CHAPTER 4730
DEPARTMENT OF HEALTH
IONIZING RADIATION

4730.0100 DEFINITIONS.

Subpart 1. **Scope.** For purposes of this chapter, the terms in this part have the meanings given them.

Subp. 2. MR 1991 [Renumbered as Subp. 13, 16 SR 485]

Subp. 2. **Absorbed dose.** "Absorbed dose" means the mean energy imparted by ionizing radiation to matter of a known mass. The special unit of absorbed dose is the rad under the conventional system of measurement and is the gray under the SI system of measurement.

Subp. 3. [Repealed by amendment, L 1977 c 305 s 39]

Subp. 4. MR 1991 [Renumbered as Subp. 37, 16 SR 485]

Subp. 4. **Accelerator.** "Accelerator" means a device that accelerates charged subatomic particles or nuclei to energies useful for research and therapy.

Subp. 5. MR 1991 [Renumbered as Subp. 39, 16 SR 485]

Subp. 5. **Accelerator–produced material.** "Accelerator–produced material" means material made radioactive by a particle accelerator.

Subp. 5a. [Repealed, 29 SR 755]

Subp. 6. **Added filtration.** "Added filtration" means filtration that is in addition to the inherent filtration.

Subp. 6a. **Adult.** "Adult" means an individual 18 or more years of age.

Subp. 7. **Aluminum equivalent.** "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

Subp. 7a. **Analytical ionizing radiation producing equipment.** "Analytical ionizing radiation producing equipment" means ionizing radiation producing equipment used for research, development, and quality control including x–ray diffractometers, fluorescence analyzers, spectroscopy analyzers, thickness measurement gauges, and electron microscopes.

Subp. 7b. [Repealed, 29 SR 755]

Subp. 8. **Applicator.** "Applicator" means an added device that determines the extent of the treatment field at a given distance from the virtual source.

Subp. 9. MR 1991 [Renumbered as Subp. 54, 16 SR 485]

Subp. 9. **Appropriate limit.** "Appropriate limit" or "appropriate limits" means the maximum permissible dose or doses of radiation that may be administered to the whole body or a given part of a human being.

Subp. 10. **Arc therapy.** "Arc therapy" means rotation of the beam during irradiation.

Subp. 11. [Repealed, 16 SR 485]

Subp. 12. **Assembler.** "Assembler" means a person engaged in the business of assembling, replacing, or installing one or more components into an x–ray system or subsystem. Assembler includes the owner of an x–ray system or the owner's employee or agent who assembles components into an x–ray system that is subsequently used to provide professional or commercial services.

Subp. 13. **Attenuation.** "Attenuation" means the reduction of exposure rate upon passage of radiation through matter.

Subp. 14. MR 1991 [Renumbered as Subp. 83, 16 SR 485]

Subp. 14. **Attenuation block.** "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

Subp. 15. MR 1991 [Renumbered as Subp. 89, 16 SR 485]

Subp. 15. **Automatic exposure control (AEC).** "Automatic exposure control" or "(AEC)" means a device that automatically controls one or more technique factors to obtain a required quantity of radiation at a preselected location.

Subp. 16. MR 1991 [Renumbered as Subp. 90, 16 SR 485]

Subp. 16. **Beam axis.** "Beam axis" means a line from the source through the centers of the x–ray fields.

Subp. 17. [Repealed, 16 SR 485]

Subp. 18. **Beam–limiting device (BLD).** "Beam–limiting device" or "(BLD)" means a device used to restrict the dimensions of the x–ray field.

Subp. 19. **Beam monitoring system.** "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

Subp. 20. MR 1991 [Renumbered as Subp. 97, 16 SR 485]

Subp. 20. **Beam scattering filter.** "Beam scattering filter" means a filter or foil used to scatter a beam of electrons.

Subp. 21. [Repealed, 16 SR 485]

Subp. 22. [Repealed, 29 SR 755]

Subp. 22a. [Repealed, 29 SR 755]

Subp. 23. **Bucky.** "Bucky" means an apparatus under the x–ray table or in a vertical cassette holder that holds the grid and cassette during the radiographic exposure.

Subp. 24. [Repealed, 29 SR 755]

Subp. 25. **C–arm.** "C–arm" means an x–ray system in which the image receptor and the x–ray tube housing assembly are connected by a common mechanical support system to maintain a desired spatial relation.

Subp. 26. MR 1991 [Renumbered as Subp. 113, 16 SR 485]

Subp. 26. **Calibration.** "Calibration" means the determination of:

A. the response or reading of an instrument relative to a series of known radiation values over the range of the instrument;

B. the strength of a source of radiation relative to a standard; or

C. the radiation dose or exposure rate at a designated distance from a radiation source under specified conditions of measurement.

Subp. 27. [Repealed, 16 SR 485]

Subp. 27a. **Central axis of the beam.** "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam–limiting device.

Subp. 28. MR 1991 [Renumbered as Subp. 125, 16 SR 485]

Subp. 28. **Cephalometric device.** "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Subp. 28a. **Certified cabinet x–ray system.** "Certified cabinet x–ray system" means an x–ray system that has been certified according to Code of Federal Regulations, title 21, part 1010, section 1010.2, April 1, 1996, and as subsequently amended, as being manufactured and assembled pursuant to Code of Federal Regulations, title 21, part 1020, section 1020.40, April 1, 1996, and as subsequently amended.

Subp. 29. [Repealed, 16 SR 485]

Subp. 30. MR 1991 [Renumbered as Subp. 129, 16 SR 485]

Subp. 30. **Certified components.** "Certified components" means components of x–ray systems that are subject to the x–ray equipment performance standards adopted under Public Law 90–602, the Radiation Control for Health and Safety Act of 1968.

Subp. 31. [Repealed, 16 SR 485]

Subp. 32. **Certified system.** "Certified system" means an x–ray system that has one or more certified components.

Subp. 33. MR 1991 [Renumbered as Subp. 135, 16 SR 485]

Subp. 33. **Changeable filter.** "Changeable filter" means a filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

Subp. 34. **Clinical range.** "Clinical range" means the range of control console technique settings that a facility would use in its routine x–ray projections. Equipment performance tests are performed over clinical ranges.

Subp. 35. MR 1991 [Renumbered as Subp. 137, 16 SR 485]

Subp. 35. **Coefficient of variation or C.** "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations.

Subp. 36. **Cold flow.** "Cold flow" means the viscous flow of a solid at ordinary temperatures; or, the distortion of a solid under sustained pressure especially with an accompanying inability to return to its original dimensions when pressure is removed.

Subp. 37. **Collimation.** "Collimation" means the restriction of the useful beam to an appropriate area.

Subp. 38. MR 1991 [Renumbered as Subp. 144, 16 SR 485]

Subp. 38. **Collimator.** "Collimator" means a mechanism connected to the x–ray tube housing that controls the dimensions of the primary radiation beam. Types of collimators are cones, diaphragms, and variable–aperture beam–limiting devices.

Subp. 39. MR 1991 [Renumbered as Subp. 146, 16 SR 485]

Subp. 39. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 39a. **Committed dose equivalent ($H_{T,50}$).** "Committed dose equivalent ($H_{T,50}$)" means the dose equivalent to organs or tissues of reference (T) that is received from an intake of radioactive material by an individual during the 50–year period following the intake.

Subp. 39b. **Committed effective dose equivalent ($H_{E,50}$).** "Committed effective dose equivalent ($H_{E,50}$)" means the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

Subp. 40. MR 1991 [Renumbered as Subp. 147, 16 SR 485]

Subp. 40. **Computed tomography (CT).** "Computed tomography" or "(CT)" means the production of a tomogram by the acquisition and computer processing of x–ray transmission data.

Subp. 41. [Repealed, 16 SR 485]

Subp. 42. MR 1991 [Renumbered as Subp. 148, 16 SR 485]

Subp. 42. **Contact therapy system.** "Contact therapy system" means an x–ray system used for therapy with the x–ray tube port placed in contact with the surface being treated.

Subp. 43. MR 1991 [Renumbered as Subp. 151, 16 SR 485]

Subp. 43. **Control panel.** "Control panel" means the part of the x–ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

Subp. 44. MR 1991 [Renumbered as Subp. 155, 16 SR 485]

Subp. 44. **Controlled area.** "Controlled area" means a defined area in which the exposure of persons to radiation is under the supervision of a radiation safety officer. (This implies that a controlled area is one that requires control of access, occupancy, and working conditions for radiation protection purposes.)

Subp. 45. MR 1991 [Renumbered as Subp. 159, 16 SR 485]

Subp. 45. **Coulomb per kilogram (C/kg).** "Coulomb per kilogram" or "(C/kg)" means the unit of exposure. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram (uC/kg).

Subp. 46. **CT conditions of operation.** "CT conditions of operation" means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in subpart 196.

Subp. 47. MR 1991 [Renumbered as Subp. 163, 16 SR 485]

Subp. 47. **CT dose index (CTDI).** "CT dose index" or "(CTDI)" means the integral from minus 7T to plus 7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness (T) and the number of tomograms produced in a single scan (n), 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; and

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 increment of adjacent scans is nT.

Subp. 48. MR 1991 [Renumbered as Subp. 164, 16 SR 485]

Subp. 48. **CT gantry.** "CT gantry" means the tube housing assemblies, beam–limiting devices, detectors, and supporting structures and frames that hold these components.

Subp. 49. **CT number.** "CT number" means the number used to represent the x–ray attenuation associated with each elemental area of the CT image.

Subp. 50. [Repealed, 29 SR 755]

Subp. 51. **Dead–man switch.** "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.

Subp. 52. MR 1991 [Renumbered as Subp. 178, 16 SR 485]

Subp. 52. **Densitometer.** "Densitometer" means an instrument that measures the optical density of a film by measuring the amount of light transmitted through the film.

Subp. 52a. [Repealed, 29 SR 755]

Subp. 53. MR 1991 [Renumbered as Subp. 188, 16 SR 485]

Subp. 53. **Diagnostic source assembly.** "Diagnostic source assembly" means the tube housing assembly with a beam–limiting device attached.

Subp. 54. **Diagnostic–type protective tube housing.** "Diagnostic–type protective tube housing" means an x–ray tube housing so constructed that the leakage radiation measured at a distance of one meter from the source cannot exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

Subp. 55. **Diagnostic radiographic imaging system.** "Diagnostic radiographic imaging system" means an assemblage of components for the generation, transmission, and reception of an x–ray and the transformation, storage, and visual display of the resultant radiographic image.

Subp. 56. MR 1991 [Renumbered as Subp. 193, 16 SR 485]

Subp. 56. **Diagnostic radiographic system.** "Diagnostic radiographic system" means an x–ray system designed for irradiation of any part of the human or animal body for diagnosis or visualization.

Subp. 57. MR 1991 [Renumbered as Subp. 197, 16 SR 485]

Subp. 57. **Dose.** "Dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent.

Subp. 58. [Repealed, 29 SR 755]

Subp. 59. **Dose equivalent (DE).** "Dose equivalent" or "(DE)" means a quantity used for radiation protection purposes that expresses on a common scale for all radiations the irradiation incurred by exposed persons. It is defined as the product of the absorbed dose and the quality factor. For x rays and gamma rays, the dose equivalent in rems is usually assumed to be numerically equal to either the exposure in roentgens or the absorbed dose in rads. The special unit dose equivalent is the rem under the conventional measurement system and is the sievert under the SI measurement system.

Subp. 60. **Dose monitoring system.** "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation that can be related to the absorbed dose at a given location within a defined geometry.

Subp. 61. **Dose monitor unit.** "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose has been calculated.

Subp. 62. **Dose profile.** "Dose profile" means the dose as a function of position along a particular plane.

Subp. 63. [Repealed, 29 SR 755]

Subp. 64. **Electron–beam generator.** "Electron–beam generator" means a type of electron accelerator in which the electron beam is brought out into the atmosphere for irradiation purposes.

Subp. 65. **Elemental area.** "Elemental area" means the smallest area within a tomogram for which the x–ray attenuation properties of a body are depicted.

Subp. 66. **Entrance exposure rate.** "Entrance exposure rate" means the exposure per unit of time at the point where the center of the useful beam enters the patient.

Subp. 67. **ESE.** "ESE" means the entrance skin exposure that is measured free in air.

Subp. 68. **Exposure.** "Exposure" means being exposed to ionizing radiation or to radioactive material. An individual receives a dose of radiation but the individual is exposed to the radiation that delivered the dose.

For purposes of part 4730.2150, exposure means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass (dm) are completely stopped in air. The unit of exposure is the Roentgen (R).

Subp. 69. **Exposure rate.** "Exposure rate" means the exposure per unit of time, such as roentgen per minute, milliroentgen per hour, sievert per minute, or millisievert per hour.

Subp. 70. **Facility.** "Facility" means the location at which one or more sources of radiation are installed or located within one building, vehicle, or under one roof, and are under the same administrative control.

Subp. 71. **Field emission equipment.** "Field emission equipment" means equipment that uses an x–ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Subp. 72. **Field–flattening filter.** "Field–flattening filter" means a permanent filter used to provide dose uniformity over the area of a useful beam of x–rays at a specified depth.

Subp. 73. **Filter or filtration.** "Filter" or "filtration" means material placed in the useful beam to absorb preferentially selected radiations.

Subp. 73a. [Repealed, 29 SR 755]

Subp. 74. **Fluoroscopic imaging assembly.** "Fluoroscopic imaging assembly" means a subsystem in which x–ray photons produce a fluoroscopic image. It includes image receptors 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.

