DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - X-RAYS IN THE HEALING ARTS

6 CCR 1007-1 Part 06

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

PART 6 X-RAYS IN THE HEALING ARTS

RH 6.1 Purpose and Scope.

This Part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these Regulations.

RH 6.2 Definitions.

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

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy [1] affording the same attenuation, under specified conditions, as the material in question.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy [1] , or other materials having equivalent attenuation.

1 The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"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").

"Barrier" (See "Protective barrier").

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

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

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

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"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.

“Certified system” means any x-ray system which has one or more certified component(s).

“Changeable filters” means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process under operator control.

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

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

where

s = Estimated standard deviation of the population.

$\bar{X}$ = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample.

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

“Control panel” means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for the operator's use for manually setting the technique factors.

“Cooling curve” means the graphical relationship between heat units stored and cooling time.

“CT” (See “Computed tomography”).

“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.

“Detector” (See “Radiation detector”).

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

“Diagnostic x-ray system” means an x-ray system designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

“Diagnostic x-ray imaging system” means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

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

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

“Equipment” (See “x-ray equipment”).

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

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

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

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

“General purpose radiographic x-ray system” means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

“Gonad shield” means a protective barrier for the testes or ovaries.

“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 by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam, is deemed to be excluded.

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

“Image intensifier” means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding visible light image and electronically amplifies the brightness of that visible image.

“Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

“Image receptor support” means, for mammographic systems, that part of the system designed to support the image receptor perpendicular to the beam axis during a mammographic examination.

“Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

“Irradiation” means the exposure of matter to ionizing radiation.

“Kilovolts peak” (See “Peak tube potential”).

“kV” means kilovolts.

“kVp” (See “Peak tube potential”).

“kWs” means kilowatt second.

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

“Leakage radiation” means radiation emanating from the diagnostic source assembly except for the useful beam.

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

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for that potential.

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

“Line-voltage regulation” means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

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

where:

V_n = No-load line potential and

V_l = Load line potential.

“mA” means milliampere.

“mAs” means milliampere second.

“Maximum line current” means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

“Mini c-arm x-ray system(s)” means a system that meets the following criteria: source-image receptor distance less than or equal to 50 cm; field of view less than or equal to six (6) inches; kVp less than or equal to 75 kVp; mA less than or equal to 0.25 mA; and entrance exposure rate less than or equal to 10 roentgen (1.29 mC/kg) per minute at the exit port.

“Mobile x-ray equipment” (See “x-ray equipment”).

“Optical Density (OD)” = Log (1/Transmittance), where the transmittance of the film is the fraction of incident light transmitted by the film.

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

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

“Phantom” means an object designed such that the interaction of ionizing radiation with the object is suitable for the evaluation of the particular characteristics of the x-ray system or anatomic region under consideration.

“Phototimer” means a method for controlling radiation exposure to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See “Automatic exposure control”).

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

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

“Protective apron” means an apron made of radiation absorbing materials used to reduce radiation exposure to the wearer.

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

(1) “Primary protective barrier” means the material, excluding filters, placed in the direct useful beam, for protection purposes, to reduce the radiation exposure;

(2) “Secondary protective barrier” means the material which attenuates stray radiation.

“Protective glove” means a glove made of radiation absorbing materials used to reduce radiation exposure to the wearer.

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

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

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

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

“Rating” means the operating limits as specified by the component manufacturer.

“Recording” means producing a permanent form of an image resulting from x-ray photons.

“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.

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

“Shutter” means a device attached to the tube housing assembly which can intercept the entire cross

sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

“Single occupancy room” means a room which has walls on all sides (excluding the room entrance) of a minimum of seven (7) feet high that has an x-ray attenuation (for the x-ray beam in use at the facility) equivalent to at least two (2) thicknesses of one-half inches of gypsum wallboard which is occupied by one individual at a time. This only applies to rooms with dental intraoral or panoramic machines.

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

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

“Spot check” means a procedure which is performed to assure that a previous calibration continues to be valid.

“Spot film” means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

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

“Source to skin distance (SSD)” means the distance between the source and the skin of the patient.

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

“Technique chart” means a chart which specifies, for common examinations performed with a specific system, the following information:

(1) technique factors to be utilized versus patient's anatomical size;

(2) type and size of the film or film-screen combination to be used;

(3) type and focal distance of the grid to be used, if any; and

(4) source to image receptor distance to be used.

“Technique factors” means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

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

(3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“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.

“Tomogram” means the depiction of the x-ray attenuation properties of a section through the body.

“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.

“Tube” means an x-ray tube, unless otherwise specified.

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

“Tube rating chart” means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors. These curves are typically displayed on a graph.

“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.

“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.

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

“Wedge filter” means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

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

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

(1) “Mobile x-ray equipment” means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

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

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

“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.

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

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

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

“X-ray tube” means any electron tube which is designed to be used primarily for the production of x-rays.

General Regulatory Provisions

RH 6.3 General Requirements .

Effective July 1, 1995, all human use radiation machines used in Colorado shall meet the Federal Performance Standards, Subchapter J - Radiological Health, 21 CFR 1020.30 through 1020.33, effective April 1, 1997. The Department may grant exemptions to machines manufactured prior to August 4, 1974, provided the registrant can demonstrate that the exemption will not result in undue risk from excessive exposure and will benefit the patient.

6.3.1 Administrative Controls .

6.3.1.1 Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of RH 6.3.1 are met in the operation of the x-ray system(s), including the use of licensed/certified/registered persons or companies (providers) to provide services to the facility. Such services include the operation of x-ray equipment, interpretation of exams, inspection of x-ray machines and facilities, installation, service and/or calibration of x-ray machines.

6.3.1.1.1 An x-ray system which does not meet the provisions of these Regulations, and is determined to be unsafe for human use, shall not be operated for diagnostic or therapeutic purposes.

6.3.1.1.2 Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

6.3.1.1.2.1 In addition to RH 6.3.1.1.2, operators, except for the licensed practitioners, shall meet the training requirements, if any, of the appropriate licensing board.

6.3.1.1.2.2 In addition to RH 6.3.1.1.2 and 6.3.1.1.2.1, operators of x-ray machine systems in mammography facilities shall meet the requirements in RH 6.10.2.1.1.

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

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

6.3.1.1.3.2 Type and size of the film or film-screen combination to be used;

6.3.1.1.3.3 Type and focal distance of the grid to be used, if any;

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

6.3.1.1.3.5 Type and location of placement of patient shielding (i.e. gonad, etc.) to be

used; and

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

6.3.1.1.4 Written safety procedures shall be provided to each individual operating x-ray equipment. These procedures shall include any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

6.3.1.1.5 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 or fluoroscopic exposure. Other than the patient being examined:

6.3.1.1.5.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent.

6.3.1.1.5.2 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, or shall be so positioned that the nearest portion of the body is at least 1.83 meters (6 feet) from both the tube head and the nearest edge of the image receptor.

6.3.1.1.5.3 Human 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 1.83 meters (6 feet) from both the tube head and the nearest edge of the image receptor.

6.3.1.1.6 Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for human patients, who have not passed beyond 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.

