspection by the department.
- (c) Spot-checks. Spot-checks shall be performed on x-ray systems operable at greater than 150 kVp. Such spot-checks shall meet the following requirements:

1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.
 2. If a radiological physicist does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
 3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot-check shall be performed during the calibration specified in (3)(b), above. The acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration specified in (3)(a), above, shall be stated.
 4. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
 5. Whenever a spot-check indicates a significant change in the operating characteristics of a system, the system shall be recalibrated as required in (3)(b), above.
 6. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for two years.
 7. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (3)(b), above, or which has been compared within the previous year with a system meeting those requirements.
- (d) Operating Procedures.
1. X-ray systems shall not be left unattended unless the system is secured against unauthorized use.
 2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
 3. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeter lead equivalency at 100 kVp.

4. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 64E-5.304. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.
5. Machines capable of having an output of more than 1,000 roentgens (258 mC per kg) per minute at any accessible place shall not be left unattended without the power being shut off at the disconnect switch in addition to the control panel switch.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6), 404.081(1) 404.22(1)(3), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.608

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64E-5.508 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above.

- (1) Definitions. In addition to the definitions provided in 64E-5.501, the following definitions shall be applicable to this section:
- (a) "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.
 - (b) "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
 - (c) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.
 - (d) "Dose monitoring system" means a system of devices for the detection, measurement and display of quantities of radiation.
 - (e) "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
 - (f) "Existing equipment" means therapy systems subject to this section which were manufactured on or before January 1, 1985.
 - (g) "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.
 - (h) "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.
 - (i) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
 - (j) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
 - (k) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beam passes in all conditions.
 - (l) "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy and rotational therapy.

- (m) "New equipment" means systems subject to this section which were manufactured after January 1, 1985.
 - (n) "Normal treatment distance" means:
 - 1. For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
 - 2. For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.
 - (o) "Radiation head" means the structure from which the useful beam emerges.
 - (p) "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.
 - (q) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam or the patient during irradiation.
 - (r) "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation
 - (s) "Virtual source" means a point from which radiation appears to originate.
- (2) Requirements for Equipment.
- (a) Leakage Radiation to the Patient Area.
 - 1. New equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons may be obtained from the manufacturer and shall be averaged over an area up to, but not exceeding, 200 square centimeters.

2. Existing equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of two meters radius centered on a perpendicular to the central axis of the beam one meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified.
 3. For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified and for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the department.
- (b) Leakage of Radiation Outside the Patient Area for New Equipment.
1. The absorbed dose in rads (grays) due to leakage radiation, except in the area specified in (2)(a), above, when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in (2)(a), above.
 2. The registrant shall determine or obtain from the manufacturer the actual leakage radiation existing at the positions specified and for specified operating conditions. Radiation measurements, excluding neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters. Neutron measurements shall be averaged over an area up to, but not exceeding, 200 square centimeters.
- (c) Beam Limiting Devices. Adjustable or interchangeable beam-limiting devices shall be provided, and such devices shall transmit no more than five percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.
- (d) Filters.

1. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
 2. If the absorbed dose rate data indicated at the control panel relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
 3. For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters:
 - a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - c. A display shall be provided at the treatment control panel showing the filter in use; and
 - d. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- (e) **Beam Quality.** The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:
1. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the values stated below. Linear interpolation shall be used for values not stated.

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction or maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

2. Compliance with (2)(e)1., above, shall be determined using:

- a. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
 - b. The largest field size available which does not exceed 15 by 15 centimeters; and
 - c. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.
- (f) Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
1. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
 2. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
 3. The detector and the system into which that detector is incorporated shall meet the following requirements:
 - a. Each detector shall be removable only with tools and shall be designed to prevent incorrect positioning.
 - b. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
 - c. Each dose monitoring system shall be capable of independently monitoring, interrupting and terminating irradiation.
 - d. For new equipment, the design of the dose monitoring systems shall assure that:
 - (I) The malfunctioning of one system shall not affect the correct functioning of the second system; and
 - (II) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