Subp. 75. **Focal spot.** "Focal spot" means the area of the anode from which x–rays originate.

Subp. 76. **Gantry.** "Gantry" means the part of the system supporting and allowing possible movements of the radiation head.

Subp. 77. **General purpose radiographic x–ray system.** "General purpose radiographic x–ray system" means a radiographic x–ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

Subp. 78. **Gonad shield.** "Gonad shield" means a protective barrier for the testes or ovaries.

Subp. 79. **Gray (Gy).** "Gray" or "(Gy)" means the unit of absorbed dose equal to one joule per kilogram. One gray is equal to 100 rad. Submultiples included in these regulations are the milligray (mGy), the microgray (μGy) and the centigray (cGy). The conventional system equivalent is the rad.

Subp. 80. **Half–value layer (HVL).** "Half–value layer" or "(HVL)" means the thickness of a specified material that attenuates the beam of radiation to such an extent that the exposure rate is reduced to one–half of its original value. The contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is considered excluded.

Subp. 81. **Healing arts.** "Healing arts" means health professions for diagnostic or healing treatment of human and animal maladies that are regulated under Minnesota Statutes, chapter 147, 153, or 156; or section 148.01, 148.106, or 150A.05, subdivision 1, clause (4), for the lawful practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

Subp. 82. **Healing arts screening or screening.** "Healing arts screening" or "screening" means the testing of individuals using x–ray equipment to detect or evaluate health conditions when the tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe the tests for the purpose of diagnosis or treatment.

Subp. 83. **High radiation area.** "High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

Subp. 84. **Human use.** "Human use" means the internal or external administration of radiation or radioactive material to an individual.

Subp. 85. **Image intensifier.** "Image intensifier" means a device, installed in its housing, that instantaneously converts an x–ray pattern into a corresponding light image of higher energy density or higher luminance.

Subp. 86. **Image receptor.** "Image receptor" means a device, such as a fluorescent screen or radiographic film, that transforms incident x–ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

Subp. 87. **Image receptor support.** "Image receptor support" means, for mammographic systems, the part of the system designed to support the image receptor during mammography.

Subp. 88. **Individual.** "Individual" means a human being.

Subp. 88a. **Industrial cabinet baggage system.** "Industrial cabinet baggage system" means an x–ray system with the x–ray tube installed in a shielded cabinet that is freestanding and is designed primarily for the inspection of carry–on baggage at airline, railroad, or bus terminals, courthouses, correctional facilities, and similar facilities. The baggage to be irradiated is contained in the shielded cabinet and the shielded cabinet is designed to exclude personnel from its interior during generation of x–rays.

Subp. 88b. **Industrial cabinet radiography.** "Industrial cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the unrestricted limitations in part 4730.0380.

Subp. 89. **Industrial radiographer.** "Industrial radiographer" means any individual who performs or who, in attendance at the site where ionizing radiation sources are being used, personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with chapter 4730.

Subp. 89a. **Industrial radiographer's assistant.** "Industrial radiographer's assistant" means an individual who uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography under the personal supervision of an industrial radiographer.

Subp. 90. **Industrial radiography.** "Industrial radiography" means a nondestructive testing method using ionizing radiation to produce images for detecting flaws in objects without destroying them and for other quality control purposes.

Subp. 91. **Inherent filtration.** "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Subp. 92. **Inspection.** "Inspection" means an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the commissioner.

Subp. 93. **Interlock.** "Interlock" means a device which automatically causes a reduction of the exposure rate upon entry by personnel into a high radiation area. Alternatively, an interlock may prevent entry into a high radiation area, or a device arranged or connected so the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

Subp. 94. **Ionizing radiation.** "Ionizing radiation" means gamma rays, x–rays, alpha particles, beta particles, high speed electrons, neutrons, protons, and other nuclear particles, capable of producing ions directly or indirectly, by interaction with matter.

Subp. 95. **Irradiation.** "Irradiation" means the exposure of matter to ionizing radiation.

Subp. 96. **Isocenter.** "Isocenter" means a fixed point in space through which pass the central axes of radiation beams for all possible beam orientations and field sizes.

Subp. 97. **Iso–line.** "Iso–line" means a line, usually irregular, along which the exposure rates are the same at any point.

Subp. 98. **Kilovolt peak (kVp).** "Kilovolt peak" or "(kVp)" means the maximum value in kilovolts of the potential difference of an x–ray generator. When only one–half of the wave is used, the value refers to the useful half of the cycle.

Subp. 99. **Kilowatt second (kWs).** "Kilowatt second" or "(kWs)" means the equivalent of 10^3 kV X mA X s.

Subp. 100. **Lead equivalence or lead equivalent.** "Lead equivalence" or "lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Subp. 101. **Leakage radiation.** "Leakage radiation" means all radiation coming from within the source or tube housing except the useful beam. Leakage radiation includes the portion of the direct radiation not absorbed by the protective source or tube housing as well as the scattered radiation produced within the housing.

Subp. 102. **Leakage technique factors.** "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly that are used in measuring leakage radiation, as defined in items A to C.

A. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum–rated kVp and the maximum–rated number of exposures in an hour for operation at the maximum–rated kVp with the quantity of charge per exposure being ten millicoulombs, for example, ten milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

B. For diagnostic source assemblies intended for field emission equipment for pulsed operation, the maximum–rated kVp and the maximum–rated number of x–ray pulses in an hour for operation at the maximum–rated kVp.

C. For all other diagnostic or x–ray tube therapeutic source assemblies, the maximum–rated kVp and the maximum–rated continuous milliamperage for the maximum–rated kVp.

Subp. 103. **Licensed practitioner of the healing arts.** "Licensed practitioner of the healing arts" means health professionals for diagnostic or healing treatment of human and

animal maladies, which are licensed under Minnesota Statutes, chapter 147, 153, or 156; or section 148.01, 148.106, or 150A.05, subdivision 1, clause (4), for the lawful practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

Subp. 104. **Light field.** "Light field" means the 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.

Subp. 105. **Line–voltage regulation.** "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.

Subp. 106. **Linear attenuation coefficient or μ.** "Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material. The linear attenuation coefficient is the photon fraction attenuated per centimeter for small thicknesses of the attenuator.

Subp. 106a. **Local components.** "Local components" means parts of an x–ray system that are struck by ionizing radiation, including radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, detectors, and shielding. Local components do not include power supplies, transformers, amplifiers, readout devices, control panels, or other areas that are not struck by ionizing radiation.

Subp. 106b. [Repealed, 29 SR 755]

Subp. 106c. [Repealed, 29 SR 755]

Subp. 107. **mA.** "mA" means milliampere.

Subp. 108. **mAs.** "mAs" means milliampere–second.

Subp. 109. **Maximum line current.** "Maximum line current" means the root–mean–square current in the supply line of an x–ray system operating at its maximum rating.

Subp. 110. **Medical particle accelerator.** "Medical particle accelerator" means a system capable of accelerating electrons, protons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV.

Subp. 111. [Repealed, 22 SR 314]

Subp. 112. **Maximum permissible dose or dose equivalent (MPD).** "Maximum permissible dose" or "dose equivalent (MPD)" means, for radiation protection purposes, the maximum dose equivalents that persons shall be allowed to receive in a stated period of time (see parts 4730.0310 to 4730.0380). This excludes patients receiving radiation for diagnostic or therapeutic purposes under supervision of licensed practitioners of the healing arts.

Subp. 113. **Maximum permissible neutron radiation.** "Maximum permissible neutron radiation" means the amount of neutron radiation in rems that is equivalent to the maximum permissible dose. Neutron flux dose equivalents are given in part 4730.3400.

Subp. 114. **NCRP.** "NCRP" means the National Council on Radiation Protection and Measurements. Specific NCRP reports are incorporated by reference in this chapter. The reports may be viewed at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, are available through the Minitex interlibrary loan system, and are not subject to frequent change.

Subp. 115. [Repealed, 29 SR 755]

Subp. 116. [Repealed, 29 SR 755]

Subp. 117. **Nominal tomographic section thickness.** "Nominal tomographic section thickness" means the full width at half–maximum at the center of the cross–sectional volume over which x–ray transmission data are collected.

Subp. 118. **Nonstochastic effects.** "Nonstochastic effects" means effects for which the severity of the effect in affected individuals varies with the dose, and for which a threshold usually exists.

Subp. 119. **Nominal treatment distance.** "Nominal treatment distance" means that distance at which the field size readouts are set. For nonisocentric equipment, this distance is usually the source–to–axis distance.

Subp. 119a. [Repealed, 29 SR 755]

Subp. 120. **Occupational dose.** "Occupational dose" means an individual's dose of radiation (1) in a restricted area; or (2) in the course of employment in which the individual's duties involve exposure to radiation; provided that occupational dose does not include radiation received for the purpose of diagnosis or therapy of the individual.

Subp. 120a. **Open–beam configuration.** "Open–beam configuration" means an x–ray system in which an individual could accidentally place some part of the body in the primary beam or secondary scattered beam path during operation.

Subp. 121. **Optical density or O.D.** "Optical density" or "O.D." means the logarithm of the incident light intensity minus the logarithm of the transmitted light intensity.

Subp. 121a. [Repealed, 29 SR 755]

Subp. 122. **Patient.** "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

Subp. 123. **Peak tube potential.** "Peak tube potential" means the maximum value of the potential difference across the x–ray tube during an exposure.

Subp. 124. **Permanent radiographic installation.** "Permanent radiographic installation" means a shielded installation or structure that is not moved and is designed or intended for radiography, and in which radiography is regularly performed.

Subp. 125. **Person.** "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, and any legal successor, representative, agent or agency of the foregoing, but not federal government agencies.

Subp. 125a. **Personal supervision.** "Personal supervision" means guidance and instruction by an industrial radiographer or logging supervisor, who:

A. is physically present at a temporary jobsite;

B. is in personal contact with an industrial radiographer's assistant or logging assistant; and

C. can give immediate assistance.

Subp. 126. **Personnel monitoring dosimeter.** "Personnel monitoring dosimeter" means a device such as a film badge, pocket dosimeter, or thermoluminescent dosimeter designed to be worn or carried by an individual for the purpose of estimating the dose received by that individual.

Subp. 127. **Phantom.** "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Subp. 128. **Phototimer.** "Phototimer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation that reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit that controls the duration of time the tube is activated. See automatic exposure control.

Subp. 128a. **Physician assistant or registered physician assistant.** "Physician assistant" or "registered physician assistant" means a person registered according to Minnesota Statutes, chapter 147A.

Subp. 129. [Repealed, 29 SR 755]

Subp. 130. **Pixel.** "Pixel" means an elemental area of a digital image.

Subp. 131. **Port film or portal imaging.** "Port film" or "portal imaging" means a diagnostic film or electronic image taken with a therapeutic x–ray system to verify proper setup of the treatment field.

Subp. 132. **Position indicating device (PID).** "Position indicating device" or "(PID)" means a device on dental radiographic x–ray equipment used to indicate the beam position and to establish the source–to–skin distance.

Subp. 132a. **Primary beam.** "Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x–ray tube or other radioactive source located in the radiation source housing.

Subp. 133. **Primary dose monitoring system.** "Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and will terminate irradiation when a preselected number of dose monitor units have been acquired.

Subp. 134. **Primary protective barrier.** "Primary protective barrier" means the material, excluding filters, placed in the useful beam for protection purposes to reduce the radiation exposure.

Subp. 135. **Protective apron.** "Protective apron" means an apron made of radiation absorbing materials, used to reduce radiation exposure.

Subp. 136. **Protective barrier or barrier.** "Protective barrier" or "barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. Types of protective barriers are primary protective barriers and secondary protective barriers.

Subp. 137. **Protective glove.** "Protective glove" means a glove made of radiation–absorbing materials used to reduce radiation exposure.

Subp. 137a. **Pulsed mode.** "Pulsed mode" means operation of an x–ray system so that the x–ray tube current is pulsed by the x–ray control to produce one or more exposure intervals of less than one–half second duration.

Subp. 138. **Quality assurance program.** "Quality assurance program" means the program and procedures contained in parts 4730.1655 to 4730.1695.

Subp. 139. **Quality factor.** "Quality factor" means a factor used for radiation protection purposes that accounts for differences in biological effectiveness between different radiations. The quality factors are: one for gamma rays, x–rays, beta particles, and electrons; five for thermal neutrons; and 20 for neutrons other than thermal, protons, alpha particles, and multiple–charged particles of unknown energy.

Subp. 140. **Rad.** "Rad" means the special unit of absorbed dose. One rad equals one one–hundredth of a joule per kilogram of any material. One millirad (mrad) equals 0.001 rad. The SI equivalent is the gray.

Subp. 141. **Radiation.** "Radiation" means ionizing radiation.

Subp. 142. **Radiation area.** "Radiation area" means an area accessible to individuals in which there exists radiation at such levels that a major portion of the body could receive in one hour a dose equivalent in excess of five millirems (0.05 millisievert), or in five consecutive days a dose equivalent in excess of 100 millirems (one millisievert).

Subp. 143. **Radiation detector or detector.** "Radiation detector" or "detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Subp. 144. **Radiation hazard.** "Radiation hazard" means a condition under which persons might receive radiation in excess of the maximum permissible dose.

Subp. 145. **Radiation head.** "Radiation head" means the structure from which the useful beam emerges.

Subp. 146. **Radiation machine.** "Radiation machine" means any device capable of producing radiation except devices which produce radiation only from radioactive material.