6.3.1.1.7 Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

6.3.1.1.7.1 exposure of an individual for training, demonstration or other non-healing arts purposes; and

6.3.1.1.7.2 exposure of an individual for the purpose of healing arts screening except as authorized by RH 6.3.1.1.11.

6.3.1.1.8 When a patient or film must be provided with auxiliary support during a radiation exposure:

6.3.1.1.8.1 mechanical holding devices shall be used when the technique permits. The written safety procedures, required by RH 6.3.1.1.4, shall list individual projections where holding devices cannot be utilized;

6.3.1.1.8.2 written safety procedures, as required by RH 6.3.1.1.4, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

6.3.1.1.8.3 the human holder shall be protected as required by RH 6.3.1.1.5.1;

6.3.1.1.8.4 no individual shall be used routinely to hold film or patients; and

6.3.1.1.8.5 in those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

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

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

6.3.1.1.9.1 The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

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

6.3.1.1.9.2 Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation, or when the practitioner determines that portable equipment is most suitable for the diagnostic procedure.

6.3.1.1.9.3 X-ray systems subject to RH 6.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.

6.3.1.1.9.4 If anti-scatter grids are used between the patient and the image receptor to decrease scattered radiation to the film and improve contrast, the grid shall:

6.3.1.1.9.4.1 be positioned properly, i.e., tube side facing the correct direction, and grid centered to the central ray;

6.3.1.1.9.4.2 be of the proper focal distance for the SID being used.

6.3.1.1.10 All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18 of these Regulations. In addition:

6.3.1.1.10.1 When protective clothing or devices are worn, personnel monitoring devices shall be worn, such that the requirements of RH 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18 shall be met.

6.3.1.1.10.2 Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

6.3.1.1.11 Healing Arts Screening. With the exception of FDA/MQSA approved facilities which are registered with the Department for the use of dedicated mammographic equipment, any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix C of this Part. If any information submitted to the Department becomes invalid or outdated, the Department shall be immediately notified.

6.3.1.1.12 Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Department:

6.3.1.1.12.1 maximum technique factors for which the machine has been rated;

6.3.1.1.12.2 model and serial numbers of each tube housing assembly and control panel;

6.3.1.1.12.2.1 The facility registrant shall assign a unique identification number to each tube housing assembly and/or control panel which lacks a clearly visible serial number from the manufacturer. The tube housing assembly and/or control panel shall be labeled or stenciled with this number. This number shall be used by the registrant to identify this machine in all correspondence with the Department.

6.3.1.1.12.3 Tube rating charts and cooling curves;

6.3.1.1.12.4 records for the previous three (3) years of surveys, measurements, calibrations, maintenance, and modifications performed on the x-ray system(s) with the names of persons who performed such services;

6.3.1.1.12.5 Except for single occupancy rooms using only dental intraoral or panoramic machines, a dimensional drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

6.3.1.1.12.5.1 the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or

6.3.1.1.12.5.2 the type and thickness of materials, or lead equivalency, of each protective barrier; and

6.3.1.1.12.6 a copy of all correspondence with this Department regarding that x-ray system.

6.3.1.1.13 Collimation. The registrant shall provide safety training to all operators on radiation safety procedures including collimation. The collimation procedure shall specify for each tube with variable collimation whether positive beam limitation (PBL) or manual collimation shall be used.

6.3.1.1.13.1 If manual collimation is used, then there shall be positive indication of collimation on all films except as provided in RH 6.10.2.6.7, or when contra indicated and diagnosis could be compromised. Tubes collimated manually need not comply with PBL requirements.

6.3.1.1.13.2 Regardless of the method of collimation, the beam size shall be limited to the smallest area which is clinically necessary.

6.3.1.1.14 Film Processing QA Program . Every human use facility which is required to be inspected on an annual basis shall have an active film processing QA program which includes:

6.3.1.1.14.1 The x-ray film must be developed following the recommendations of the film manufacturer for development time and temperature. Those manufacturers recommendations must be available for review.

6.3.1.1.14.1.1 In lieu of the requirements of RH 6.3.1.1.14.1, the facility may adopt a continuous, documented sensitometric quality control program.

6.3.1.1.14.2 If manual processing of films is done the temperature of the developer must be measured and logged each day the processing system is used.

6.3.1.1.14.3 If an automatic film processor is used then its developer temperature must be monitored and logged at least once per week.

6.3.1.1.14.4 For both manual and automated processing there must be an adequate method used to monitor and/or determine processing time.

6.3.1.1.14.5 An adequate developer replenishment system must be functional to meet the manufacturer's recommendations for automated film processors. For manual developing procedures the developer chemicals must be changed at least every month and documented in a written log.

6.3.1.1.14.6 The darkroom lighting must be such that exposure of a film to the darkroom safelight for one minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure. If used, daylight film handling boxes shall preclude fogging of the film.

6.3.1.1.14.7 The base plus fog of an unexposed film must not exceed 0.25 optical density units when developed by the routine procedure used by the facility.

6.3.1.1.14.7.1 All film storage, including pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

6.3.1.1.15 Every human use facility which is required to be inspected on a three year basis shall have their film(s) developed according to the film manufacturer's recommendation for development time and temperature.

6.3.2 Plan Review and Shielding Design.

6.3.2.1 Prior to the construction of a new x-ray facility, the floor plans and equipment arrangement shall be submitted to a qualified expert for the determination of shielding requirements. Prior to the modification or renovation of an existing x-ray facility, or installation of a new x-ray machine in an existing x-ray facility, the plans and equipment arrangements shall be submitted to a qualified expert for determination of shielding requirements when there is a change in primary beam orientation, or a change in primary shielding due to the modification or renovation of a facility, or there is a projected increase in the x-ray workload from that which was used for the original x-ray shielding design. In such cases shielding shall meet the criteria in Appendix B and the recommendations of the qualified expert. The required information is denoted in Appendices A and B of this Part.

6.3.2.1.1 Facilities using only dental intraoral machines in an open bay area are exempt from the requirement of RH 6.3.2.1, provided that there is a distance of at least 1.83 meters (6 feet) between two (2) adjacent chairs. Facilities using only bone densitometry machines,

mini-c-arms, dental intraoral or panoramic machines in single occupancy rooms are exempt from the requirements of RH 6.3.2.1.

6.3.2.2 The review of such plans, and determination of shielding requirements, shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in RH 4.6, 4.12, 4.13, and 4.14 of these Regulations.

Diagnostic X-Ray Systems

RH 6.4 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:

6.4.1 Warning Label.

The control panel containing the main power switch shall bear this or an 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.”

6.4.2 Battery Charge Indicator.

On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6.4.3 Leakage Radiation from the Diagnostic Source Assembly.

The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgen) 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.

6.4.4 Radiation from Components Other Than the Diagnostic Source Assembly.

The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.516 μC/kg (2 milliroentgen) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6.4.5 Beam Quality.