- e. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall
 - (I) Maintain a reading until intentionally reset to zero;
 - (II) Have only one scale and no scale multiplying factors;
 - (III) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and
 - (IV) In the event of power failure, the dose monitoring information required to be displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.
- (g) **Beam Symmetry.** In new equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ten percent, the irradiation is terminated.
- (h) **Selection and Display of Dose Monitor Units.**
 - 1. Irradiation shall not be possible until a selection of a number of dose monitor units or exposure time has been made at the treatment control panel.
 - 2. The pre-selected number of dose monitor units or exposure time shall be displayed at the treatment control panel until reset manually for the next irradiation.
 - 3. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated
 - 4. For new equipment, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.
- (i) **Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.**

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
 2. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 3. For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than ten percent or 30 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 4. For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
- (j) Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.
- (k) Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.
- (l) Timer.
1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 3. For new equipment, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

4. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
- (m) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 2. An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 4. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
 5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
 6. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- (n) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 3. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
- (o) Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

2. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 4. The mode of operation shall be displayed at the treatment control panel.
 5. For new equipment, an interlock system shall be provided to terminate irradiation if:
 - a. Movement of the gantry occurs during stationary beam therapy; or
 - b. Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
 6. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - a. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than 20 percent from the selected value.
 - b. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.
 7. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by (2)(i), above.
- (p) Absorbed Dose Rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:
1. The dose monitor unit rate shall be displayed at the treatment control panel.
 2. The radiation detectors specified in (2)(f), above, may form part of this system.

- (q) Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
 - 1. The x-ray target or the virtual source of x rays; and
 - 2. The electron window or the virtual source of electrons if the system has electron beam capabilities.
 - (r) System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
- (3) Facility and Shielding Requirements. In addition to Part III, the following design requirements shall apply:
- (a) Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - (b) Control Panel. The control panel shall be located outside the treatment room.
 - (c) Viewing System. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
 - (d) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (e) Room Entrance. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors or other entrances to indicate when the useful beam is on.
 - (f) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any barrier penetration or door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- (4) Surveys, Calibrations, Spot Checks and Operating Procedures.
- (a) Surveys.

1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 2. The registrant shall obtain a written report of the survey from the qualified person, and a copy of the report shall be transmitted by the registrant to the department within 30 days of receipt of the report.
 3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.
- (b) Calibration.
1. The calibration of systems subject to 64E-5.508 shall be performed in accordance with an established calibration protocol acceptable to the department, such as the calibration protocol published by the American Association of Physicists in Medicine, before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution or other characteristics of the therapy beam.
 2. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.
 3. Calibration radiation measurements required by (4)(b), above, shall be performed using a dosimetry system:
 - a. Having a calibration factor for cobalt 60 gamma rays traceable to a national standard;
 - b. Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
 - c. Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
 - d. Which has had constancy checks performed on the system as specified by a radiological physicist.
 4. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

5. The calibration of the therapy beam shall include the following determinations:
 - a. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.
 - b. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
 - c. The uniformity of the radiation field and any dependency upon the direction of the useful beam.
 - d. Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
 - e. Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.
 6. Records of calibration measurements and dosimetry system calibrations required in (4)(b), above, shall be maintained for five years after completion of the full calibration.
 7. A copy of the latest calibration performed shall be available in the facility for inspection by the department.
- (c) Spot-checks. Spot-checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot-checks shall meet the following requirements:
1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. Acceptable tolerance for each parameter measured in the spot-check shall not exceed manufacturer's recommendations.
 2. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration.
 4. At intervals established in the spot-check procedures, spot-checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.
 5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
 6. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
 7. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in (4)(b), above.
 8. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for a period of two years.
 9. Where a spot-check involves an absolute radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (4)(b)3, above, or which has been compared with a system meeting those requirements within the previous year.
- (d) Additional Operating Procedures.
1. No individual other than the patient shall be in the treatment room during treatment of a patient.
 2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used
 3. The system shall not be used in the administration of radiation therapy unless the requirements of (4)(a), (4)(b) and (4)(c), above, have been met.

Specific Authority: 404.031, 404.051, 404.071, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4)(5)(6), 404.071(1), 404.081(1), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.609

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64E-5.509 Veterinary Medicine X-ray Operations.