Subp. 147. **Radiation protection.** "Radiation protection" means the use of shielding, protective clothing, protective equipment, and other means to eliminate or reduce exposure to ionizing radiation.

Subp. 148. **Radiation safety.** "Radiation safety" means a condition assumed to exist when following a policy of minimization the doses of radiation are eliminated or reduced to the lowest practicable amount and are less than those shown under the definitions of maximum permissible concentrations, maximum permissible doses, and maximum permissible neutron radiation.

Subp. 149. **Radiation safety officer.** "Radiation safety officer" means an individual who has the knowledge and training to apply appropriate radiation protection regulations, and who has been designated by the facility in compliance with part 4730.0400, item B.

Subp. 150. **Radiation therapy simulation system.** "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.

Subp. 151. [Repealed, 29 SR 755]

Subp. 152. [Repealed, 29 SR 755]

Subp. 153. **Radiograph.** "Radiograph" means an image that is created directly or indirectly by x–rays resulting in a permanent record or image.

Subp. 154. **Radiography.** "Radiography" means the process of making an image on a radiosensitive surface, such as a photographic film, by radiation other than visible light, especially by x–rays passed through an object or by photographing a fluoroscopic image.

Subp. 155. [Repealed, 29 SR 755]

Subp. 156. **Rating.** "Rating" means the operating limits as specified by the component manufacturer.

Subp. 157. **Recording.** "Recording" means producing a permanent form of an image resulting from x–ray photons.

Subp. 157a. **Reference man.** "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus as described in Report No. 23, "Report of the Task Group on Reference Man," prepared by the International Commission on Radiological Protection (ICRP), and published by Pergamon Press (1975). The ICRP report is incorporated by reference, is not subject to frequent change, and is available through the Minitex interlibrary loan system.

Subp. 158. **Reference plane.** "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

Subp. 159. **Registrant.** "Registrant" means a person having possession of any source of radiation except those specifically exempted under part 4730.0400 or 4730.0700, who has complied with part 4730.0400, item B.

Subp. 160. **Registration.** "Registration" means registration with the commissioner according to parts 4730.0400 to 4730.0700.

Subp. 161. **Rem.** "Rem" means a special unit of dose equivalence. One millirem (mrem) equals 0.001 rem. The SI equivalent is the sievert. For the purpose of this chapter, any of the following is considered to be equal to one rem:

A. an exposure of one roentgen of x or gamma radiation;

B. an absorbed dose of one rad due to x, gamma, or beta radiation;

C. an absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye; or

D. an absorbed dose of 0.1 rad due to neutrons or high energy protons.

Note: If it is more convenient to measure the neutron flux or equivalent than to determine the neutron absorbed dose in rads, one rem of neutron radiation may, for purposes of this chapter, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the neutron flux dose equivalence table.

Neutron Flux Dose Equivalence

Neutron energy (MeV)	Number of neutrons per square centimeter for a dose equivalent of 1 rem (10 millisieverts) (neutrons/cm^2)	Average flux density to deliver 100 millirems (one millisievert) in 40 hours (neutrons/ cm^2 per second)
Thermal	970 x 10^6	670
0.0001	720 x 10^6	500
0.005	820 x 10^6	570
0.02	400 x 10^6	280
0.1	120 x 10^6	80
0.5	43 x 10^6	30
1.0	26 x 10^6	18
2.5	29 x 10^6	20
5.0	26 x 10^6	18
7.5	24 x 10^6	17
10.0	24 x 10^6	17
10 to 30	14 x 10^6	10

Subp. 162. **Response time.** "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.

Subp. 163. **Restricted area.** "Restricted area" means any area to which access or egress may be limited by the registrant for purposes of protection of individuals from exposure to radiation and radioactive materials.

Subp. 164. **Roentgen (R).** "Roentgen (R)" means a special unit of exposure equal to 2.58 x 10^{-4} coulomb per kilogram of air. One milliroentgen (mR) equals 0.001 roentgen.

Subp. 165. **Scan.** "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.

Subp. 166. **Scan increment.** "Scan increment" means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of the displacement.

Subp. 167. **Scan sequence.** "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Subp. 168. **Scan time.** "Scan time" means the time between the beginning and end of x–ray transmission data accumulation for a single scan.

Subp. 169. **Scattered radiation.** "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction and may have also been modified by a decrease in energy.

Subp. 169a. [Repealed, 29 SR 755]

Subp. 170. **Secondary dose monitoring system.** "Secondary dose monitoring system" means a system that will terminate irradiation if the primary system fails.

Subp. 171. **Secondary protective barrier.** "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation to the required degree.

Subp. 172. **Secondary radiation.** "Secondary radiation" means radiation emitted by an irradiated material such as bone or tissue and all inanimate objects.

Subp. 173. **Sensitometer.** "Sensitometer" means an instrument designed to produce a series of exposures with known ratios to each other.

Subp. 174. **Shadow tray.** "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

Subp. 174a. **Shielded position.** "Shielded position" means the location within a radiographic exposure device or storage container that, by manufacturer's design, is the location for storage of the sealed source.

Subp. 175. **Shutter.** "Shutter" means a device attached to the tube housing assembly that can totally intercept the useful beam and has a lead equivalency not less than that of the tube housing assembly.

Subp. 176. **SI equivalent.** "SI equivalent" means units that conform to the international system of units.

Subp. 177. **Sievert (Sv).** "Sievert" or "(Sv)" means the unit of dose equivalent that is equal to one joule per kilogram. One rem is equal to 0.01 sievert or ten millisievert (mSv). Submultiples included in this chapter are the millisievert (mSv) and the microsievert (μSv).

Subp. 178. **Source.** "Source" means a discrete amount of radioactive material or the target (focal spot) of the x–ray tube.

Subp. 179. **Source of radiation.** "Source of radiation" means a radioactive material, device, or equipment which emits, or is capable of producing, radiation.

Subp. 180. **Source–to–image distance (SID).** "Source–to–image distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.

Subp. 181. **Source–to–skin distance (SSD).** "Source–to–skin distance" or "SSD" means the distance between the source and the skin of the patient.

Subp. 181a. [Repealed, 29 SR 755]

Subp. 182. **Spot check.** "Spot check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

Subp. 183. **Spot film.** "Spot film" means a radiograph that is made during a fluoroscopic examination.

Subp. 184. **Spot–film device.** "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 to make a radiograph.

Subp. 185. **Stationary beam therapy.** "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subp. 186. **Stepless adjustment.** "Stepless adjustment" means a method of adjusting collimator blades continuously rather than in fixed increments.

Subp. 187. **Stochastic effects.** "Stochastic effects" means effects, the probability of which, rather than their severity, is a function of radiation dose without threshold. More generally, stochastic means random in nature.

Subp. 187a. [Repealed, 29 SR 755]

Subp. 188. [Repealed, 29 SR 755]

Subp. 189. **Stray radiation.** "Stray radiation" means the sum of leakage radiation and scattered radiation.

Subp. 190. **Survey or radiation safety survey.** "Survey" or "radiation safety survey" means an evaluation of the adequacy of radiation protection and assessment of the situation incident to the production, use, release, disposal, or presence of sources of ionizing radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present in and around the facility.

Subp. 191. **Target.** "Target" means the part of a radiation head that by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

Subp. 192. **Technique factors.** "Technique factors" means the conditions of operation, specified as follows:

A. for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

B. for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x–ray pulses;

C. 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 milliamperage, x–ray pulse width, and the number of x–ray pulses in mAs;

D. 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 milliamperage and exposure time in mAs and the scan time when the scan time and exposure time are equivalent;

E. for phototimed or automatic exposure controlled equipment, all necessary indicators including anatomical, if applicable, that must be activated before exposure; and

F. for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of milliamperage and exposure time in mAs.

Subp. 193. **Television receiver.** "Television receiver" means an electronic product designed to receive and display a television picture through broadcast, cable, or closed–circuit television.

Subp. 193a. **Temporary jobsite.** "Temporary jobsite" means a location where:

A. industrial radiography is performed, other than a location listed in a specific registration; or

B. NARM materials are present for performing nuclear well logging.

Subp. 194. **Teratogenic effects.** "Teratogenic effects" means effects occurring in offspring as a result of insults sustained in utero.

Subp. 195. **Termination of irradiation.** "Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Subp. 196. **Therapeutic field size.** "Therapeutic field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation. The therapeutic field size is that distance between the 50 percent of central axis values locations on the beam profile measured at the depth of dose maximum. Material shall be placed in the beam so that dose maximum is produced at the normal treatment distance when field size is being determined.

Subp. 197. **Therapeutic–type protective tube housing.** Therapeutic–type tube housing:

A. For x–ray therapy equipment not capable of operating at 500 kilovolt peak (kVp) or above, the following definition applies: An x–ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

B. For x–ray therapy equipment capable of operation at 500 kilovolt peak (kVp) or above, the following definition applies: An x–ray tube housing so constructed that leakage radiation at a distance of one meter from the source does not exceed either one roentgen in an hour or 0.1 percent of the useful beam dose rate at one meter from the source, whichever is greater, when the machine is operated at its maximum rated continuous current for the maximum rated accelerating potential.

C. In either case, small areas of reduced protection are acceptable provided the average reading over any 100 square centimeters area at one meter distance from the source does not exceed the values given above.

Subp. 198. **Tomogram.** "Tomogram" means an x–ray image of a thin section of the body.

Subp. 199. **Tomographic plane.** "Tomographic plane" means the geometric plane that is identified as corresponding to the output tomogram.

Subp. 200. **Tomographic section.** "Tomographic section" means the volume of an object whose x–ray attenuation properties are imaged in a tomogram.

Subp. 201. **Traceable to a standard.** "Traceable to a standard" means a comparison, either directly or indirectly, to a standard maintained by the National Institute of Standards and Technology (NIST) and that all comparisons have been documented.

Subp. 201a. [Repealed, 29 SR 755]

Subp. 202. **Tube housing assembly.** "Tube housing assembly" means the tube housing with tube installed.

Subp. 203. **Tube rating chart.** "Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

Subp. 204. **Type 1100 aluminum alloy.** "Type 1100 aluminum alloy" means an alloy of aluminum that has a nominal chemical composition of 99 percent minimum aluminum and 0.12 percent copper.

Subp. 205. **Unit of exposure.** "Unit of exposure" means the roentgen in the conventional system of measurement or the coulomb per kilogram in the SI system of measurement.

Subp. 206. [Repealed, 29 SR 755]

Subp. 207. **Units of radiation dose.** "Units of radiation dose" means the rad (unit of absorbed dose) and the rem (radiation to body tissues in terms of its estimated biological effect relative to a dose of one rad of x–ray). Under the SI measurement system the equivalent is the gray and the sievert.

Subp. 208. **Unrestricted area.** "Unrestricted area" means an area, the access to which is not controlled by the registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

Subp. 209. **Useful beam.** "Useful beam" means radiation that passes through the window, aperture, cone, or other collimating device of the source housing by a direct path from the x–ray tube or a radioactive source located in the radiation source housing.

Subp. 210. **Variable–aperture beam–limiting device.** "Variable–aperture beam–limiting device" means a beam–limiting device that has a capacity for stepless adjustment of the x–ray field size at a given SID.

Subp. 210a. **Very high radiation area.** "Very high radiation area" means an area accessible to an individual, where radiation levels are such that the individual could receive an absorbed dose in excess of 500 rad (5 Gy) in one hour at one meter from a source of radiation or from a surface that the radiation penetrates.

Subp. 211. **Virtual source.** "Virtual source" means a point from which radiation appears to originate.

Subp. 212. **Visible area.** "Visible area" means the portion of the input surface of the image receptor over which incident x–ray photons are producing a visible image.

Subp. 213. **Wedge filter.** "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

Subp. 213a. [Repealed, 29 SR 755]

Subp. 213b. **Worker.** "Worker" means an individual who engages in activities with sources of ionizing radiation that require registration by the commissioner and that are controlled by a registrant.

Subp. 214. **X–ray control.** "X–ray control" means a device that controls input power to the x–ray high–voltage generator and/or the x–ray tube. It includes components such as timers, phototimers or automatic exposure controls, automatic brightness stabilizers, and similar devices that control the technique factors of an x–ray exposure.

Subp. 215. **X–ray equipment.** "X–ray equipment" means an x–ray system, subsystem, or component. Types of x–ray equipment are listed in items A to D.

A. "Mobile x–ray equipment" means x–ray equipment mounted in a self–contained transport vehicle.

B. "Portable industrial x–ray equipment" means industrial x–ray equipment designed to be brought to a temporary jobsite to perform temporary industrial radiography.

C. "Portable x–ray equipment" means x–ray equipment designed to be brought to a patient.

D. "Stationary x–ray equipment" means x–ray equipment installed in a fixed location within a facility.

Subp. 216. **X–ray field.** "X–ray field" means the 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.

Subp. 217. **X–ray generator.** "X–ray generator" means a type of electron accelerator in which the electron beam is used mainly for the production of x–rays.

Subp. 218. **X–ray high–voltage generator.** "X–ray high–voltage generator" means a device that transforms electrical energy from the potential supplied by the x–ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current filament transformers for the x–ray tube, high–voltage switches, electrical protective devices, and other appropriate elements.

Subp. 219. **X–ray subsystem.** "X–ray subsystem" means a combination of two or more components of an x–ray system.