6.4.5.1 Half-Value Layer .

6.4.5.1.1 The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)	Half-value layer (m aluminum)
.	.	Other Systems	Dental Systems

Below 50	30	0.3	1.5
.	40	0.4	1.5
.	49	0.5	1.5
50 to 70	50	1.2	1.5
.	60	1.3	1.5
.	70	1.5	1.5
Above 70	71	2.1	2.1
.	80	2.3	2.3
.	90	2.5	2.5
.	100	2.7	2.7
.	110	3.0	3.0
.	120	3.2	3.2
.	140	3.8	3.8
.	150	4.1	4.1

6.4.5.1.2 The requirements of RH 6.4.5.1.1 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 in Table II.

Table II - Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	**Total Filtration (inherent plus added) (mm aluminum equivalent)**	**Other Systems**	**Dental Systems**
Below 50	. . . . .	0.5	1.5
50 - 70	. . . . .	1.5	1.5
Above 70	. . . . .	2.5	2.5

6.4.5.1.3 Beryllium window tubes, except those used for mammography, shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

6.4.5.1.4 For capacitor energy storage equipment, compliance with the requirements of RH 6.4.5 shall be determined with the system fully charged and a minimum setting of 10 mAs for each exposure.

6.4.5.1.5 The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

6.4.5.2 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RH 6.4.5.1 is in the useful beam for the given kVp which has been selected.

6.4.6 Multiple Tubes.

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 and at or near the tube housing assembly which has been selected.

6.4.7 Mechanical Support of Tube Head.

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

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

6.4.8 Technique Indicators .

6.4.8.1 The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

6.4.8.2 The requirement of RH 6.4.8.1 may be met by permanent markings on equipment having fixed technique factors.

RH 6.5 Fluoroscopic X-Ray Systems Except for Computed Tomography X-Ray Systems.

All fluoroscopic x-ray systems shall meet the following requirements:

6.5.1 Limitation of Useful Beam.

6.5.1.1 Primary Barrier .

6.5.1.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

6.5.1.1.2 The x-ray tube used for fluoroscopy shall not produce x rays unless the barrier is in position to intercept the entire useful beam.

6.5.1.2 X-Ray Field.

6.5.1.2.1 Non-Intensified Fluoroscopic Equipment .

6.5.1.2.1.1 Only image-intensified fluoroscopic equipment shall be used.

6.5.1.2.1.2 For fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three (3) percent of the SID. The sum of the excess length and the excess width shall be no greater than four (4) percent of the SID. In addition:

6.5.1.2.1.3 means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

6.5.1.2.1.4 all equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125

square centimeters or less. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less;

6.5.1.2.1.5 for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and the entire cross section of the useful beam shall be intercepted by the primary protective barrier at any SID.

6.5.1.2.1.6 Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video/tv monitor image. For collimating systems which are not circular, measurement shall be made along the directions closest to the vertical and horizontal direction on the video monitor image yielding the smallest dimension in each direction.

6.5.1.2.2 Spot-film devices shall meet the following additional requirements :

6.5.1.2.2.1 means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

6.5.1.2.2.2 Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three (3) percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four (4) percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6.5.1.2.2.3 it shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

6.5.1.2.2.4 the center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two (2) percent of the SID; and

6.5.1.2.2.5 on spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6.5.1.2.3 Override . If a means exists to override any of the automatic x-ray field size

adjustments required in RH 6.5.1.2, that means:

6.5.1.2.3.1 shall be designed for use only in the event of system failure;

6.5.1.2.3.2 shall incorporate a signal visible at the operator's position which will indicate whenever the automatic field size adjustment is overridden; and

6.5.1.2.3.3 shall be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

6.5.2 Activation of the Fluoroscopic Tube.

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time.

6.5.3 Exposure Rate Limits.

6.5.3.1 Entrance Exposure Rate Limits for Fluoroscopic Equipment Manufactured Before May 19, 1995 .

6.5.3.1.1 Equipment with Automatic Exposure Rate Control (AERC). Fluoroscopic equipment that is provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} coulomb per kilogram (C/kg) per minute [10 roentgens per minute (10 R/min)] at the point where the center of the useful beam enters the patient, except:

6.5.3.1.1.1 During recording of fluoroscopic images or;

6.5.3.1.1.2 When an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29 mC/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is being employed.

6.5.3.1.2 Equipment Without AERC (Manual Mode). Fluoroscopic equipment that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29 mC/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, except:

6.5.3.1.2.1 during recording of fluoroscopic images, or;

6.5.3.1.2.2 when an optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is being employed.

6.5.3.1.3 Equipment with Both an AERC Mode and a Manual Mode. Fluoroscopic equipment that is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} C/kg per minute (10 R/min) in either mode at the point where the

center of the useful beam enters the patient except:

6.5.3.1.3.1 During recording of fluoroscopic images, or;

6.5.3.1.3.2 When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an entrance exposure rate in excess of 1.29 mC/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level is being employed.

6.5.3.1.3.3 Fluoroscopic units which have the high level control activated and an entrance exposure rate exceeding 5.16×10^{-3} C/kg per minute (20 R/min) shall be posted with the measured maximum entrance exposure rate, visible at the operator's position. Such sign will note that the entrance exposure rate of fluoroscopic equipment manufactured after May 19, 1995, which have the high level control activated, are limited to 5.16×10^{-3} per minute (20 R/min).

6.5.3.2 Entrance Exposure Rate Limits For Fluoroscopic Equipment Manufactured On and After May 19, 1995.

6.5.3.2.1 Fluoroscopic equipment operable at any combination of tube potential and current that results in an exposure rate greater than 1.29 mC/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of technique factors may be provided.

6.5.3.2.2 Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} C/kg per minute (10 R/min) at the point where the center of the useful beam enters the patient except;

6.5.3.2.2.1 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; or

6.5.3.2.2.2 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 5.16×10^{-3} C/kg per minute (20 R/min) at the point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is being employed.

6.5.3.3 Compliance with the requirements of RH 6.5.3 shall be determined as follows:

6.5.3.3.1 If the source is below the table, exposure rate shall be measured one centimeter above the tabletop or cradle.

6.5.3.3.2 If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

6.5.3.3.3 All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure

rate limits in RH 6.5.3.1.1, 6.5.3.1.2, and 6.5.3.1.3, 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 spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

6.5.3.3.4 All lateral type fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits in RH 6.5.3.1.1, 6.5.3.1.2, and 6.5.3.1.3; measured at a point 15 centimeters from the centerline of the 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 table.

6.5.3.3.5 Periodic measurement of entrance exposure rate shall be performed as follows :

6.5.3.3.5.1 Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

6.5.3.3.5.2 Conditions of periodic measurement of entrance exposure rate are as follows:

6.5.3.3.5.2.1 The measurement shall be made under the conditions that satisfy the requirements of RH 6.5.3.3;

6.5.3.3.5.2.2 The kVp shall be the maximum kVp which can be produced by the x-ray system;

6.5.3.3.5.2.3 The x-ray system(s) that incorporates automatic exposure rate control shall have the beam collimated to the size of the detector and have sufficient material placed in the useful beam to intercept the entire beam so that output of the machine is a maximum for the x-ray system; and

6.5.3.3.5.2.4 X-ray system(s) that do not incorporate an automatic exposure rate control shall utilize the maximum milliamperage typical of the clinical use of the x-ray system. [2]

2 Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

6.5.4 Barrier Transmitted Radiation Rate Limits .

6.5.4.1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.516 μC/kg per hour (2 milliroentgen) at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

6.5.4.2 Measuring Compliance of Barrier Transmission.

6.5.4.2.1 The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6.5.4.2.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the

tabletop.