- (1) Applicable Regulations. Veterinary medical x-ray operations shall conform with requirements of the following sections of these regulations:
 - (a) 64E-5.502, General Requirements, except 64E-5.502(1)(a)5., 64E-5.502(1)(a)6., 64E-5.502(1)(a)7. and 64E-5.502(1)(a)8.
 - (b) 64E-5.503, General Requirements for all Diagnostic X-Ray Systems.
 - (c) 64E-5.504, Fluoroscopic x-ray Systems.
- (2) Additional Requirements.
 - (a) Positive means of beam alignment shall be provided in the form of accurate linear rulings, beam defining or beam centering lights, optical viewing devices or the equivalent. Such alignment means or devices shall be adjusted to indicate the beam center or beam area to within two percent of the SID.
 - (b) Means shall be provided to limit the useful beam to the area of diagnostic interest or to the area of the image receptor used in each particular case. Beam limitation may be accomplished by any of the means described in 64E-5.505(1).
 - (c) Each x-ray system shall be equipped with a device which will terminate the exposure after a preset time or exposure.
 - (d) Each exposure switch shall be of the dead-man type.
 - (e) Each exposure switch shall be located in such a way as to meet the following criteria:
 1. The operator shall stand as far as practicable and at least six feet (1.8 m) from the animal and tube head and outside the useful beam or behind a protective barrier during exposures.
 2. In lieu of distance or a protective barrier the operator shall wear a protective apron and monitoring device as provided in (3)(c), below.
- (3) Operating Procedures.
 - (a) The operator shall stand in a protected position as indicated in (2)(e), above, during radiographic exposures with no other individuals in the x-ray room unless assistance of the nature described in (3)(c), below, is required.

- (b) To the greatest practicable extent, animals must be immobilized by anesthetics, straps, sandbags, foam wedges, and other supporting or restraining devices.
- (c) If an animal must be held by an individual, that individual shall be protected by appropriate shielding devices such as a protective apron and gloves, and the holder shall be so positioned that no part of his body will be struck by the useful beam. The exposure of that individual shall be monitored when engaged in such purposes.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.610

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64E-5.510 Mammographic Systems.

- (1) Mammographic medical x-ray systems shall meet the requirements of 64E-5.502 and 64E-5.503. Registrants who provide mammography services shall:
 - (a) Have a written quality assurance program specific to mammography imaging that includes an equipment quality control program for performance monitoring and an evaluation of all components of the equipment from the x-ray generator to the image processor.
 - (b) Establish standards for clinical image evaluations that include breast positioning, compression and overall image quality.
 - (c) Assign qualified and trained personnel to each part of the quality assurance program.
 - (d) Conduct a general review of the effectiveness of the quality assurance program annually and maintain a written report of the review.
 - (e) Have available the services of a medical physicist to furnish diagnostic x-ray physics support who is able to establish and conduct the equipment quality control program and who meets the requirements specified in (12), below. The specific duties of the medical physicist must include:
 1. Monitoring equipment performance or verifying the qualifications and training of others to monitor equipment performance.
 2. Evaluating the monitoring results to identify problems.
 3. Verifying that corrections are effective and meet regulatory requirements.
- (2) Mammographic x-ray examinations shall be performed on systems specifically designed for and used only for mammography. Mammographic medical x-ray systems shall meet the following requirements:
 - (a) Image receptor. The image receptor systems and their individual components must be designed for mammography.
 - (b) Target/filter. The x-ray system must be able to provide kVp/target/filter combinations that are compatible with the image receptor systems.
 - (c) Focal spot size measurement. Focal spot dimensions shall be measured both parallel and perpendicular to the anode-cathode axis with a slit camera or star pattern. Measured focal spot size shall result in minimal acceptable phantom image as specified in (8)(c) or comply with the manufacturer's specified nominal focal spot size within the following tolerances:

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions *	
	Width (mm)	Length (mm)
0.01	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

* Width is the dimension perpendicular to the anode-cathode axis, length is the dimension parallel to the anode-cathode axis.