Subp. 220. **X–ray system.** "X–ray system" means an assemblage of components for the controlled production of x–rays. It includes minimally an x–ray high–voltage generator, an x–ray control, a tube housing assembly, a beam–limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

Subp. 221. **X–ray tube or tube.** "X–ray tube" or "tube" means an electron tube designed to be used primarily for the production of x–rays.

Statutory Authority: *MS s 144.05; 144.12; 144.1202; 144.1203; 144.121*

History: *16 SR 485; 22 SR 314; 23 SR 1760; 29 SR 755*

4730.0200 PURPOSE AND SCOPE.

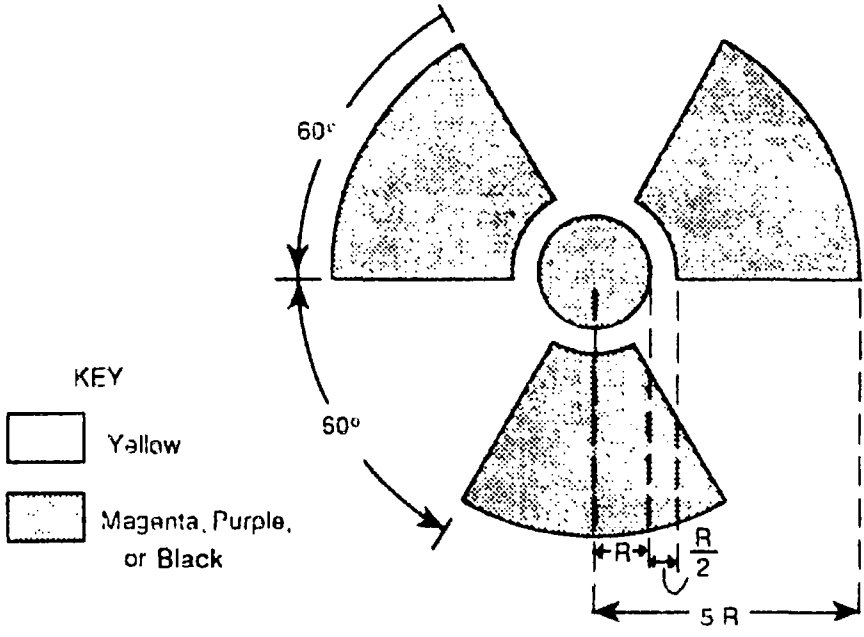
Whereas, ionizing radiation can be instrumental in the improvement of health, welfare, and productivity of the public if properly used, and may impair the health of the people and the industrial and agricultural potentials of the state if improperly used, and the commissioner of health has the statutory authority and duty to adopt, alter, and enforce regulations for the preservation of the public health and thereby to control sources of ionizing radiation and the handling, storage, transportation, use, and disposal of radioactive isotopes and fissionable materials within this state, and to observe their effect upon human health, it is hereby declared to be the purpose of the commissioner of health in this chapter to secure information concerning the nature and extent of the employment of ionizing radiation equipment and radioactive materials within this state, and to control or prevent dangers to health from ionizing radiation without limiting or interfering with the constructive uses of ionizing radiation consistent with a policy of reducing ionizing radiation exposure to persons and the general public by all practical means. The scope of this chapter does not include, except for the provision of registration, those sources of ionizing radiation known as by–product materials, source materials, or special nuclear material.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *L 1977 c 305 s 39; 16 SR 485*

4730.0300 PRECAUTIONARY PROCEDURES.

Subpart 1. **Radiation symbol and labeling.** Each radiation sign or label must bear the standard symbol specified in this subpart and the printed warning, in capital block letters, specified in subpart 1a. The standard symbol for designating any radiation hazard is a circle with three propeller–like blades arranged around it as illustrated:



The boundaries of the three blades of the propeller–like symbol must be confined within a 60–degree sector of the circle delineated by their outer edges, and the blades must be symmetrically distributed 60 degrees apart. The radius (R) of the central circle of the symbol must be the standard for its other dimensions as follows: Overall radius of symbol = 5R, shortest distance from circumference of central circle to inner edge of nearest blade = R/2. The standard color specifications must be a background of yellow with lettering and distinctive symbol in magenta, purple, or black. The symbol and lettering must be as large as practical, consistent with the size of the equipment or material upon which they appear.

Subp. 1a. **Warning signs.** Warning signs are required as follows:

A. The warning "CAUTION RADIATION AREA" or "DANGER RADIATION AREA" must appear on signs in an area in which a radiation hazard may exist.

B. The warning "CAUTION HIGH RADIATION AREA" or "DANGER HIGH RADIATION AREA" must appear on signs in an area in which a high radiation hazard may exist.

C. The warning "CAUTION VERY HIGH RADIATION AREA" or "DANGER VERY HIGH RADIATION AREA" must appear on signs in an area in which a very high radiation hazard may exist.

D. Analytical ionizing radiation producing equipment complying with part 4730.2550 must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words: "CAUTION – HIGH INTENSITY X–RAY BEAM," or words having a similar intent on the x–ray source housing.

E. Industrial x–ray equipment, nonmedical accelerator equipment, and analytical ionizing radiation producing equipment must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words: "CAUTION RADIATION – THIS EQUIPMENT PRODUCES IONIZING RADIATION WHEN ENERGIZED," or words having a similar intent, (1) near any switch, (2) on the enclosure containing the x–ray head that energizes an industrial or analytical x–ray tube, and (3) on the radiation source housing.

F. The warning "CAUTION RADIOACTIVE MATERIAL" or "DANGER RADIOACTIVE MATERIAL" must appear on containers having quantities of radioactive materials greater than the applicable quantities listed in part 4730.3500 and Code of Federal Regulations, title 10, part 20, Appendix B, January 1, 1997, and as subsequently amended.

Subp. 2. **Prohibitions on use of symbol.** The use of the specified radiation symbol for any purpose other than designating or referring to an area of detectable radiation is prohibited.

Subp. 3. **Placement of symbol and labels.** Containers of radioactive material for storage and disposal, storage areas, work areas, and other normally occupied areas where a radiation hazard may exist must be conspicuously posted with radiation warning labels when the containers of radioactive material hold quantities equal to or greater than the registration possession exemption limits specified in part 4730.3500. Conspicuous radiation warning labels must be posted in areas in which a radiation hazard may exist. This applies even if the area is not normally occupied. All radiation hazard labels posted when a radiation hazard existed must be removed when the hazard is no longer present.

Subp. 4. [Repealed, 16 SR 485]

Subp. 5. **Warning devices; industrial ionizing radiation sources.** This subpart applies only to industrial uses of ionizing radiation sources.

A. Open–beam configurations must have a readily discernible indication of:

(1) x–ray tube "on–off" status located near the radiation source housing, if the primary beam is controlled in an "on–off" manner; or

(2) shutter "open–closed" status located near each port on the radiation source housing, if the primary beam is controlled in "open–closed" manner.

B. An easily visible warning light labeled with the words "X–RAY ON" or other visible warning indicator that clearly shows the equipment is producing ionizing radiation, must be:

(1) located near a switch that energizes an x–ray tube and illuminated only when the tube is energized; or

(2) in the case of a radioactive source, located near a switch that opens a housing shutter and illuminated only when the housing shutter is open.

C. Warning devices must be labeled so that their purpose is easily identified.

D. On equipment installed on or after March 1, 1998, warning devices must have fail–safe characteristics.

Subp. 6. **Warning and control devices; high and very high radiation areas.** This subpart applies only to areas of high and very high radiation.

A. Except as provided in item C, each entrance or access point to a high or very high radiation area must be:

(1) equipped with a control device that causes the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems (1.0 mSv) in one hour upon entry into the area;

(2) equipped with a warning device that energizes a visible or audible alarm to alert an individual entering the high or very high radiation area and other nearby nonoccupationally exposed workers; or

(3) maintained locked except during periods when access to the area is required, with access to each individual entry monitored or supervised.

B. The devices required by this subpart must not prevent an individual from leaving a high or very high radiation area.

C. When a high or very high radiation area is established for 30 calendar days or less, direct surveillance to prevent unauthorized entry may be substituted for the devices required by this subpart.

Subp. 7. **Radiation survey instruments.** To ensure correct response to radiation, each radiation survey instrument must:

A. be calibrated:

(1) for portable industrial x–ray equipment, industrial sealed source radiography, industrial radiography with NARM, use of active NARM devices or nuclear logging, at periods not to exceed six months;

(2) for equipment other than portable industrial x–ray equipment, at periods not to exceed one year; and

(3) after each servicing;

B. be calibrated at energy levels and over a range appropriate for the use;

C. be calibrated to accuracy within plus or minus 20 percent over the applicable range of the instrument; and

D. have records of the calibrations maintained according to part 4730.1520.

Subp. 8. **Alarming ratemeters.** To ensure correct response to radiation, each alarming ratemeter must:

A. be tested before use at the start of each shift to ensure that the alarm sounds;

B. be set to sound at a pre–set exposure rate of 500 mR/hr (1.29×10^{-4} C/kg/hr);

C. require special means to change the pre–set alarm function;

D. be calibrated at periods not to exceed one year;

E. alarm, vibrate, activate a light, or otherwise signal within plus or minus 20 percent of the true radiation exposure rate; and

F. have records of the tests and calibrations maintained according to part 4730.1520.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 22 SR 314; 23 SR 1760*

4730.0310 PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS.

Subpart 1. **Applicability.** This part applies to all registrants.

Subp. 2. **Radiation dose standards for individual workers in restricted areas.** To determine the doses specified in item A, a dose from x–rays or gamma rays up to ten million electron volts (MeV) may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

A. According to part 4730.0340, and except as provided in subpart 3, no registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation, excluding natural background radiation and radiation received for diagnosis and medical treatment, a total occupational dose in excess of the standards specified in the following table:

Radiation limits per calendar quarter:

(1) Effective dose equivalent (stochastic effects)... 1.25 rem (12.5 mSv);

(2) Dose equivalent for tissues and organs (nonstochastic effects):

(a) Lens of eyes... 3.75 rem (37.5 mSv);

(b) All others (red bone marrow, breast, lungs, gonads, skin, thyroid, and extremities)... 12.5 rem (125 mSv);

(3) Cumulative effective dose equivalent... one rem X age in years (ten mSv X age in years).

B. A registrant may permit an individual worker in a restricted area to receive a planned special occupational exposure to the whole body, including gonads, red bone marrow, breast, lungs, head and trunk, or lens of eye, provided:

(1) the individual worker receives an effective dose equivalent of no more than five rems (50 mSv) in a single planned event and five rems (50 mSv) from a normal occupational dose in a year;

(2) the effective dose equivalent received in all special planned exposures does not exceed 25 rems (250 mSv) over the individual's working lifetime;

(3) the registrant has determined the individual worker's accumulated occupational dose to the whole body and has otherwise complied with the requirements of this subpart;

(4) all planned special exposures are authorized in writing by the registrant and the radiation safety officer before exposure;

(5) individual workers who are without procreative potential and have low lifetime effective dose equivalents are selected whenever possible; and

(6) doses resulting from planned special exposures are included in the lifetime record of dose for each individual worker but are separately identified.

Subp. 3. **Pregnant workers.**

A. When a woman declares her pregnancy in writing and if her embryo or fetus has a potential of receiving greater than 0.125 rem (1.25 mSv) during her entire pregnancy, the registrant must:

(1) provide a dosimeter to be worn at the level of the abdomen and under any lead shielding worn; and

(2) ensure that:

(a) a reasonable effort is made to limit the dose to the embryo or fetus to 0.05 rem (0.5 mSv) in any one month of pregnancy, excluding medical exposure; and

(b) the total effective dose equivalent to the embryo and fetus for a full-term pregnancy does not exceed 0.5 rem (five mSv).

B. If the dose to the embryo or fetus is found to have exceeded 0.5 rem (five mSv) or is within 0.05 rem (0.5 mSv) of this dose by the time the woman declares her pregnancy, the registrant is exempt from item A, subitem (2), unit (b), but must ensure that additional occupational dose to the embryo or fetus does not exceed 0.05 (0.5 mSv) during the remainder of the pregnancy.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.0340 DETERMINATION OF ACCUMULATED OCCUPATIONAL DOSE.

Subpart 1. **Disclosure before first entry into registrant's restricted area.** Within the first calendar quarter of an individual starting work in the registrant's restricted area where the individual will receive or is likely to receive in one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in part 4730.0310, subpart 2, item A, subitem (1), the registrant must require that the individual disclose in a written, signed statement, either:

A. that the individual had no prior occupational dose; or

B. the nature and amount of any occupational dose which the individual may have received from sources of radiation possessed or controlled by another person.

The registrant must maintain records of the statements for the lifetime of the individual worker or a minimum of 30 years after termination of employment with the facility, whichever is less.

Subp. 2. [Repealed, 23 SR 1760]

Subp. 3. **Preparation of accumulated dose records.** In preparing accumulated dose records, the registrant must make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the registrant obtains such reports, the dose shown in the report must be used. In any case where a registrant is unable to obtain reports of the individual's occupational dose, it must be assumed that the individual worker has received the occupational dose specified in whichever of the following columns that applies:

	Column 1	Column 2
Part of Body	Assumed dose in rems (mSv) for calendar quarters before January 1, 1961	Assumed dose in rems (mSv) for calendar quarters beginning on or after January 1, 1961

Whole body, gonads active blood–forming organs, head and trunk, lens of eye	3.75 rem (37.5 mSv)	1.25 rem (12.5 mSv)

The registrant must retain and preserve records used in preparing the accumulated dose record for the lifetime of the individual worker or a minimum of 30 years after the individual's termination of employment with the facility, whichever is less. If calculation of the individual worker's accumulated occupational dose for all periods before January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in part 4730.0310, subpart 2, item B, the excess may be disregarded.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.0360 EXPOSURE OF MINORS.

No registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual within a restricted area who is under 18 years of age to receive any occupational radiation dose greater than 0.1 rem (1.0 mSv) per year.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.0380 PUBLIC PERMISSIBLE LEVELS OF RADIATION FROM EXTERNAL SOURCES IN UNRESTRICTED AREAS.

No registrant shall possess, use, or transfer sources of radiation in a manner that creates in any unrestricted area radiation levels that could result in an individual receiving an annual effective dose equivalent in excess of 0.1 rem (1.0 mSv).

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

REGISTRATION

4730.0400 REGISTRATION REQUIREMENTS.

The owner or person having possession of any source of ionizing radiation except those specifically exempted under this part or under part 4730.0800 shall:

A. Register all sources with the commissioner of health within 30 days of its acquisition or its proposed temporary use in Minnesota, except demonstration units in place for 15 days or less, upon forms prescribed and provided for that purpose.

B. Designate an individual who will be responsible for radiation protection from the source. The individual who is the radiation safety officer, shall:

(1) be qualified by training and knowledge concerning all hazards and precautions involved in operating or in using the source for which the radiation safety officer is responsible;

(2) establish a detailed program of radiation safety for effective compliance with the applicable requirements of this chapter;

(3) give instructions concerning hazards and safety practices to individuals under the radiation safety officer's supervision who may be exposed to radiation from the source;

(4) make, or arrange to have performed, radiation safety surveys and carry out other procedures as required by this chapter; and

(5) ensure that there is documentation of all formal instruction, test results, calibrations, safety surveys, equipment performance tests, and maintenance on x–ray equipment and radiographic processors.

When, in the opinion of the commissioner of health, the individual designated to be responsible for radiation safety does not have qualifications sufficient to ensure safe operation

or use of the source, the commissioner of health may require the registrant to designate another individual who meets the requirements of this item.

C. Every facility in which radioisotopes are used shall have a committee which coordinates the use of radioisotopes within the facility and ensures the radiation safety of the patients and persons involved during the use of these isotopes.

D. The registrant shall notify the commissioner of health within 30 days of any change in the ownership or disposition of registered sources.

E. No person in any advertisement shall refer to the fact that a source is registered with the commissioner of health, and no person shall state or imply that any activity under such registration has been approved by the commissioner of health.

F. The registrant shall be subject to all applicable requirements of this chapter.

G. The registration requirements specified in parts 4730.0400 to 4730.0700 shall not apply to sources or conditions exempted under part 4730.0800, nor to by–product materials, source materials, or special nuclear materials licensed by the United States Nuclear Regulatory Commission not in excess of the kind and quantity specified in part 4730.3500 and Code of Federal Regulations, title 10, part 20, Appendix B, January 1, 1997, and as subsequently amended.

H. The registrant must notify the commissioner in writing 30 days prior to any temporary use of radiation sources in Minnesota, except demonstration units in place for 15 days or less. The notification must include locations at which the source is to be used, the estimated time period of use in the state, and the estimated date of completion.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *L 1977 c 305 s 39; 16 SR 485; 22 SR 314; 23 SR 1760*

4730.0500 RENEWAL OF REGISTRATION.

Subpart 1. **Biennial renewal of registration.** Each registration pursuant to this chapter shall be renewed biennially according to the staggered schedule specified in subpart 2 so long as the activity requiring registration continues. If there has been no substantial change in the matters described in the last prior registration or renewal, the renewal of the registration shall so state. If there has been any accession of additional radiation sources or other substantial change in the matters described in the preceding registration or renewal, the renewal shall state the accession or other change and give the information relating to the accession or other change that would be required upon original registration.

Subp. 2. **Staggered schedule for renewal of registration.** Each registration pursuant to this chapter shall be renewed on or before the first day of the calendar quarter specified in items A to H. The schedule is based on the registrant's business address within the state.

A. January 1 of the odd–numbered years: Hennepin County dentists and all radiation sources in the University of Minnesota system, regardless of location.

B. April 1 of the odd–numbered years: Hennepin County registrants other than those included in item A.

C. July 1 of the odd–numbered years: Ramsey County registrants.

D. October 1 of the odd–numbered years: Anoka, Dakota, and Washington County registrants.

E. January 1 of the even–numbered years: Aitkin, Benton, Carlton, Cass, Chisago, Cook, Crow Wing, Isanti, Itasca, Kanabec, Koochiching, Lake, Mille Lacs, Morrison, Pine, and St. Louis County registrants.

F. April 1 of the even–numbered years: Becker, Beltrami, Big Stone, Chippewa, Clay, Clearwater, Douglas, Grant, Hubbard, Kittson, Lac Qui Parle, Lake of the Woods, Mahnomen, Marshall, Norman, Ottertail, Pennington, Polk, Pope, Red Lake, Roseau, Stearns, Stevens, Swift, Todd, Traverse, Wadena, and Wilkin County registrants, and registrants whose business addresses are outside the state.

G. July 1 of the even–numbered years: Brown, Carver, Cottonwood, Faribault, Jackson, Kandiyohi, Lincoln, Lyon, Martin, McLeod, Meeker, Murray, Nicollet, Nobles, Pipestone, Redwood, Renville, Rock, Sherburne, Sibley, Watonwan, Wright, and Yellow Medicine County registrants.

H. October 1 of the even–numbered years: Blue Earth, Dodge, Fillmore, Freeborn, Goodhue, Houston, Le Sueur, Mower, Olmsted, Rice, Scott, Steele, Wabasha, Waseca, and Winona County registrants.

Subp. 3. **Renewals affected by change of location.** A registrant whose business address changes from one county to another must renew the registration with the county of relocation according to the schedule in subpart 2, and shall not accrue penalty fees for not renewing with the county of previous location.

Subp. 4. **Effective date of staggered biennial renewals.** The change in the date that registrants are required to submit biennial renewals takes effect with the 1989–1990 biennial renewal. The first staggered biennial renewal begins on January 1, 1989.

Statutory Authority: *MS s 144.05; 144.12; 144.121; 144.122*

History: *13 SR 1652; 16 SR 485*

4730.0600 REGISTRATION FEES.

Subpart 1. **Fee for initial or renewal registration.**

A. The initial or renewal biennial registration of every source of ionizing radiation required to be registered by parts 4730.0400 to 4730.0800 must be accompanied by fees as prescribed in this part and Minnesota Statutes, section 144.121, subdivision 1a.

B. A facility with x–ray machines or other sources of ionizing radiation must biennially pay a registration fee consisting of a base facility fee of $132 and an additional fee for each x–ray machine or other source of ionizing radiation as follows:

(1) medical or veterinary equipment, $106;

(2) dental x–ray equipment, $66;

(3) accelerator, $132;

(4) radiation therapy equipment, $132;

(5) x–ray equipment not used on humans or animals, $106;

(6) devices with sources of ionizing radiation not used on humans or animals, $106; and

(7) sources of radium, $198.

Subp. 2. **Penalty fee for late registrations.** Applications for initial or renewal registrations submitted to the commissioner of health after the time specified by parts 4730.0400, item A; 4730.0500; and this part shall be accompanied by a penalty fee of $20 in accordance with Minnesota Statutes, section 144.121, subdivision 1a, in addition to the fee prescribed in subpart 1.

Subp. 3. **Fee for sources requiring registration during last 12 months of a biennial registration period.** In accordance with Minnesota Statutes, section 144.121, subdivision 1a, the initial registration fee of x–ray machines or other sources of radiation required to be registered during the last 12 months of a biennial registration period shall be 50 percent of the applicable registration fee prescribed in subpart 1.

Statutory Authority: *MS s 144.05; 144.12; 144.121; 144.122*

History: *L 1977 c 305 s 39; 10 SR 1687; 15 SR 738; 23 SR 1760*

4730.0700 PERIODIC TESTING REQUIREMENTS.

Subpart 1. [Repealed, 16 SR 485]

Subp. 2. [Repealed, 16 SR 485]

Subp. 3. **Periodic testing requirements.** Each owner, renter, or other person in possession of a source of radiation shall perform or cause to be performed such reasonable procedures as are necessary to ensure radiation safety including, but not limited to, tests of:

A. sources of radiation;

B. facilities where sources of radiation are used or stored; and

C. radiation detectors, monitoring instruments, and other equipment and devices used in connection with use or storage of sources of radiation.

Results of such tests shall be available for submission to the commissioner of health when requested.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *L 1977 c 305 s 39; 16 SR 485; 23 SR 1760*

4730.0800 EXEMPTIONS.

This chapter shall not apply to the following sources or conditions:

A. natural radioactive materials of an equivalent specific radioactivity not exceeding that of natural potassium;

B. timepieces, instruments, or devices containing self–luminous elements, except during manufacture or repair of the self–luminous elements themselves;

C. electrical equipment that is not intended primarily to produce radiation and that, by nature of design, does not produce radiation at the point of nearest approach at a weekly rate higher than one–tenth of the appropriate limit for any critical organ exposed. The production testing or production servicing of such equipment shall not be exempt;

D. a radiation machine not being used in a manner such that it produces radiation;

E. domestic television receivers, provided the dose rate at 5 cm from any outer surface of ten cm^2 is less than 0.5 mrem per hour;

F. any radioactive material being transported in conformity with regulations adopted by the United States Department of Transportation and other agencies of the United States having jurisdiction;

G. any quantities of thorium contained in: incandescent gas mantles; vacuum tubes; welding rods; electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium; germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium; and rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these;

H. radiation sources specifically designated by the commissioner of health as exempt by virtue of being known to be without hazard to health.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *L 1977 c 305 s 39; 16 SR 485*

4730.0850 VARIANCE TO RULES RELATING TO IONIZING RADIATION.

The commissioner shall grant a variance to parts 4730.0100 to 4730.3610, except parts 4730.0400 and 4730.0600 only according to the procedures and criteria specified in parts 4717.7000 to 4717.7050.

Statutory Authority: *MS s 14.05*

History: *15 SR 1597*

4730.0900 VENDOR RESPONSIBILITY.

Subpart 1. **Generally.** No person shall make, sell, lease, transfer, lend, or install x–ray or fluoroscopic imaging assembly equipment or the supplies used in connection with such equipment unless the supplies and equipment, when properly placed in operation and properly used, meet the requirements of this chapter. This includes, but is not restricted to, responsibility for the delivery of cones or collimators, filters, accurate timers, and fluoroscopic shutters (where applicable).

Subp. 2. **Notification requirements.** Persons selling, leasing, or transferring registerable sources of radiation shall notify the commissioner of health in writing within 30 days of such sale, lease, or transfer, and shall supply the name and address of the purchaser and such pertinent information as is requested by the commissioner of health.

Subp. 3. **Calibration reports at time of installation.** A vendor must perform calibrations on the radiation producing machine according to parts 4730.1691 to 4730.2475, when applicable, at the time of installation, and provide the facility with written numerical results

of the calibration. If the result of the test is not a numerical answer, a pass or fail or yes or no answer is acceptable.

Subp. 4. **Personnel dosimeters.** A vendor must provide its employees with individual personnel radiation monitoring dosimeters and reports for recording occupational exposure according to parts 4730.0310, 4730.1140, and 4730.1520.

Subp. 5. **Phantom use.** For maintenance, demonstrations, and training, a vendor must use phantoms instead of humans.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *L 1977 c 305 s 39; 16 SR 485; 23 SR 1760*

4730.1000 [Repealed, 29 SR 755]

4730.1100 [Repealed, 16 SR 485]

4730.1110 REPORTS OF THEFT OR LOSS OF RADIATION SOURCES.

A registrant must report to the commissioner the theft or loss of any radiation source immediately after the theft or loss becomes known. The report must be made by telephone or facsimile. After normal business hours or on weekends, this report must be made through the Minnesota Department of Public Safety's duty officer.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485*

4730.1120 REPORTS OF INCIDENTS INVOLVING RADIATION SOURCES.

Subpart 1. [Repealed, 23 SR 1760]

Subp. 2. **Notification within 24 hours.** A registrant possessing any source of radiation must notify the commissioner within 24 hours of discovering any incident involving that source which may have caused or threatens to cause an unintended or unprescribed:

A. dose to the whole body of any individual of five rems (50 mSv) or more of radiation;

B. dose to the skin or the extremities of any individual of 50 rems (500 mSv) or more of radiation; or

C. release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed the annual occupational limits specified for the material in Code of Federal Regulations, title 10, part 20, Appendix B, January 1, 1997, and as subsequently amended.