6.5.4.2.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

6.5.4.2.4 Movable grids and compression devices shall be removed from the useful beam during the measurement.

6.5.4.2.5 The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

6.5.5 Indication of Potential and Current.

During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated on certified units.

6.5.6 Source-to-Skin Distance.

The SSD shall not be less than:

6.5.6.1 38 centimeters on stationary fluoroscopes installed after September 1, 1992,

6.5.6.2 35.5 centimeters on stationary fluoroscopes which were in operation on or before September 1, 1992,

6.5.6.3 30 centimeters on all mobile fluoroscopes;

6.5.6.4 20 centimeters for fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of these systems; and

6.5.6.5 9 centimeters for mini c-arms.

6.5.7 Fluoroscopic Timer.

6.5.7.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.

6.5.7.2 A signal to the operator shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset

6.5.8 Control of Scattered Radiation.

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

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

6.5.8.2.1 is at least 120 centimeters from the center of the useful beam, or

6.5.8.2.2 the radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RH 6.3.1.1.5.1.

6.5.8.3 The Department may grant exemptions to RH 6.5.8.2 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 exemption.

6.5.8.4 The Department may grant exemptions to RH 6.5.8.2 when the use of drapes or self-supporting curtains are contra indicated and the diagnosis could be compromised.

6.5.9 Radiation Therapy Simulation Systems.

Radiation therapy simulation systems shall be exempt from all the requirements of RH 6.5.1, 6.5.3, 6.5.4, and 6.5.7 provided that:

6.5.9.1 such systems are designed and used in such a manner that no individual other than the patient, required staff and ancillary personnel are in the x-ray room during periods of time when the system is producing x-rays; and

6.5.9.2 systems which do not meet the requirements of RH 6.5.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

RH 6.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinary, Computed Tomography, or Mammography X-Ray Systems.

6.6.1 Beam Limitation.

The useful beam shall be limited to the area of clinical interest.

6.6.1.1 General Purpose Stationary and Mobile X-Ray Systems .

6.6.1.1.1 There shall be provided a means for stepless adjustment of the size of the x-ray field.

6.6.1.1.2 A method 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 (2) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

6.6.1.1.3 The Department may grant an exemption on non-certified x-ray systems to RH 6.6.1.1.1 and 6.6.1.1.2 provided the registrant makes a written application for such exemption and in that application:

6.6.1.1.3.1 demonstrates it is impractical to comply with RH 6.6.1.1.1 and 6.6.1.1.2; and

6.6.1.1.3.2 the purpose of RH 6.6.1.1.1 and 6.6.1.1.2 will be met by other methods.

6.6.1.2 Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of RH 6.6.1.1, stationary general purpose x-ray systems, shall meet the following requirements:

6.6.1.2.1 A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the

center of the image receptor to within two (2) percent of the SID, and to indicate the SID to within two (2) percent;

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

6.6.1.2.3 Indication of field size dimensions and SID's shall be specified in inches and/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 (2) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

6.6.1.3 X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6.6.1.4 X-Ray Systems Other Than Those Described in RH 6.6.1.1, 6.6.1.2 and 6.6.1.3.

6.6.1.4.1 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 (2) percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

6.6.1.4.2 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6.6.1.4.3 RH 6.6.1.4.1 and 6.6.4.2 may be met with a system that meets the requirements for a general purpose x-ray system as specified in RH 6.6.1.1 or, when alignment means are also provided, may be met with either:

6.6.1.4.3.1 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 with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

6.6.1.4.3.2 a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

6.6.2 Radiation Exposure Control Devices.

6.6.2.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, 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.

6.6.2.2 X-Ray Control.

6.6.2.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

6.6.2.2.1.1 exposure of one-half (0.5) second or less, or

6.6.2.2.1.2 during serial radiography when a means shall be provided to permit completion of any single exposure of the series in process.

6.6.2.2.2 Except for bone mineral densitometry devices, each x-ray control shall be located in such a way as to meet the following requirements:

6.6.2.2.2.1 stationary x-ray systems, and mobile or portable systems used routinely in one location, shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

6.6.2.2.2.2 mobile and portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 1.83 meters (6 feet) from the patient, the x-ray tube and the useful beam. Mobile and portable x-ray systems used in surgery are considered to be not routinely used in one location.

6.6.2.2.2.3 The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6.6.2.3 Automatic Exposure Controls. When an automatic exposure control is provided:

6.6.2.3.1 indication shall be made on the control panel when this mode of operation is selected;

6.6.2.3.2 if the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;

6.6.2.3.3 the minimum exposure time for all equipment other than that specified in RH 6.6.2.3.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

6.6.2.3.4 either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

6.6.2.3.5 a visible signal shall indicate when an exposure has been terminated at the limits required by RH 6.6.2.3.4, and manual resetting shall be required before further automatically timed exposures can be made.

6.6.2.4 Timer Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests exposures are performed:

$T_{avg} \geq 5(T_{max} - T_{min})$.

6.6.3 Source-to-Skin Distance.

All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

6.6.4 Exposure Reproducibility.

When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. The facility registrant may request an exemption for any machines manufactured prior to 1974, which cannot meet this requirement. The exemption request must verify that this exposure reproducibility variation will not result in unnecessary patient radiation exposure due to the need for repeat examinations.

6.6.5 Radiation from Capacitor Energy Storage Equipment in Standby Status.

Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.516 μC/kg (2 milliroentgen) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6.6.6 Additional Requirements Applicable to Certified Systems Only.

Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

6.6.6.1 Linearity. When the equipment allows a choice of x-ray tube current or mAs settings for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratio of exposure to the indicated milliampere-seconds product obtained at any two (2) consecutive tube current or mAs settings shall not differ by more than 0.10 times their sum:

$$|X_1 - X_2| \leq 0.10 (X_1 + X_2),$$

where X_1 and X_2 are the average mR/mAs (microcoulomb/kilogram per mAs) values obtained at each of two (2) consecutive tube current settings or at two settings differing by no more than a factor of two (2) when the mAs selector provides continuous selection.

6.6.6.2 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. If manufacturer specifications are not available, the following criteria shall be used:

6.6.6.2.1 The kVp shall not deviate from indicated values by more than ten (10) percent.

6.6.6.2.2 The timer accuracy shall not deviate from indicated values by more than:

6.6.6.2.2.1 ten (10) percent for an indicated time of greater than 20 ms; or

6.6.6.2.2.2 fifty (50) percent for an indicated time of 20 ms or less.

6.6.6.3 Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems .

6.6.6.3.1 There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

6.6.6.3.2 When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon

measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

6.6.6.3.3 For collimators manufactured prior to August 1, 1974, average net illuminance measurement made in the approximate center of each quadrant of the light field shall not be less than the values indicated below:

Column 1	**Column 2**
Ambient Light Illuminance	**Net Minimum Light Illuminance Above Ambient**
5 to 25 lux	25 lux
26 to 50 lux	50 lux
51 to 75 lux	75 lux
76 to 100 lux	100 lux
101 to 159 lux	100 lux

6.6.6.3.3.1 If the ambient light was reduced to achieve a net light localizer illuminance of any value in column 2, operating procedures shall be written, describing steps which must be taken for reducing the ambient light to allow enhancement of the light field during positioning. All x-ray machine operators shall be trained in these procedures. The operating procedures shall be filed in the written safety procedures manual and maintained on the premises of the registered facility.