- (d) Compression. Devices parallel to the imaging plane must be available to immobilize and compress the breast. These devices must be able to compress the breast with a force of at least 25 pounds and be able to maintain this compression for at least 15 seconds. For systems with automatic compression, the maximum force applied without manual assistance shall not be allowed to exceed 40 pounds. The chest wall edge of the compression paddle must be aligned with the chest wall edge of the image receptor to within one percent of the SID when the compression paddle is placed six centimeters above the patient support device.
- (e) Anti-scatter grids. A mammographic x-ray system using screen-film image receptors shall be able to use anti-scatter grids that are integral to the x-ray system and available for all image receptor sizes of the system.
- (f) Automatic exposure control. The department recommends that all x-ray equipment installed after September 1, 1993 have automatic exposure control that meets the requirements of 64E-5.503(14). The automatic exposure control shall be able to maintain constant film density within the diagnostic range of 1.05 to 1.60 optical density for 2, 4, and six centimeters of acrylic or of BR-12 phantoms. Density selection and kVp can be manually adjusted and recorded on technique charts if necessary to maintain film density.
- (3) Beam quality. The useful beam shall have a half-value layer between the values of measured kVp/100 and measured kVp/100 ± 0.1 millimeter aluminum equivalent when used with screen-film image receptors and the contribution to filtration made by the compression device is included. For xeroradiography, the half-value layer of the useful beam with the compression device in place shall be at least 1.0 and not more than 1.6 mm aluminum equivalent, tested at the kVp recommended by the manufacturer. Mammographic units using only rhodium filters and anodes are exempt from these beam quality requirements.

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- (4) The x-ray system shall meet safety standards and be free from unnecessary hazards to patients, personnel and others. Identified hazards must be corrected promptly. Technique charts, procedures for all equipment use, proper safety precautions for both mechanical and electrical operation, adequate shielding, and emergency procedures must be available to the equipment operator. Staff or a medical physicist as specified in (12), below, shall conduct and document periodic inspections of the equipment and of the adequacy of procedures as part of the annual quality assurance review.
- (5) Collimation. The mammographic system shall be able to limit the useful beam so that the x-ray field at the plane of the image receptor at any SID does not extend beyond the left, right, and nipple edges of the image receptor and does not extend beyond the image receptor adjacent to the chest wall by more than two percent of the SID. The sum of the collimated light field edges shall not differ from the sum of the respective edges of the x-ray field along either the length or the width of the visually defined field by more than two percent of the SID.
- (6) Average glandular tissue dose. The average glandular tissue dose for one craniocaudal view of a 4.5 centimeter compressed breast with 50 percent adipose/50 percent glandular tissue shall not exceed the following values:
- (a) One hundred millirads (one milligray) for film/screen without grid.
 - (b) Three hundred millirads (three milligray) for film/screen with grid.
 - (c) Four hundred millirads (four milligray) for Xeroradiographic systems.
- (7) The film processor shall be optimized for the specific mammography film used by the facility. Its performance shall be checked for consistency of speed, contrast, and base plus fog prior to processing patient films and after being idle more than six hours.
- (a) These performance checks shall be plotted and compared to established limits. If these limits are exceeded, documented corrective actions including an image quality check as specified in (8), below, are required.
 - (b) Corrective action shall be taken when:
 - 1. Optical density deviates by more than 0.15 from established operating levels for readings of mid-density and density difference on the sensitometric control charts
 - 2. Base plus fog exceeds the established operating level by more than 0.03 optical density.
 - (c) These records for processor optimization, performance, image quality checks and documented corrective actions shall be maintained for inspection by the department for at least one year.