Subp. 3. **Report to individual worker exposed beyond occupational levels.** A registrant must report to an individual worker who was exposed beyond the worker's normally expected occupational level the radiation dose data for that individual. The information reported must include the dose data and results obtained under this chapter, as shown in records maintained by the registrant pursuant to part 4730.1520, subpart 4. Each notification and report must:

A. be in writing;

B. include appropriate identifying data, including the name of the registrant, the name of the exposed individual worker, and the date of the dose; and

C. include the results of any measurements, analyses, or calculations of radioactive material deposited or retained in the body of the individual worker.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 22 SR 314; 23 SR 1760*

4730.1130 MANDATORY REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS.

Subpart 1. **Additional reports.** In addition to any notification required by part 4730.1120, a registrant must submit a written report within 30 days to the commissioner of:

A. each dose to an individual of radiation in excess of the applicable standards in part 4730.0310, subpart 2, or 4730.0360;

B. any incident for which notification is required by part 4730.1120;

C. levels of radiation or concentrations of radioactive material, whether or not any individual is excessively exposed, if in an unrestricted area and the exposure is in excess of ten times any applicable limit specified by part 4730.0380 or Code of Federal Regulations, title 10, part 20, Appendix B, January 1, 1997, and as subsequently amended; and

D. corrective actions taken or planned to ensure against a recurrence.

Subp. 2. **Reports on individuals.** In the report required under subpart 1 the registrant must describe the extent of the dose of radiation to any individual, including:

A. the name and birth date of each individual;

B. estimates of each individual's dose;

C. the levels of radiation and concentrations of radioactive material involved;

D. the cause of the dose, levels, or concentrations; and

E. corrective steps taken or planned to ensure against a recurrence.

Subp. 3. [Repealed, 23 SR 1760]

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 22 SR 314; 23 SR 1760*

4730.1140 NOTIFICATIONS AND REPORTS TO INDIVIDUAL WORKERS.

Subpart 1. [Repealed, 23 SR 1760]

Subp. 2. **Quarterly dosimetry report.** A registrant must advise each worker at least quarterly of the worker's dose of radiation as shown in records maintained by the registrant under part 4730.1520, subpart 4.

Subp. 3. **Report at end of employment.** A registrant must furnish to a worker who is terminating employment, or to a worker who, while employed by another person, is terminating a work assignment involving radiation dose in the registrant's facility within a calendar quarter, a report of the worker's dose of radiation. The report must be furnished within 30 days from the time of termination of employment or within 30 days after the exposure of the worker has been determined by the registrant. The report must cover each calendar quarter in which the worker's activities involved exposure to radiation sources and must include the dates and locations of work under the registrant in which the worker participated.

Subp. 4. **Report to worker of dose.** When a registrant is required under parts 4730.1120 and 4730.1130 to report to the commissioner any radiation dose of an individual, the registrant must also provide the worker with a report of the worker's dose data. The reports must be transmitted at a time no later than the transmittal to the commissioner.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1200 [Repealed, 16 SR 485]

4730.1210 PROHIBITED USES OF RADIATION.

Subpart 1. **General provision.** No individual shall be exposed to the useful beam except for healing arts purposes and only if the exposure has been authorized by a licensed practitioner of the healing arts. Any exposure of an individual for the following other purposes is prohibited:

A. exposure for training, instruction, demonstration, or research except when the research has been approved by an institutional review board and is conducted under federal regulations for the protection of human subjects in research, Code of Federal Regulations, title 21, part 56, or title 45, part 46. Any other exposure of a human subject for the purpose of research may be made only with an approved variance as described in parts 4717.7000 to 4717.7050. Documentation of the research approval process must be on site and available to the commissioner upon request; and

B. exposure for the purpose of healing arts screening except as authorized by part 4730.1310.

Subp. 1a. **Other prohibited radiation dose levels.** No worker shall be subjected to a radiation dose occupationally or for training that would exceed the doses specified in parts 4730.0310 and 4730.0360.

Subp. 2. **Prohibited radiation producing equipment and procedures.** The equipment specified in this subpart shall not be used nor the specified procedures performed:

A. fluoroscopic devices for fitting shoes;

B. photofluorographic equipment;

C. dental fluoroscopic imaging assemblies;

D. hand–held radiographic or fluoroscopic imaging devices, or hand–held therapy units, except for contact therapy units operated according to part 4730.2350, subpart 17;

E. the use of fluoroscopy by x–ray machine operators for positioning a patient for radiographic imaging, except when done by a licensed practitioner of the healing arts, or except for radiation therapy simulators;

F. the use of fluoroscopy by a person other than a licensed practitioner of the healing arts when the licensed practitioner of the healing arts is not physically present in the room except during therapy simulations, maintenance activities, and training courses;

G. the use of direct exposure x–ray film (without intensifying screens) for all radiological imaging other than intraoral dental radiography, therapeutic portal imaging, industrial radiography, and radiographic absorptiometry using readipack film especially designed for radiographic absorptiometry;

H. nonimage intensified fluoroscopic x–ray equipment;

I. dental intraoral radiography units operating at 50 kVp or less;

J. the use of mammographic imaging systems not specifically designed by the manufacturer for imaging of the breast;

K. fishpole radiography; and

L. demonstrations or training without the use of phantoms, when necessary, and without proper shielding for observers and x–ray machine operators as specified in subpart 1, item A, and part 4730.1510, subpart 6.

Subp. 3. **Unauthorized exposure of personnel monitoring dosimeters.** Exposure of personnel monitoring dosimeters to deceptively indicate a dose delivered to an individual is prohibited.

Subp. 4. **Possession of radium–226 by secondary or elementary schools.** The possession by secondary or elementary schools of radium–226 in excess of those quantities exempted in part 4730.3500 is prohibited.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 22 SR 314; 23 SR 1760*

4730.1300 [Repealed, 16 SR 485]

4730.1310 HEALING ARTS SCREENING.

Subpart 1. **General.** Any person who desires to perform diagnostic x–ray screening in Minnesota must seek commissioner approval before x–ray screening may proceed. All applicants must meet the requirements specified in parts 4730.0100 to 4730.1950 and 4730.2150 to 4730.2250. In addition:

A. all applicants must be registered with the commissioner before application for screening is initiated; and

B. the registrant must submit an application to the commissioner requesting permission to perform diagnostic x–ray screening.

Subp. 2. **Content of application.** In the application for screening the registrant must:

A. Provide his or her business name and address. If the registrant is a corporation or other business or nonbusiness association, the name of the person and phone number representing the association must be given.

B. Give the location of the proposed screening and the name and telephone number of a contact person at each location.

C. State the purpose of the proposed screening program planned. The purpose must include a detailed statement specifying the compelling health reasons, health benefits, and health emergency, if any, that justifies the radiation exposure to which any individual will be subjected by the proposed screening.

D. Explain why alternate screening methods that do not require the use of ionizing radiation are not being used.

E. Name all practitioners of the healing arts who will interpret the radiographic images.

F. State the proposed interval for which permission to perform screening is requested.

G. List the radiographic projections or views being proposed in the screening program.

H. Specify the x–ray equipment to be used in connection with the proposed x–ray screening.

I. Describe the retention or disposition of the images and other records pertaining to the screening x–ray examinations after the screening project is completed.

J. Describe the population to be examined in the screening program, including age, sex, and physical condition.

K. Provide exposure measurements of the exposure at skin entrance (ESE) and specific organ doses, for the type of screening proposed. These exposures must be consistent with those produced with state–of–the–art techniques. If no guidelines are available for exposure measurements, the commissioner may request peer review to establish such guidelines.

L. Provide a written evaluation of the radiation safety survey and the quality assurance program as required by parts 4730.1655, 4730.1670, 4730.1675, 4730.1690, and 4730.1691. This must have been performed within three months prior to the application.

M. Any individual screened must be personally informed by the registrant of the results, interpretation, or findings. The screening application must:

(1) describe how this information will be communicated to the individual who has been screened;

(2) describe where the results, interpretation, or findings will be sent; and

(3) describe what arrangements will be made to ensure that the individual who has been screened will be informed as to the need for further medical and health care evaluation or treatment.

Subp. 3. **Additional information.** The commissioner may request the submission of additional information and data subsequent to the submission of the original or renewal application.

Subp. 4. **Notification of commissioner's decision.** The registrant shall be notified in writing of the commissioner's decision. If an application is granted, the notification shall specify the time, not to exceed one year, for which the application will be effective.

Subp. 5. **Changes in screening program.** The registrant is responsible for informing the commissioner of any changes in the screening program from that which was described in the content of the application in subpart 2. The registrant must obtain commissioner approval of the changes before the commencement of the requested changes in the screening program.

Subp. 6. **Denial of approval.** The commissioner may deny or revoke approval of any healing arts screening program if the registrant fails to or refuses to comply with this chapter.

Subp. 7. **Appeal procedure.** The registrant may appeal the denial, revocation, or refusal to approve an application or renewal application by requesting a contested case hearing under the provisions of the Administration Procedure Act, Minnesota Statutes, chapter 14. The registrant shall submit, within 15 days of the receipt of the department's decision, a written request for a hearing. The request for a hearing shall set forth in detail the reasons why the registrant contends the decision of the department should be reversed or modified.

Subp. 8. **Renewal of screening application.** Any request for the renewal of a screening program application shall be submitted in writing before its expiration date. Renewal requests shall contain the information specified in subpart 2.

Subp. 9. **Commissioner–approved healing arts screening.** The commissioner may inspect the healing arts screening program while in progress to ensure that it is carried out as described in the registrant's application and in compliance with this chapter.

Subp. 10. **Withdrawal of approval for conditions allowing overexposure.** Approval may be withdrawn immediately if, after an inspection, the commissioner finds the existence of conditions that would result in serious overexposure. All screening procedures shall be terminated immediately upon receipt of the written notice of existence of such overexposure. The applicant may request a contested case hearing within five days after receipt of the notice. The request for hearing does not stay the commissioner's order of immediate cessation of the screening program. The hearing shall be scheduled within ten days of receipt of the request for the hearing.

Subp. 11. **Withdrawal of approval for noncompliance with application.** Approval for healing arts screening may be withdrawn if, after an inspection, the commissioner finds discrepancies between the screening program as implemented and as described in the application in this part or for violation of this chapter. A hearing shall be held if requested by the applicant within three days after the receipt of the notice of withdrawal of approval. The hearing may be held upon granting the applicant three days' notice. If a hearing is requested, withdrawal of approval shall not take effect until a final order is issued by the commissioner.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1400 [Repealed, 23 SR 1760]

4730.1450 OPPORTUNITY TO INSPECT.

Each registrant, owner, renter, or other person possessing a radiation source subject to registration or exempted under part 4730.0400 or 4730.0800 must allow the commissioner at all reasonable times and during the hours of operation to inspect radiation sources and the premises and facilities where these radiation sources are used or stored, and must make available to the commissioner records required by this chapter.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485*

4730.1475 [Repealed, 17 SR 3414]

4730.1500 [Repealed, 16 SR 485]

4730.1510 REGISTRANT'S SAFETY REQUIREMENTS.

Subpart 1. **Registrant responsibility.** The registrant is responsible for directing the operation of all x–ray and accelerator systems under the registrant's administrative control.

A. The registrant or the registrant's agent must ensure that the requirements specified in this part are met in the operation of all diagnostic and therapeutic x–ray systems and medical accelerators.

B. The registrant or the registrant's agent must ensure that the requirements in subparts 2 and 11 to 13 are met in the operation of all industrial x–ray systems and nonmedical accelerators.

Subp. 2. **X–ray system and accelerator compliance.** An x–ray system or accelerator that does not meet the provisions of this chapter shall not be operated for diagnostic, therapeutic, or industrial purposes.

Subp. 3. **Individuals who may apply radiation.** Only those individuals who are licensed practitioners of the healing arts or individuals who have successfully passed an examination specified in parts 4730.5000 to 4730.5500, may intentionally apply radiation to an individual.

Subp. 4. **Procedure and safety instruction.** All individuals who operate an x–ray system shall be initially instructed and annually retrained in facility–specific and system–specific safe operating procedures, emergency procedures for malfunctioning equipment, and quality assurance procedures. Written safety procedures for the facility and x–ray systems shall be provided by the registrant to the individuals specified in subpart 3 including:

A. information on the effects of radiation exposure to the human body and the embryo–fetus;

B. projections where holding devices cannot be used; and

C. any restrictions of the operating technique required for the safe operation of the particular x–ray system.

Subp. 5. **Radiographic technique chart.** A radiographic technique chart shall be provided in the vicinity of the x–ray system's control panel which specifies, for all examinations performed with that system, the following information:

A. the patient's anatomical size and corresponding technique factors to be used;

B. the type of the screen–film combination, or direct exposure x–ray film for dental intraoral radiography, to be used;

C. the grid focal distance and the grid ratio to be used, if any;

D. the source–to–image distance to be used; and

E. for automatic exposure control (AEC) or phototimed units, the percent differences between the AEC increments.

For computed tomography systems, a current technique chart for each routine examination, and the computed tomography conditions of operation must be provided.

Subp. 6. **Exposure of individuals other than the patient.** All radiographic procedures and therapeutic x–ray procedures must meet the requirements of this subpart.

A. Except for the patient, only the staff and ancillary personnel required for the medical, dental, and veterinary medicine procedure or training shall be in the room during the radiographic exposure.

B. All staff and ancillary personnel required for assistance with the radiographic procedures shall be positioned so no part of the body, including the hands, will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent material.

C. All staff and ancillary personnel who must remain in the room to assist during radiographic, fluoroscopic, portable, or computed tomography procedures must be protected from scattered radiation by protective aprons or whole body protective barriers of not less than 0.5 millimeter lead equivalence.

D. Patients and individuals who are not involved in diagnostic radiographic procedures or demonstrations using either stationary or portable x–ray equipment, who cannot leave the room and who cannot be protected by adequate distance for the exam being performed must be protected from scattered radiation by protective lead aprons or whole body protective barriers of at least 0.25 millimeters lead equivalence.

E. During any radiographic or fluoroscopic exposure, any door which is part of the protective barrier must be closed.

F. No individual other than the patient shall be in a therapy treatment room during exposures from a therapeutic x–ray system operating above 50 kVp.

G. Thyroid and eyes must be protected if the potential exposure to the worker would exceed 25 percent of the dose limits listed in part 4730.0310, subpart 2, item A, subitem (2).