6.6.6.4 Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of RH 6.6.1.1 and 6.6.6.3.

6.6.6.5 Positive Beam Limitation (PBL).

6.6.6.5.1 When a PBL system is provided, it shall prevent x-ray production when:

6.6.6.5.1.1 either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three (3) percent of the SID; or

6.6.6.5.1.2 The sum of the length and width differences as stated in RH 6.6.6.5.1.1 of this section without regard to sign exceeds four (4) percent of the SID.

6.6.6.5.1.3 The beam limiting device is at a SID for which PBL is not designed for sizing.

6.6.6.5.2 Conditions for PBL. When provided, the PBL system shall function as described in RH 6.6.6.5.1 of this section whenever all the following conditions are met:

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

6.6.6.5.2.2 The image receptor length and width are less than 50 centimeters;

6.6.6.5.2.3 The x-ray beam axis is within + or - three (3) degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within + or - three (3) degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

6.6.6.5.2.4 The x-ray beam axis is perpendicular to the plane of the image receptor to

within + or - three (3) degrees;

6.6.6.5.2.5 Neither tomographic nor stereoscopic radiography is being performed;

6.6.6.5.2.6 Manual collimation is not used;

6.6.6.5.2.7 The machine is used for procedures other than therapy simulation; and

6.6.6.5.2.8 The PBL system has not been intentionally overridden.

6.6.6.5.3 If a means of overriding the PBL system exists, that means:

6.6.6.5.3.1 Shall be designed for use only in the event of PBL system failure, or if the system is being serviced; and

6.6.6.5.3.2 If in a position that the operator would consider it part of the operational controls, or if it is referenced in the operator's manual, or in other materials intended for the operator,

6.6.6.5.3.2.1 shall require that a key be utilized to defeat the PBL;

6.6.6.5.3.2.2 shall require that the key remain in place during the entire time the PBL system is overridden; and

6.6.6.5.3.2.3 shall require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

6.6.6.5.4 Compliance with RH 6.6.6.5 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of RH 6.6.6.5.2 are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

6.6.6.5.5 The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

6.6.6.5.6 The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in RH 6.6.6.5, then any change of image receptor size or SID must cause the automatic return.

6.6.6.6 Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero” .

RH 6.7 Intraoral Dental Radiographic Systems.

In addition to the provisions of RH 6.3 and 6.4, the requirements of RH 6.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extra-oral dental radiographic systems are covered in RH 6.6.

6.7.1 Source-to-Skin Distance (SSD).

X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit

SSD, to not less than:

6.7.1.1 18 centimeters if operable above 50 kVp, or

6.7.1.2 10 centimeters if not operable above 50 kVp.

6.7.2 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:

6.7.2.1 if the minimum 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 7 centimeters; and

6.7.2.2 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 6 centimeters.

6.7.3 Timers.

Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

6.7.3.1 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.

6.7.3.2 Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero” .

6.7.3.3 Timer Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed:

$$T_{avg} \geq 5(T_{max} - T_{min}).$$

6.7.4 X-Ray Control .

6.7.4.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (0.5) second or less.

6.7.4.2 Each x-ray control shall be located in such a way as to meet the following requirements:

6.7.4.2.1 stationary x-ray systems, and mobile or portable systems used routinely in one location, shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure, or the exposure control shall be such that the operator can stand at least 1.83 meters (6 feet) from the patient, the x-ray tube and the useful beam;

6.7.4.2.2 mobile and portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 1.83 meters (6 feet) from the patient, the x-ray tube and the useful beam.

6.7.4.3 The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced.

6.7.5 Exposure reproducibility.

The estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected technique factors.

6.7.6 Linearity.

When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any two (2) consecutive tube current or mAs settings shall not differ by more than 0.10 times their sum:

$$|X_1 - X_2| \leq 0.10 (X_1 + X_2),$$

where X_1 and X_2 are the average mR/mAs values obtained at each of two (2) consecutive tube current or mAs settings.

6.7.7 Accuracy.

Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. If those are not available, accuracy of all exposure factors shall be within ten (10) percent of the selected factor(s).

6.7.8 Beam Quality.

All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent Systems operating above 70 kVp are subject to the filtration requirements of RH 6.4.5.1.

6.7.9 Administrative Controls.

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

6.7.9.2 The tube housing and the PID shall not be hand-held during an exposure.

6.7.9.3 The x-ray system shall be operated in such a manner that the area of the useful beam at the patient's skin is minimized.

6.7.9.4 Dental fluoroscopy without image intensification shall not be used.

Other Diagnostic X-Ray Systems

RH 6.8 Veterinary Medicine Radiographic Installations.

6.8.1 Equipment.

6.8.1.1 The protective tube housing shall be equivalent to the requirements of RH 6.4.3.

6.8.1.2 Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

6.8.1.3 The total filtration permanently in the useful beam shall meet the requirement of RH 6.4.5.1.

6.8.1.4 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant.

6.8.1.5 A method 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 5 (five) 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.

6.8.1.6 A device shall be provided to terminate the exposure after a preset time or exposure.

6.8.1.7 A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam.

6.8.2 Structural Shielding.

All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with RH 4.6, 4.12, 4.13, and 4.14 of these Regulations.

6.8.2.1 Veterinary facilities are exempt from the requirements of Appendix B, provided that the operator is adequately protected by distance and/or shielding.

6.8.3 Operating Procedures .

6.8.3.1 Whenever possible, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

6.8.3.2 No individual, other than the operator, shall be in the x-ray room while exposures are being made, unless such individual's assistance is required and the person is adequately protected by shielding and/or distance.

6.8.3.3 When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he/she shall be so positioned that no part of his/her body will be struck by the useful beam. The exposure of any individual used for this purpose shall be maintained below the limits specified in RH 4.6, 4.12, and 4.13.

6.8.3.4 No human shall hold the image receptor during radiography unless that individual is protected with appropriate shielding devices, such as protective gloves and apron, and that any part of his/her body struck by the useful beam shall be monitored. The exposure of any individual used for this purpose shall be maintained below the limits specified in RH 4.6, 4.12, and 4.13.

RH 6.9 Computed Tomography X-Ray Systems.

6.9.1 Definitions.

In addition to the definitions provided in RH 1.4 and 6.2 of these Regulations, the following definitions shall be applicable to RH 6.9:

"Computed tomography dose index (CTDI)" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

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

“Contrast scale (CS)” means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$(CTN)_x$ = CTN of the material of interest.

$(CTN)_w$ = CTN of water.

“CT conditions of operation” means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in RH 6.2.

“CT gantry” means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

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

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

where:

k = A constant [3]

3 The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

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

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

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS = Contrast scale

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

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

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

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

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

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

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

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

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

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

6.9.2 Requirements for Equipment.

6.9.2.1 Termination of Exposure.

6.9.2.1.1 Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

6.9.2.1.2 A visible signal shall indicate when the x-ray exposure has been terminated through the means required by RH 6.9.2.1.1.