- (8) Mammographic x-ray systems shall be monitored and evaluated using the following standards:
- (a) The image quality shall be checked using a standard phantom approved by the U.S. Food and Drug Administration which meets the criteria below at least monthly and whenever service which could affect image quality is performed on the x-ray system or the film processor. The image quality shall be scored on the ability to image fibers, specks, and low density masses. If quality control limits are exceeded, image quality checks also must be performed after any corrective actions have been taken. This standard phantom must be designed to evaluate image quality in the 1.05 to 1.60 optical density range, shall not change more than 0.2 optical density from its previous reading, and must be composed of material that is equivalent to a nominal 4.5 centimeter compressed breast of average density of approximately 50 percent adipose and 50 percent glandular tissue. It shall contain the following objects:
 - 1. Nylon fibers with thicknesses of 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeters.
 - 2. Aluminum oxide specks with diameters of 0.54, 0.40, 0.32, 0.24, and 0.16 millimeters.
 - 3. Phenolic plastic spherical masses with thicknesses of 2.00, 1.00, 0.75, 0.50, and 0.25 millimeters.
 - (b) Phantom checks which indicate a decrease in image quality shall require immediate investigation of possible corrective actions.
 - (c) The minimum acceptable image quality of a standard phantom described in (8)(a), above, shall demonstrate the ability to image at least 1.56, 1.12, 0.89, and 0.75 millimeter fibers; 0.54, 0.40, and 0.32 millimeter specks; and 2.00, 1.00, and 0.75 millimeter spherical masses. Mammographic examinations shall not be performed on systems which do not meet the minimum image quality standard.
 - (d) The registrant must document in the annual review required in (1), above, that the following equipment quality control items were performed under the direction and approval of the medical physicist when the equipment or components were initially installed or replaced and were performed thereafter at least as often as the frequency specified in (8)(e), below. When the results of performed tests do not meet established limits, corrective action must be taken and documented. The equipment quality control items which must be monitored are:
 - 1. Processor performance through sensitometric-densitometric means, before processing patient films and as specified in (7), above.
 - 2. Darkroom cleaning, daily.

3. Screen cleaning, weekly.
 4. Image quality, monthly and as specified in (8)(a),(b) and (c), above.
 5. Equipment observation check, monthly.
 6. Analysis of fixer retention in film, quarterly
 7. Compression device performance, semiannually
 8. Screen film contact and screen artifact detection, semiannually.
 9. Uniformity of screen speed, annually.
 10. Beam limiting device alignment, annually.
 11. Accuracy of kVp, annually.
 12. Output reproducibility and linearity, annually.
 13. Automatic exposure control reproducibility, kVp response and phantom thickness response, annually.
 14. Half-value layer, annually.
 15. Average glandular tissue dose, annually.
 16. Focal spot size, annually.
 17. Analysis of clinical images repeated or rejected, quarterly.
Corrective action shall be taken and documented if the retake rate of the facility exceeds five percent.
 18. Viewbox uniformity and integrity of devices used to block extraneous light, semiannually. A means shall be provided to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the film size or area of clinical interest.
 19. Darkroom integrity, semiannually. Darkroom fog shall not exceed 0.05 optical density when sensitized film is exposed to darkroom conditions with the safelight on for two minutes.
- (e) Mammography system performance must be evaluated regularly. The registrant must document the evaluation of the equipment quality control tests in the annual review specified in (1), above. Those components and parameters of the equipment quality control program tested for performance daily, weekly, monthly or quarterly shall be evaluated quarterly. The annual evaluation by the medical physicist must include a summary of the quarterly evaluations and the following:

1. Unit assembly.
 2. Collimation assessment.
 3. Focal spot size measurement.
 4. Accuracy and reproducibility of the kVp.
 5. Beam quality assessment.
 6. Automatic exposure control system performance.
 7. Uniformity of screen speed.
 8. Breast entrance exposure and average glandular tissue dose.
 9. Image quality.
 10. Artifacts.
- (f) The registrant shall document the qualifications and training of the personnel responsible for each part of the mammography quality assurance program, including the clinical image review, the establishment, monitoring, and evaluation of the equipment quality control program, and the annual review of the quality assurance program effectiveness.
- (9) All image receptors shall be clearly marked to indicate on the film which receptor was used on any given examination to facilitate the detection and removal of artifacts.
- (10) Xerox mammography systems shall be exempt from the requirements of (2)(e), (2)(f), (7), (8)(d)1., 2., 3., 6., 8., 9., 13., 18., 19., (8)(e)6., and 7 above.
- (11) Xerox mammography systems which exceed an average glandular dose for one craniocaudal view of a 4.5 centimeter compressed breast with a 50/50 percent ratio of glandular/fat tissue of 400 mrad (4 mGy) shall have the exposure techniques, processing, and image quality of the system investigated by a medical physicist, as specified in (12), below.
- (12) The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.
- (a) Interpreting physicians shall meet the following requirements
1. Licensed to practice medicine in the State of Florida, as specified in Chapters 458 and 459, Florida Statutes.
 2. a. Certified by a certifying body approved by the U.S. Food and Drug Administration; or