Subp. 7. **Gonad protection.** Except for cases in which it would interfere with the diagnostic procedure, during radiographic procedures in which the gonads are in or within two inches (5cm) of the useful beam, gonad shielding of not less than 0.5 millimeter lead equivalence must be used for patients who have procreative potential. All x–ray machine operators must be instructed as to the proper placement, size, and type of gonad shielding to be used. Documentation of the instruction must be retained for review by the commissioner.

Subp. 8. **Holding.** When a patient, film cassette, or intraoral film must be provided with auxiliary support during a radiation exposure, items A to E apply.

A. Mechanical holding devices shall be used when the technique permits.

B. Written safety procedures, as required by part 4730.1510, subpart 4, must indicate the requirements for selecting the individual holding and the procedure that individual shall follow.

C. The human holder must be protected as required by part 4730.1510, subpart 6.

D. No individual shall be used routinely to hold intraoral film, film cassettes, or patients. In those cases where the patient must hold the film cassette, 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.

E. If a patient must be held in position during therapeutic x–ray treatment, mechanical supporting or restraining devices shall be used.

Subp. 9. **Prevention of unauthorized use.** Therapy x–ray systems shall not be left unattended unless they are secured against unauthorized use.

Subp. 10. **Radiological practice standards.** Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be used.

A. The speed of screen–film combinations, or direct exposure x–ray film in intraoral dental radiography, shall be the fastest speed consistent with the diagnostic objective of the examinations.

B. Intensifying screens shall be used in combination with the compatible film, with the exception of dental intraoral films and radiation therapy port films.

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

D. The darkroom for film development must be free of extraneous light so fog is not added to film during handling and processing.

E. Darkroom safelight filters must be compatible with the films being processed.

F. The darkroom for film development must be tested for film fog at least every six months; any time fog is suspected; whenever there is a change in film speed or a change of safelight bulb or filters; or any time the integrity of any seal around the processor, other equipment, or the darkroom may have been compromised.

(1) The darkroom fog test and sensitometry must, at a minimum, be performed on the film most sensitive to light and processor changes.

(2) The amount of fog (increase in optical density) for a two–minute fog test must not exceed 0.05 for facilities doing mammographic film development and 0.08 for all other radiographic film development.

G. Film processing must meet the following requirements:

(1) all film must be processed to achieve optimal sensitometric performance;

(2) the film manufacturer's published recommendations for processing time and temperature must be followed;

(3) chemicals must be mixed according to the chemical manufacturer's recommendations;

(4) the daily sensitometry must be charted, reviewed, and corrective action taken, if necessary, before patients' films are processed; and

(5) all radiographs must be free of artifacts that could cause a misinterpretation.

H. Portable x–ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x–ray system.

I. Radiographic systems subject to part 4730.1850, other than fluoroscopic, dental intraoral, and dental panoramic systems must not be used in procedures where the source–to–skin distance is less than 30 centimeters (11.8 inches), except as described in part 4730.2150, subpart 9, item D.

J. Protective aprons and gloves shall be monitored annually for lead protection integrity. A record of the monitoring shall be maintained until the next inspection by the commissioner.

K. Viewboxes must be kept clean and be of uniform intensity. Bulbs must be of the same color. Luminance of the viewboxes located where films are checked for quality must be similar to those located where radiographs are interpreted.

Subp. 11. **Personnel monitoring.** Each registrant must supply the personnel specified in items A to D with individual personnel monitoring dosimeters and require the personnel to wear the dosimeter.

A. Each individual who enters a restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter over 25 percent of the applicable value specified in part 4730.0310, subpart 2, item A, subitem (1) or (2).

B. Each individual who enters a high radiation area or very high radiation area.

C. Each individual monitoring the controls for class A, B, and E industrial ionizing radiation producing equipment or nonmedical accelerators.

(1) The registrant must not permit an individual to operate industrial x-ray equipment or nonmedical accelerators unless the individual wears a direct reading pocket dosimeter and either a whole body film badge or a whole body thermoluminescent dosimeter at all times during radiographic operations.

(2) Direct reading pocket dosimeters must have a range from zero to 200 milliroentgens (5.16×10^{-5} C/kg).

(3) If a direct reading pocket dosimeter is reassigned each day or shift, the direct reading pocket dosimeter must be read and recharged daily or at the start of each shift.

(4) If a direct reading pocket dosimeter is assigned to only one individual, the direct reading pocket dosimeter must be read and recharged when there is a 50 percent elevation in the radiation reading.

(5) Each film badge or thermoluminescent dosimeter must be assigned to and worn by only one individual.

(6) Direct reading pocket dosimeters must be checked for correct response to radiation at periods not to exceed one year. Acceptable direct reading pocket dosimeters must read within plus or minus 30 percent of the actual radiation exposure.

(7) Records of the response to the radiation check must be maintained according to part 4730.1520, subpart 5.

(8) If an individual's direct reading pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual must cease and the individual's film badge or thermoluminescent dosimeter must be processed immediately. The individual may not return to work with sources of radiation until a determination of the radiation exposure has been made by the registrant or the registrant's radiation safety officer.

(9) If a film badge or thermoluminescent dosimeter is lost or damaged, the worker must cease work immediately until a replacement film badge or thermoluminescent dosimeter is provided and the dose is calculated for the time period from issuance to loss or damage of the film badge or thermoluminescent dosimeter.

D. All veterinarians and their staff who are being occupationally exposed during a radiation procedure must be provided a personal monitoring dosimeter according to Minnesota Statutes, section 144.121, subdivision 4.

Subp. 12. **Placement of personnel monitoring dosimeter.** When protective clothing is worn and personnel monitoring dosimeters are required, at least one such dosimeter shall be worn, according to items A and B.

A. When a protective apron is worn, the personnel monitoring dosimeter shall be worn at the collar outside of the protective apron.

B. When more than one personnel monitoring dosimeter is used, the record must identify the location of the monitor on the body and must state whether it was worn outside or under the protective clothing. The effective dose equivalent shall be recorded in the reports required by part 4730.1520, subpart 4.

Subp. 12a. **Control dosimeters.** The control dosimeter which accompanies personnel monitoring dosimeters during shipment must be obtained and kept in an area of natural background radiation at the facility between shipments.

Subp. 13. **Facility design requirements.** The registrant must ensure that the applicable structural shielding requirements specified in parts 4730.1600 to 4730.1640 are met. If an analysis of operating conditions indicates the possibility of an individual receiving a dose over the limits in part 4730.0310, the commissioner may require that structural shielding modifications be made.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414; 21 SR 916; 22 SR 314; 23 SR 1760*

4730.1520 RECORDS TO BE MAINTAINED BY REGISTRANT.

Subpart 1. **Individual x–ray systems.** The registrant must maintain on the premises the following information for each x–ray system and accelerator for inspection by the commissioner.

A. The maximum rating of the x–ray tube and generator.

B. The manufacturer and serial numbers or other permanent identification number of the control console and x–ray tubes.

C. For diagnostic x–ray systems, the half–value layer of the x–ray beam and the kVp at which the half–value layer was measured.

D. For diagnostic and therapeutic x–ray systems, records of site–specific radiation safety surveys, radiation leakage measurements, calibrations, equipment performance measurements, maintenance, and equipment modifications performed on the x–ray system with the names of individuals who performed the services.

E. For industrial ionizing radiation producing equipment and nonmedical accelerators, records as specified in subpart 5.

Subp. 2. **Mammographic image retention.** All mammography images must be retained as required by the Mammography Quality Standards Act of 1992, United States Code, title 42, section 263b, and regulations adopted thereunder.

Subp. 3. **Record keeping.** The registrant must have available at the time of inspection by the commissioner, records of personnel monitoring, radiation safety surveys for all types of x–ray equipment and accelerators, and equipment performance measurements for x–ray equipment.

A. Current copies of delegation agreements from physician assistants, registered physician assistants, certified nurse practitioners, and certified nurse midwives must be available at the time of inspection by the commissioner. Each delegation agreement must be signed by all supervising physicians.

B. Each registrant must maintain records, in the radiation measurement units used in this chapter, of:

(1) the personnel monitoring required by subpart 4; and

(2) the information required by parts 4730.1655 to 4730.1695, 4730.2510, and 4730.2710 for diagnostic and therapeutic x–ray equipment.

C. Each registrant must maintain records in any of the following forms: the original, a computer file, a reproduced copy, or microfilm. A reproduced copy or microfilm must be duly authenticated by the registrant and must be clear and legible.

D. At all times, the registrant is responsible for record retention required by this chapter. If the registrant ceases operation for any reason, provision must be made for record retention required by this chapter.

E. Each facility doing radiographic and fluoroscopic imaging procedures, except dental procedures, must keep a record of the following information:

(1) age of patient, if under age 18;

(2) imaging procedures performed; and

(3) name or initials of person performing the imaging procedure.

Subp. 4. **Personnel monitoring records.** Each registrant must maintain records showing the radiation doses of all individuals for whom personnel monitoring is required under part 4730.1510, subpart 11. The records must be clear and legible. The doses entered on the

records must be for periods of time not exceeding one calendar quarter or the period covered in the personnel monitoring reports.

A. Records of individual doses of radiation as specified in part 4730.0340, subpart 1, and the personnel monitoring records in this subpart shall be preserved for the lifetime of the individual worker or a minimum of 30 years after termination of employment with the facility, whichever is less.

B. In the absence of personnel monitoring data, records of the results of incident exposure surveys to determine external radiation dose shall be preserved for the lifetime of the individual worker or for a minimum of 20 years after termination of employment with the facility, whichever is less.

C. A registrant must advise each worker at least quarterly of the worker's dose of radiation as shown in records maintained by the registrant pursuant to this subpart.

D. The results of radiation safety surveys of particle accelerators and records of the results of surveys used to evaluate the release of radioactive effluents to the environment must be preserved until the next inspection by the commissioner.

Subp. 5. **Industrial radiography and nonmedical accelerator records.** Until the next inspection by the commissioner, each registrant must maintain a current radiation source inventory, a use log according to part 4730.2510, subpart 8, survey meter calibration records, direct reading pocket dosimeter check records, and inspection and maintenance logs.

A. For each x–ray machine, nonmedical accelerator, sealed source, and radiographic exposure device containing a sealed source, the radiation source inventory must contain:

(1) the serial number or other unique identification of the source of radiation;

(2) the identity of the radiographer assigned to the source of radiation;

(3) all locations where the source of radiation is used and the dates of use; and

(4) the dates on which the source of radiation is removed from and returned to storage, if applicable.

B. Each registrant must ensure that records are maintained of:

(1) inspection and maintenance;

(2) each direct reading pocket dosimeter's response to radiation;

(3) the survey meter calibrations required by part 4730.0300, subpart 7;

(4) the alarming ratemeter calibrations required by part 4730.0300, subpart 8;

(5) the radiation safety surveys performed according to part 4730.2510, subpart 6; and

(6) any maintenance and equipment modification performed on industrial radiography machines, analytical ionizing radiation producing equipment, and nonmedical accelerator systems, with the name of the individual who performed the service.

Subp. 6. **Jobsite records; industrial radiography.** Each registrant using a source of ionizing radiation for industrial radiography must have acceptable records available at each jobsite for inspection by the commissioner. Records must include:

A. a copy of the current registration for each source of ionizing radiation;

B. a copy of operating and emergency procedures for each source;

C. radiation safety survey records as required by subpart 5, item B, subitem (5); and

D. the latest instrument calibration records for instruments, survey meters, and devices in use at the site. Acceptable records for instruments, survey meters, and devices include tags or labels affixed to the survey meter or device.

Subp. 7. **Recording of fluoroscopic on–time.** All fluoroscopic on–time for each fluoroscopic procedure in excess of five minutes must be recorded and dictated on the patient's radiology report or procedure report.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 22 SR 314; 23 SR 1760*

4730.1530 ORDERING OF RADIOGRAPHIC EXAMINATIONS.

The registrant shall be responsible for ensuring that the following requirements on ordering radiographic examinations are met except when the radiographic examination is part of a healing arts screening program approved by the commissioner.

A. The order for a radiographic examination can be made only by a physician, dentist, veterinarian, chiropractor, podiatrist, or osteopath. A certified nurse midwife, certified nurse practitioner, physician assistant, or registered physician assistant must show eligibility to order radiographic procedures through a written delegation agreement.

B. The radiographic provider must not carry out a radiographic procedure ordered by a certified nurse midwife, certified nurse practitioner, physician assistant, or registered physician assistant unless a copy of a written delegation agreement is on file with the facility.

C. The order for a radiographic procedure must include clearly stated clinical indications for the examination and be available to procedure personnel at the time of the examination.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1600 REQUIREMENTS FOR SHIELDING AGAINST IONIZING RADIATION.

Shielding:

A. Each installation where radiation is used shall be provided with such primary barriers or secondary barriers as are necessary to ensure radiation safety. Each installation shall comply with the special shielding requirements applicable to the type of installation under consideration as specified in subsequent parts of this chapter. Primary or secondary barrier requirements shall be deemed to be met if the thicknesses of such barriers are equivalent to those calculated in accordance with NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X–rays and Gamma Rays of Energies Up to 10 MeV," National Council on Radiation Protection and Measurements, September 15, 1976, and where applicable, ANSI N43.3–1993, "American National Standard for General Radiation Safety: Installations Using Nonmedical X–Ray and Sealed Gamma–Ray Sources, Energies up to 10 MeV," American National Standards Institute, January 28, 1993. The NCRP report and the ANSI Standard are incorporated by reference, are not subject to frequent change, and are available through the Minitex interlibrary loan system. An alternative to NCRP Report No. 49 is that the thickness of primary or secondary barriers be sufficient to limit the radiation exposure levels to below 1/10 of those stated in part 4730.0310, subpart 2, item A, subitem (1), or 4730.0380 whichever is applicable.