6.9.2.1.3 The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

6.9.2.2 Tomographic Plane Indication and Alignment.

6.9.2.2.1 For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

6.9.2.2.2 For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

6.9.2.2.3 If a device using a light source is used to satisfy RH 6.9.2.2.1 or 6.9.2.2.2, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (46 foot candles).

6.9.2.3 Beam-On and Shutter Status Indicators and Control Switches.

6.9.2.3.1 The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

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

6.9.2.4 Indication of CT Conditions of Operation.

The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

6.9.2.5 Extraneous Radiation.

When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by RH 6.4.3.

6.9.2.6 Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 2, 1992.

6.9.2.6.1 The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

6.9.2.6.2 If the x-ray production period is less than one-half second, the indication of x-ray production

shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

6.9.2.6.3 The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

6.9.2.6.4 Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

6.9.3 Facility Design Requirements.

6.9.3.1 Aural Communication.

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

6.9.3.2 Viewing Systems.

6.9.3.2.1 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

6.9.3.2.2 Patient scanning shall be allowed only when a viewing system is available and in use.

6.9.4 Surveys, Evaluations, Calibrations, Spot Checks, and Operating Procedures.

6.9.4.1 Surveys and Evaluations.

6.9.4.1.1 All CT x-ray systems installed after September 1, 1992 and those systems not previously surveyed shall have a shielding survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.9.4.1.2 The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Department upon request.

6.9.4.1.3 Notwithstanding the provisions of RH 2.5.1.2, CT x-ray systems that have undergone a tube change within 12 months of the last annual evaluation do not require a complete calibration provided that the CT x-ray system operation after the tube change meets the criteria established by the qualified expert. The certification evaluation (CE) need not be performed each time an x-ray tube is replaced. However, each CT system shall receive a CE at least within one year of the previous CE.

6.9.4.2 Radiation Calibrations.

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

6.9.4.2.2 The calibration of a CT x-ray system shall be performed at intervals, not exceeding one year, specified by a qualified expert.

6.9.4.2.3 The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years.

6.9.4.2.4 CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

6.9.4.2.4.1 CT dosimetry phantom(s) shall be right circular cylinders of water or polymethyl methacrylate. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32 centimeters for testing CT x-ray systems designed to image any section of the body and 16 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

6.9.4.2.4.2 CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

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

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

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

6.9.4.2.6 Calibration shall meet the following requirements:

6.9.4.2.6.1 The CTDI [4] along the two axes specified in RH 6.9.4.2.4.2 shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

4 For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

6.9.4.2.6.2 The spot checks specified in RH 6.9.4.3 shall be made.

6.9.4.2.7 Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for a period of three (3) years for inspection by the Department.

6.9.4.3 Spot Checks.

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

6.9.4.3.2 The spot-check procedures shall incorporate the use of a CT performance phantoms which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

6.9.4.3.3 All spot checks shall be included in the calibration required by RH 6.9.4.2 and at time intervals

and under system conditions specified by a qualified expert.

6.9.4.3.4 Spot checks shall include acquisition of images obtained with the CT performance phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by RH 6.9.4.2. The images shall be retained, until a new calibration is performed, as follows:

6.9.4.3.4.1 photographic copies of the images obtained from the image recording device; or

6.9.4.3.4.2 images stored in digital form on a storage medium compatible with the CT x-ray system.

6.9.4.3.5 Written records of the spot checks performed shall be maintained for inspection by the Department.

6.9.4.4 Operating Procedures

6.9.4.4.1 The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

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

6.9.4.4.2.1 dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

6.9.4.4.2.2 instructions on the use of the CT performance phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

6.9.4.4.2.3 the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

6.9.4.4.2.4 when operators must select technique factors, a current technique chart shall be available at the control panel which specifies for each routine examination the CT conditions of operation and the typical number of scans per examination.

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

RH 6.10 Mammography.

6.10.1 Definitions.

“Continuing education unit (CEU)” means one contact hour of training or education, which is documentable.

“Established operating level” means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

“Facility” means a hospital, outpatient Department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of

equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation.

“Laterality” means the designation of either the right or left breast.

“Mammogram” means a radiographic image produced through mammography.

“Mammography” means radiography of the breast, but for the purposes of this Part, does not include: radiography of the breast performed during invasive interventions for localization or biopsy procedures; or radiography of the breast performed with an investigational mammography device as part of a scientific study conducted.

“Mammography phantom” means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. For the purpose of this section, phantom means mammography phantom.

“Mammography medical outcomes audit” means a systematic collection of mammography results and the comparison of those results with outcomes data.

“Patient” means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

“Standard breast” means a 4.2 centimeter (cm) thick compressed breast consisting of fifty(50) percent glandular and fifty (50) percent adipose tissue.

6.10.2 Quality Standards.

6.10.2.1 Personnel.

6.10.2.1.1 Radiologic Technologists. All mammographic examinations shall be performed by a person who meets the following requirements.

6.10.2.1.1.1 General Requirements. Be approved by the Department as a mammographer, as defined in RH 2.2 and has met the requirement of RH 2.4.4.1.1.1; or as a provisional mammographer, as specified under RH 2.4.4; or as a student radiographer working under the provision of RH 2.4.4.1.3; and

6.10.2.1.1.2 Continuing Education. The mammographer shall document fifteen (15) hours of continuing education which are no more than 36 months old. Mammographers who fail to meet this continuing education requirement shall obtain a sufficient number of continuing education units (CEU) in mammography to bring their total up to at least fifteen (15) CEU.

6.10.2.1.1.3 Continuing Experience. The mammographer shall have performed a minimum of 200 mammography examinations every 24 months. Mammographers who fail to meet the continuing experience requirement of RH 6.10.2.1.1.3 shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified mammographer, before resuming the performance of unsupervised mammography examinations.

6.10.2.1.2 Qualified Inspectors. All qualified inspectors conducting mammography facility and x-ray machine evaluations shall meet the requirements of Appendix B, c. of Part 2.

6.10.2.2 Equipment.

Only x-ray systems meeting the following standards shall be used:

6.10.2.2.1 System Design. The x-ray system shall be specifically designed for mammography; and

6.10.2.2.2 Image Receptor Sizes. Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm. The image receptors shall be equipped with moving grids matched to all image receptor sizes provided. Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor;

6.10.2.2.3 Beam Limitation and Light Fields. All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor and shall meet the requirement of RH 6.10.2.6.8. When a light localizer is used to define the x-ray field, it shall meet the requirement of RH 6.6.6.3.2.

6.10.2.2.4 Magnification. Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator. Systems used for magnification procedures shall provide, as a minimum, at least one magnification value within the range of 1.4 to 2.0.

6.10.2.2.5 Focal Spot Selection. When more than one focal spot is provided, the system shall indicate, prior to the exposure, which focal spot is selected. When more than one target material is provided, the system shall indicate, prior to the exposure, the preselected target material. When the target material and/or focal spot is automatically selected by the machine, the system shall display, after the exposure, the used target material and/or focal spot.

6.10.2.2.6 Compression . All mammography systems shall incorporate a compression device.

6.10.2.2.6.1 Application of Compression. Effective October 28, 2002, each system shall provide an initial power driven compression activated by hands-free controls and fine adjustment compression controls operable from both sides of the patient.