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- b. (I) Have two months of documented full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection; and
 - (II) Have 40 hours of documented continuing medical education in mammography. Time spent in residency specifically devoted to mammography is acceptable if documented in writing by the physician.
 - 3. a. Have read and interpreted mammograms from the examinations of at least 240 patients in the last six months; or
 - b. Have read and interpreted mammograms as specified above under the direct supervision of a fully qualified interpreting physician.
 - 4. a. Read and interpret mammograms from the examinations of an average of at least 40 patients per month over 24 months; and
 - b. Teach or complete an average of at least five continuing medical education credits in mammography per year.
 - (b) Radiologic technologists shall meet the following requirements
 - 1. Certified as a general radiographer in the state of Florida as specified in Chapter 64E-3, Florida Administrative Code.
 - 2. Obtain training specific to mammography, either through a training curriculum or special mammography course.
 - 3. Accumulate an average of five continuing education hours in mammography per year.
 - (c) 1. Prior to April 28, 1999, a medical physicist qualified to conduct surveys of mammography facilities and provide oversight of the facility quality assurance program shall meet the criteria specified in
 - a. and b. and c., below:
 - a. Licensed in Florida as a medical physicist as specified in Chapter 483, F.S.; and

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- b. (I) Holds a Master of Science, Master of Arts, or a higher degree in an appropriate field from an accredited institution. Appropriate fields include physics, applied physics, radiological physics, biophysics, health physics, engineering, and public health when the Bachelor's degree is in a physical science; and
- (II) Has had training in biological sciences; and
- (III) Has had at least 1 year of training in medical physics in the area of diagnostic radiological physics; and
- (IV) Has had at least 2 years of experience conducting mammography equipment performance evaluations..

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- c. Has received or taught at least an average of 5 hours of documented continuing education related to mammography per year.

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- 2. After April 28, 1999, the medical physicist must meet the criteria specified in 1.a. and 1.b.(I), above, and the qualification and experience specified in 21 CFR 900.12(a)(3)(i), (iii), and (iv), which is herein incorporated by reference and which is available from the department.

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- (13) Documentation, records and surveys. Each facility shall maintain records, policies, procedures and documentation to demonstrate compliance with these requirements, including corrective actions taken.

- (a) Clinical images. Each facility shall establish and maintain a clinical image quality control program, including:

- 1. Monitoring of mammograms repeated because of poor image quality; and
- 2. Maintaining records, analysis of results, and a description of any remedial action taken as a result of this monitoring.

(b) Clinical image interpretation. To ensure that quality clinical images are produced routinely at the facility, each facility shall submit clinical images to the department for review as required by the department. Each facility also will establish a system to review outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

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(c) Surveys. A medical physicist who meets the qualifications specified in (12), above, and who establishes, monitors, evaluates, and directs the equipment quality control program must perform an on-site survey of the facility to assure that it meets quality control and equipment standards. These surveys shall be performed at least annually and shall be available for inspection by the department. Each survey report shall be retained by the facility until the next annual survey is completed satisfactorily.

(d) Medical records.

1. Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

- a. For at least five years, or, if no additional mammograms of the patient are performed at the facility, for at least ten years; or
- b. Until the records are transferred as requested by the patient to a medical institution, to a physician of the patient, or to the patient.

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2. Each facility shall prepare a written report of the results of each mammography examination. This report shall be completed as soon as reasonably possible and shall:

- a. Be signed by the interpreting physician; and
- b. Be provided to the patient's physician or to the patient if the patient's physician is not available or if the patient does not have a physician. If this report is sent to the patient, it shall include a summary written in language easily understood by a lay person. A copy of the report shall be maintained in the patient's medical record.

(14) In addition to the above requirements, effective October 1, 1994, no facility can conduct mammography procedures unless the facility also obtains a certificate issued by the U.S. Food and Drug Administration as described in Public Law 102-539, the Mammography Quality Standards Act of 1992.