6.10.2.2.6.2 Compression Paddle. Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.

6.10.2.2.6.2.1 The compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1 cm at any point on the surface of the compression paddle when compression is applied.

6.10.2.2.6.2.2 Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements. Such equipment is exempt from the requirement of RH 6.10.2.2.6.2.1.

6.10.2.2.6.2.3 The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

6.10.2.2.6.2.4 The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

6.10.2.2.7 Technique Factor Selection and Display. Manual selection of milliampere seconds (mAs) or at least one of its component parts [milliampere (mA) and time] shall be available.

6.10.2.2.7.1 The technique factors (kVp, mA and time in second or milliseconds, or mAs) to be used during an exposure shall be indicated prior to the exposure, except when the automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

6.10.2.2.7.2 Following AEC mode use, the system shall indicate the actual kVp and mAs used during the exposure. The mAs may be displayed as mA and time.

6.10.2.2.8 Automatic Exposure Control. All systems shall provide an AEC mode that is operable in all combinations of equipment configuration provided, i.e., grid, nongrid, magnification, non-magnification, and various target-filter combinations.

6.10.2.2.8.1 The size and available positions of the detector shall be clearly indicated on the compression paddle.

6.10.2.2.8.2 The system shall provide means for the operator to vary the selected optical density (OD) from the normal or zero setting to the positive and/or negative values of density settings.

6.10.2.2.9 X-ray Film and Intensifying Screens. The registrant shall use x-ray film and intensifying screens that have been designated by the manufacturers as appropriate and screen/film compatible for mammography.

6.10.2.2.10 Film Processing Solutions. The registrant shall use chemical solutions that are capable of developing the mammography films in a manner equivalent to the minimum requirements specified by the film manufacturer.

6.10.2.2.11 Lighting. Hot lights, capable of producing light levels greater than that provided by the view box, shall be available for use.

6.10.2.2.12 Film Masking Devices. The registrant shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available and used.

6.10.2.2.13 Viewboxes used for interpreting mammograms and clinical quality review by the technologist shall be capable of producing a luminance of at least 3,000 candela per square meter (cd/m_2).

6.10.2.3 Medical Records And Mammography Reports.

6.10.2.3.1 Contents and Terminology. The registrant shall prepare a written report of the results of each mammography examination performed. The report shall include: the name of the patient and an additional patient identifier; the date of the examination; the name of the interpreting physician who interpreted the mammogram; and the overall final assessment of findings.

6.10.2.3.2 Communication of Mammography Results to the Patient. The registrant shall maintain a system to ensure that the results of each mammography examination are communicated to the patient in a timely manner.

6.10.2.3.2.1 The registrant shall send the mammography report, as described in RH 6.10.2.3.1, in addition to a written notification of results in lay terms, within thirty (30) days from the date of the mammography examination, to all patients who do not name a health care provider to receive the report.

6.10.2.3.2.2 Registrants that accept patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically needed.

6.10.2.3.3 Communication of Mammography Results to Health Care Providers. When the patient has named a referring health care provider, the registrants shall provide a written report of the mammography examination, within thirty (30) days from the date of the exam, to that provider.

6.10.2.3.4 Record Keeping. The registrant shall maintain mammography films and reports in a permanent medical record of the patient for a period of not less than five (5) years, or not less than ten (10) years if no additional mammograms of the patient are performed at the facility.

6.10.2.3.4.1 The registrant shall upon request or on behalf of, by the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports as directed by the patients or their representatives.

6.10.2.3.4.2 Any fee charged to the patients for providing the services described in RH 6.10.2.3.4.1 shall not exceed the documented costs associated with this service.

6.10.2.3.5 Mammographic Image Identification. Each mammography image shall clearly indicate the patient's name and an additional patient identifier; the date of the examination; the view and laterality; the facility name and location; the technologist identification; the cassette/screen identification; and the mammography unit.

6.10.2.4 Quality Assurance - General Requirements.

The registrant shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

6.10.2.5 Quality Assurance - Quality Control of Mammography Operations.

6.10.2.5.1 All tests specified in RH 6.10.2.5 shall be performed by a qualified mammographer or provisional mammographer.

6.10.2.5.2 Daily Quality Control Tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be done on each day that examinations are provided prior to clinical films being developed. The test shall include the following assessment:

6.10.2.5.2.1 The base plus fog density shall be within 0.03 of the established operating level.

6.10.2.5.2.2 The mid-density shall be within + or - 0.15 of the established operation level.

6.10.2.5.2.3 The density difference shall be within + or - 0.15 of the established operation level. For any mammography registrant using film processors at multiple locations, such as a mobile service processor performance by sensitometric strips shall be performed prior to the development of patient's films.

6.10.2.5.3 Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly. The test shall include the following assessment:

6.10.2.5.3.1 The optical density at the center of the phantom image shall be at least 1.20 when using clinical technique factors.

6.10.2.5.3.2 The optical density at the center of the phantom image shall not change by more than + or - 0.20 from the established operating level.

6.10.2.5.3.3 The phantom image shall achieve at least the minimum score to observe the image of a 0.75 mm fiber, 0.32 mm speck, and a 0.75 mm mass.

6.10.2.5.3.4 The density difference between the background of the phantom and an added test object, used to assess image contrast, shall not vary by more than + or - 0.05 from the

established operating level.

6.10.2.5.4 Quarterly Quality Control Tests. Facilities with screen-film systems shall perform the following tests at least quarterly:

6.10.2.5.4.1 Fixer Retention in Film. The residual fixer shall be no more than 5 micrograms per square cm.

6.10.2.5.4.2 Repeat Analysis. If the total repeat or reject rate changes from the previously determined rate by more than two (2) percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

6.10.2.5.5 Semiannual Quality Control Tests. Facilities with screen-film systems shall perform the following tests at least semiannually:

6.10.2.5.5.1 Darkroom Fog. The darkroom fog level of a phantom image with an optical density of at least 1.20 and shall not exceed 0.05 OD. The fog test film shall be exposed to typical darkroom conditions for two (2) minutes with the emulsion side up.

6.10.2.5.5.2 Screen-film Contact. All cassettes used at the facility for mammography shall be tested using 40 mesh copper screen. Cassettes shall not be used for mammography if one or more areas > 1 cm in diameter or poor contact that are not eliminated by screen cleaning. Five or more small areas <1 cm in diameter are acceptable, and the cassette may be returned to clinical use.

6.10.2.5.5.3 Compression Device Performance. A compression force of at least 111 newtons (25 pounds) shall be provided. Effective October 28, 2002, the maximum compression force of the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (47 pounds).

6.10.2.6 Quality Assurance - Facility and Equipment Evaluation.

Facilities with screen-film systems shall perform the following tests at least annually.

6.10.2.6.1 All tests specified in RH 6.10.2.6 shall be performed by a mammography approved qualified inspector.

6.10.2.6.2 Automatic Exposure Control Performance. The AEC shall be capable of maintaining film optical density within + or - 0.30 of the mean OD when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that an OD within + or - 0.30 of the average under phototimed conditions can be produced.