R1 Specific Authority: 404.051, 404.22, F.S.

R1 Law Implemented: 404.051(1)(4), 404.141, 404.22(1)(3)(6), F.S.

History: New March 17, 1992, Amended January 1, 1994

R1 Amended November 20, 1994, Formerly 10D-91.611, Amended May 18, 1998

64E-5.511 Registration of Radiation Machines.

(1) Exemptions.

- (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from registration and notification requirements if the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (five μ Sv) per hour at five centimeters from any accessible surface of the equipment. The production, testing or factory servicing of such equipment shall not be exempt.
- (b) Radiation machines that are non-operational and under the control of a registered vendor prior to final installation are exempt from the registration and fee requirements of this section.

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(2) Application and Fees for Registration of Radiation Machines.

- (a) Each person who acquires a radiation machine or an additional radiation machine shall:
 - 1. Apply for registration of the radiation machine with the department within 30 days after acquisition and before use. Application for registration shall be on DH 1107 3/07, which is herein incorporated by reference and available from the department at <http://www.doh.state.fl.us/environment/radiation/>.
 - 2. Designate an individual who will be responsible for radiation protection.
 - 3. Prohibit any person who is not registered with the department as a provider of services as specified in (3), below, from furnishing radiation machine servicing or services to his radiation machine
- (b) An annual fee for the registration and inspection of radiation machines shall be paid according to the following schedule:

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Medical or Chiropractic or Osteopathic or Naturopathic	One Tube\$ 145 Each Additional Tube\$ 85
Veterinary	One Tube\$ 50 Each Additional Tube\$ 34
Educational or Industrial	One Tube\$ 47 Each Additional Tube\$ 23
Dental or Podiatry	One Tube\$ 31 Each Additional Tube\$ 11
Medical Accelerator	One Unit\$ 258 Each Additional Unit\$ 148

Non Medical	One Unit	\$ 81
	Each Additional Unit	\$ 48

1. Renewal fees are due before October 28 annually.
 2. Registration fees are due within 30 days after acquiring a radiation machine. If the machine is acquired within 120 days before the October 28 annual renewal date, the registration fee will be due on October 28 and shall be the annual renewal fee.
- (3) Application for Registration of Servicing and Services.
- (a) Each person who installs or offers to install radiation machines or furnishes or offers to furnish radiation machine servicing or services in Florida shall apply to the department to register such services before furnishing or offering to furnish such services.
 - (b) Application for registration shall be completed on DH Form 1113, which is herein incorporated by reference and which is available from the department.
 - (c) Services include the installation or servicing of radiation machines and associated radiation machine components.
- (4) Report of Changes. The registrant shall report in writing within 30 days any changes to the information in the Certificate of Registration. The report shall include name, address of installation change, receipt, sale, transfer, or disposal of any radiation machine or major component.
- (5) Assembler or Transferor Obligation.
- (a) Any person who sells, leases, transfers, relocates, lends, assembles, installs or disposes of radiation machines or major components of such machines shall notify the department within 15 days after such action. Notification shall be made on DH Form 1114, which is herein incorporated by reference and available from the department, or, if the system contains certified components, on FORM FDA 2579, which is herein incorporated by reference and which is available from the department.
 - (b) No person shall sell, offer to sell, lease, transfer, lend or install radiation machines unless such machines meet the requirements of these regulations.

- (6) Out-of-State Radiation Machines.
- (a) Any person proposing to bring a radiation machine into Florida shall notify the department in writing at least ten days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine will be used. If the 10-day period is an undue hardship, the department can grant permission to proceed sooner.
 - (b) Any person proposing to bring a radiation machine into Florida shall register the machine with the department and pay the registration fee.
 - (c) Any out-of-state person using a radiation machine in Florida shall notify the department when the use of the machine has been completed.
- (7) Enforcement. The General Statement of Policy and Procedure for Radiation Machine Enforcement Actions, August 1996, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.

R7 Specific Authority 404.051, F.S.
R7 Law Implemented 404.071, 404.091, 404.101, 404.141, 404.161, 404.162, 404.163, 404.22, F.S.
R7 History--New December 12, 1996, Formerly 10D-91.612, Amended August 16, 2007