6.10.2.6.2.1 After October 28, 2002, the AEC shall be capable of maintaining film OD within + or - 0.15 of the mean OD.

6.10.2.6.2.2 The OD at the center of the phantom image shall not be less than 1.20.

6.10.2.6.3 kVp Accuracy and Reproducibility. The kVp shall be accurate within + or - five (5) percent of the indicated kVp at:

6.10.2.6.3.1 The lowest clinical kVp that can be measured by a kVp test device;

6.10.2.6.3.2 The most commonly used clinical kVp;

6.10.2.6.3.3 The highest available clinical kVp; and

6.10.2.6.3.4 At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. Not all commonly used clinical settings of kVp need to be tested.

6.10.2.6.4 Focal Spot Condition. Focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

6.10.2.6.4.1 System Resolution. Mammography systems, in combination with the mammography screen-film combination, shall provide a minimum resolution of 11 cycles/millimeter (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

6.10.2.6.4.1.1 The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within one cm of the chest wall edge of the image receptor.

6.10.2.6.4.1.2 When more than one target is provided, the measurement described in RH 6.10.2.6.3.1 shall be made using the magnification and contact radiography with all available targets.

6.10.2.6.4.1.3 When more than one SID is provided, the test shall be performed at the most commonly used clinical SID.

6.10.2.6.4.1.4 The kVp shall be set at the clinical value for a standard breast and the system resolution test shall be performed such that the background optical density of the film should be between 1.2 and 1.8.

6.10.2.6.4.2 Focal Spot Dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table I.

Table I - Focal Spot Tolerance Limit

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions	Maximum Measured Dimensions
.	Width (mm)	Length (mm)
0.10	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
0.50	0.90	1.30

6.10.2.6.5 Beam Quality and Half-value Layer (HVL). The HVL shall meet the following specifications for minimum HVL.

$$\frac{kVp}{100} \leqslant HVL$$

6.10.2.6.6 Breast Entrance Air Kerma and AEC Reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6.10.2.6.7 Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast, using the clinical technique factors and conditions for that phantom, shall not exceed 3.0 milligray (0.3 rad) per exposure.

6.10.2.6.8 X-ray Field/Light Field/Image Receptor/Compression Alignment. All systems shall have beam -limiting devices that allow the useful x-ray beam to extend to or beyond the edges of the image receptor but by no more than two (2) percent of the SID at the chest wall side.

6.10.2.6.8.1 If a light localizer is provided, the resultant light field shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed two (2) percent of the SID.

6.10.2.6.8.2 The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness.

6.10.2.6.9 Uniformity of Screen Speed. Uniformity of screen speed of all the cassettes shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.3. Screen artifacts shall also be evaluated during this test.

6.10.2.6.10 System Artifacts. System artifacts shall be performed for all cassettes sizes using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

6.10.2.6.11 Radiation Output. The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milliroentgen per second) when operating at 28 kVp in the moly/moly mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place as clinically used. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 milli roentgen per second).

6.10.2.6.11.1 The system shall be capable of maintaining the required minimum radiation output averaged over a three (3) second period.

6.10.2.6.12 Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

6.10.2.6.12.1 An override capability to allow maintenance of compression;

6.10.2.6.12.2 A continuous display of the override status; and

6.10.2.6.12.3 A manual emergency compression release that can be activated in the event of power or automatic release failure.

6.10.2.7 Additional Mammography Equipment Evaluations.

An evaluation of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is dissembled and reassembled at the same or new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be performed by a mammography approved qualified inspector.

6.10.2.8 Quality Control Tests-Other Modalities.

For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems as specified in RH 6.10.2.6.6.

6.10.2.9 Mobile Units.

Mobile mammography systems shall meet the requirements of RH 6.10.2.5 through 6.10.2.8. In addition, at each examination location, the registrant shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit, prior to its use on patients.

6.10.2.10 Facility Cleanliness.

The registrant shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness. The registrant shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

6.10.2.11 Infection Control.

The registrant shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography systems after contact with blood or other potentially infectious materials.

6.10.2.12 Quality Assurance-Mammography Medical Outcomes Audit.

Each registrant shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. The facility's first audit analysis shall be initiated no later than twelve (12) months after the date the facility becomes certified, or twelve (12) months after the effective date of these Regulations whichever date is latest. This audit analysis shall be completed within an additional twelve (12) months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every twelve (12) months.

6.10.2.13 All mammography facilities which have a current MQSA certificate or provisional certificate and a certification evaluation (not exceeding twelve (12) months old) performed by a qualified inspector authorized in mammography are considered to have met the requirements of RH 6.10, only if any deficiencies or violations cited have been corrected within thirty (30) days.

RH 6.11 Severability.

The provisions of these Regulations are severable, and if any provisions or the application of the provisions to any circumstances is held invalid, the application of such provision to other circumstances, and the remainder of these Regulations shall not be affected thereby.

PART 6 APPENDIX A. INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN

REVIEWS

In order to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information shall be submitted to the qualified expert.

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(s) 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(s) concerned.

    (c) The dimensions of the room(s) concerned and inter-floor distances if occupied.

    (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

    (e) The make and model of the equipment, the maximum technique factors, and the energy waveform (single phase, three phase, etc.)

    (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

PART 6 APPENDIX B. DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH [5]

5 Exceptions from the above design requirements may be granted by the Department. To apply for such an exception, the facility registrant must submit a facility design review from a Qualified Expert to the Department. The review must specify the reason for the exception and it must demonstrate that the operator will have equivalent protection from radiation by use of the proposed shielding design.

1. <u>Space Requirements:</u>

    (a) The operator shall be allotted not less than 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

    (b) The operator's booth may be of any geometric configuration with no dimension of less than 2 feet (0.61 m).

    (c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

    (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's location within the booth.

2. <u>Structural Requirements:</u>

    (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

    (b) When a door or movable panel is used as an integral part of the booth structure, it must have

an interlock which will prevent an exposure when the door or panel is not closed in its shielding position.

(c) Shielding shall be provided to meet the requirements of Part 4 of these Regulations.

3. Viewing System Requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have either an interlock controlling the exposure which will prevent the exposure if the door is not closed; or a warning light must be activated at the control panel when the door is opened.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m^2).

(2) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457 m) from the edge of the booth.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of paragraph 3.(a) of this Appendix.

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of paragraph 3.(a) of this Appendix.

(2) There shall be an alternate viewing system as a backup for the primary system, unless the x-ray room is not used in the case of viewing system failure.

PART 6 APPENDIX C. INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

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

1. Name and address of the applicant and, when applicable, the names and addresses of all locations within this State, where the service will be provided.

2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

3. A detailed description of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

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

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program prior to being placed into operation. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these Regulations.

7. A description of the diagnostic film quality control program, if applicable.

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

9. The qualifications of each individual who will be operating the x-ray system(s). In the case of non-licensed operators of bone densitometry unit(s), include a copy of the waiver granted by the Board of Medical Examiners to the non-licensed operators from taking the limited scope examination.

10. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s) or other results from the x-ray examinations.

12. Name and current license from Board of Medical Examiners of Physician(s) who will oversee the program.

13. A copy of the order prescribed by a Colorado licensed practitioner for the healing art screening program to be conducted.

14. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

15. A description of the procedures for the retention or disposition of the radiographs, if applicable, and other records pertaining to the x-ray examinations.

EDITOR'S NOTES

6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

History

[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]