B. Lead barriers shall be mounted in such a manner that they will not sag or cold–flow because of their own weight and shall be protected against mechanical damage.

C. Joints between different kinds of protective materials shall be so designed that the overall protection of the barrier is not impaired.

D. Holes in protective barriers shall be covered so that the overall attenuation is not impaired.

E. Windows, window frames, doors, and door frames shall have the same lead equivalent as that required of the adjacent wall.

F. All records of shielding designs or results of safety surveys must be permanently kept at the facility and as described in parts 4730.1520, subpart 1, items A to E, and 4730.1670, subparts 1 to 3.

G. All portable or mobile x–ray units, CT scanners, and therapy units must comply with the shielding requirements of this chapter.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *23 SR 1760*

4730.1610 GENERAL SHIELDING REQUIREMENTS FOR MEDICAL, CHIROPRACTIC, PODIATRIC, OSTEOPATHIC, AND VETERINARY MEDICINE FACILITIES.

Subpart 1. **Applicability.** This part applies to all medical, chiropractic, podiatric, osteopathic, and veterinary medicine facilities.

Subp. 2. **General shielding requirements for diagnostic radiographic facilities constructed or structurally remodeled six months after September 10, 1991.** For diagnostic radiographic facilities constructed or structurally remodeled six months after September 10, 1991, the requirements of this part apply. In addition, these facilities must meet the criteria for the particular type of installation as presented in:

A. NCRP Report Number 36, "Radiation Protection in Veterinary Medicine" (1970);

B. NCRP Report Number 38, "Protection Against Neutron Radiation" (1971);

C. NCRP Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X–rays and Gamma Rays of Energies Up to Ten MeV" (1976); and

D. NCRP Report Number 51, "Radiation Protection Design Guidelines for 0.1–100 MeV Particle Accelerator Facilities" (1977).

The NCRP reports in this subpart are incorporated by reference, are not subject to frequent change, and are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system.

Subp. 3. **Requirements for lead or lead equivalent shielding for a diagnostic radiographic facility constructed or structurally remodeled six months after September 10, 1991.** The requirements specified in this subpart apply to a diagnostic radiographic facility constructed or structurally remodeled six months after September 10, 1991.

A. Sheet lead must be installed so it is supported to prevent cold flow.

B. All lead lining must extend to a height of seven feet (2.1 meters).

C. If the wall containing a door is shielded, the door must have the same lead equivalency as the adjoining walls.

D. All lead must be installed so that adjoining pieces of lead are overlapped by a minimum of one–half inch (1.3 centimeters). The shielding of the diagnostic radiographic room must be constructed so the protection is not impaired by joints; openings such as ducts and pipes passing through the barriers; or conduits or service boxes embedded in the barriers.

E. All protective barriers that attenuate the primary x–ray beam must be shielded as primary protective barriers. This includes, but is not limited to, areas of walls containing chest cassette holders and upright buckys.

Subp. 4. **Design requirements for a diagnostic radiographic facility.** For a diagnostic radiographic facility constructed or structurally remodeled six months after September 10, 1991, the design requirements specified in subparts 5 to 8 apply.

Subp. 5. **Space requirements for an operator's booth in a diagnostic radiographic facility.** The requirements in items A to D are required for an operator's booth in a diagnostic radiographic facility.

A. The operator must be allotted not less than 7.5 square feet (0.7 square meters) of unobstructed floor space in the operator's booth.

B. The operator's booth may be any geometric configuration provided no dimension is less than two feet (0.6 meters).

C. Space allocated for the operator's booth must exclude any space occupied by the x–ray control panel, including an overhang, cables, or other encroachments.

D. The booth must be located and constructed so the unattenuated direct scattered radiation originating on the examination or treatment table, or at the upright cassette position does not reach the operator's station in the booth and does not exceed the dose limits specified in part 4730.0310.

Subp. 6. **Structural requirements for an operator's booth in a diagnostic radiographic facility.** The requirements in items A to D apply to an operator's booth in a diagnostic radiographic facility:

A. The booth walls must be permanently fixed barriers of at least seven feet (2.1 meters) high.

B. The booth must not be used as a primary barrier.

C. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which prevents the exposure when the door or panel is not closed.

D. Shielding must be provided to meet the requirements of part 4730.0310. If a facility's workload does not exceed 100 milliampere–minutes per week and all walls in the diagnostic exposure room are shielded with a minimum of 1.6 millimeter lead (1/16th inch or four pounds per square foot) including the protective barrier, then it is not necessary to estimate the shielding requirements necessary to meet the requirements of part 4730.0310.

Subp. 7. **X–ray control placement for an operator's booth in a diagnostic radiographic facility.** The x–ray control must be fixed within the booth so:

A. the exposure button is at least 39 inches (one meter) from any open edge of the control booth wall which is nearest to the examining table; and

B. the operator is able to use the full viewing window.

Subp. 8. **Viewing system requirements for an operator's booth in a diagnostic radiographic facility.** An operator's booth in a diagnostic radiographic facility must meet the requirements in items A and B.

A. A booth must have at least one viewing device which is placed so the operator:

(1) can view the patient during any exposure;

(2) has full view of any occupant of the room; and

(3) can view any entry into the room.

B. When the viewing system is a window, the requirements in subitems (1) to (4) apply.

(1) The window must have the same lead equivalency as the surrounding barrier.

(2) The viewing area must be at least eight inches (20.32 cm) by ten inches (25.4 cm).

(3) The booth must be designed so the operator's expected viewing position is at least 18 inches (0.46 meters) from the edge of the booth.

(4) In diagnostic radiographic facilities constructed or structurally remodeled after September 10, 1991, the minimum window size must be 24 inches high (0.61 meters) X 18 inches wide (0.46 meters) and placed on a five foot two inch (1.57 meters) center with the long dimension of the window in the vertical direction.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1620 GENERAL SHIELDING REQUIREMENTS FOR DENTAL RADIOGRAPHIC FACILITIES.

Subpart 1. **General requirements.** The structural shielding requirements in this subpart apply to all dental radiographic facilities.

A. Dental rooms containing intraoral radiographic systems must provide barriers at all areas struck by the useful beam. Shielding must meet the criteria in NCRP Report Number 35, "Dental X–Ray Protection," (1970).

B. When dental intraoral radiographic systems are installed in adjacent rooms or areas, protective barriers must be provided between the rooms or areas.

C. Each installation must be provided with a protective barrier for the operator or must be arranged so the operator can stand at least six feet from the patient and the tubehead and not be in the path of the useful beam.

Subp. 2. **Requirements for new or structurally remodeled facilities.** Dental radiographic facilities constructed or structurally remodeled six months after September 10, 1991, must meet the shielding requirements in this part.

A. For an intraoral dental radiographic facility, the facility must meet the criteria in NCRP Report Number 35, "Dental X-Ray Protection," (1970).

B. For a facility using dental radiographic equipment for extraoral radiographs including but not limited to cephalometric, temporomandibular joint and panoramic radiographs, the general lead or lead equivalent shielding requirements in part 4730.1610, subpart 2, apply. In addition, the facility must meet the criteria presented in NCRP Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to Ten MeV" (1976).

The NCRP reports specified in this part are incorporated by reference, are not subject to frequent change, and are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through Minitex interlibrary loan system.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485*

4730.1630 GENERAL REQUIREMENTS FOR THERAPEUTIC X-RAY FACILITIES.

Subpart 1. **Applicability.** All therapeutic x-ray facilities must meet the criteria for the particular type of installation as presented in:

A. NCRP Report Number 38, "Protection Against Neutron Radiation" (1971);

B. NCRP Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to Ten MeV" (1976);

C. NCRP Report Number 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977);

D. NCRP Report Number 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range Ten keV to 50 MeV" (1981);

E. NCRP Report Number 72, "Radiation Protection and Measurement for Low Voltage Neutron Generators" (1983);

F. NCRP Report Number 79, "Neutron Contamination from Medical Electron Accelerators" (1984); and

G. NCRP Report Number 102, "Medical X-ray, Electron Beam and Gamma Ray Protection for Energies Up To 50 MeV (Equipment Design, Performance and Use)" (1989).

The NCRP reports in items A to G are incorporated by reference, are not subject to frequent change, and are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system.

Subp. 2. **Shielding requirements for therapeutic x-ray systems and medical particle accelerators.** Each therapeutic x-ray system and medical particle accelerator system installed in a facility must be provided with primary and secondary barriers to ensure compliance with parts 4730.0310, 4730.0340, 4730.0360, and 4730.0380.

Subp. 3. **Facility design requirements for therapeutic x-ray systems with energies of 50 kVp and above.** Therapeutic x-ray systems with energies of 50 kVp and above:

A. must have two-way audio communication between the patient and the operator at the control panel; and

B. must provide for patient observation using:

(1) a closed circuit television system; or

(2) for systems with energies of 150 kVp or less, a window containing the appropriate lead equivalence so the operator at the control panel may directly observe the patient, any other individual in the room, and any doorways into the room.

Subp. 4. **Additional requirements for therapeutic x-ray systems with energies of 150 kVp and above, and medical particle accelerators.** In addition to the requirements specified in subpart 3, therapeutic x-ray systems with energies of 150 kVp and above and medical particle accelerators must have protective barriers which are fixed except for entrance doors or beam interceptors and the control panel must be located outside the treatment room.

Subp. 5. **Additional requirements for medical particle accelerators.** In addition to the requirements specified in subparts 3 and 4, facilities with a medical particle accelerator must meet the standards in items A to D.

A. Closed circuit television, or an equivalent system, must be provided to permit continuous observation of the patient during irradiation and must be located so the operator may observe the patient from the control panel.

B. Two–way audio communication between the patient and the operator must be provided at the control panel. However, where excessive noise levels or treatment requirements make audio communication impractical, other methods of communication must be used.

C. Treatment room entrances must be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is in the on position.

D. Interlocks or safety devices must be in place so all access into the room is blocked before treatment is initiated or continued. If the useful radiation beam is interrupted by any door opening or tripping of a safety device, it must not be possible to restore the system to operation without closing the door or resetting the safety device and reinitiating irradiation by manual action at the control panel.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1640 GENERAL SHIELDING REQUIREMENTS FOR INDUSTRIAL X–RAY, NONMEDICAL ACCELERATOR, AND SEALED SOURCE RADIOGRAPHY FACILITIES.

Subpart 1. **Applicability.** This part applies to all new construction and structural remodeling that commences on or after March 1, 1998. All registrants who possess industrial x–ray, nonmedical accelerator, and sealed source radiography facilities, except industrial cabinet, industrial cabinet baggage, portable industrial x–ray, and analytical ionizing radiation producing equipment, must meet the requirements of this part.

Subp. 2. **General shielding and design requirements.**

A. X–ray, sealed source radiography, and nonmedical accelerator facilities must be designed to meet the dose criteria in parts 4730.0310 to 4730.0380.

B. The following documents or equivalent documents must be used in the design process:

(1) National Council on Radiation Protection, Report Number 38, "Protection Against Neutron Radiation" (1971);

(2) National Council on Radiation Protection, Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X–rays and Gamma Rays of Energies Up to 10 MeV" (1976); and

(3) National Council on Radiation Protection, Report Number 51, "Radiation Protection Design Guidelines for 0.1–100 MeV Particle Accelerator Facilities" (1977).

The reports in subitems (1) to (3) are incorporated by reference, are not subject to frequent change, and are available through the Minitex interlibrary loan system.

Subp. 3. **Shielding requirements; Class A and Class E facilities.** Class A stationary industrial ionizing radiation producing facilities and Class E stationary nonmedical accelerator facilities as described in part 4730.2510, subpart 2, must have fixed protective barriers, except for entrance doors or beam interceptors. The control panel must be located outside the radiography or nonmedical accelerator room.

Statutory Authority: *MS s 144.05; 144.12*

History: *22 SR 314*

4730.1650 [Repealed, 16 SR 485]

4730.1655 REQUIRED EQUIPMENT PERFORMANCE TESTS FOR QUALITY ASSURANCE PROGRAM.

Subpart 1. **General.** Within three months after September 10, 1991, each registrant must implement a quality assurance program which includes:

A. the equipment performance tests specified in parts 4730.1655 and 4730.1665;

B. radiation safety surveys as specified in parts 4730.1520, subpart 1, item D, and 4730.1670, subpart 1;

C. calibrations as required in part 4730.1675;

D. in–service education for employees as specified in parts 4730.1510, subpart 4, and 4730.1688; and

E. the records required in part 4730.1690.

In addition to items A to E, each registrant with therapeutic x–ray equipment must also make spot checks as specified in part 4730.1680. Medical particle accelerators must have separate equipment performance procedures as specified in part 4730.1685.

Subp. 2. **General quality assurance program procedures.** Each registrant conducting radiographic procedures or therapeutic x–ray procedures must implement a quality assurance program. The program must include:

A. a site–specific quality assurance manual that contains written policies and procedures for radiation protection and describes the quality assurance program;

B. the numeric results of equipment performance tests and the correction of any deficiencies as specified in the quality assurance manual; and

C. the calibration record of any electronic equipment used in the equipment performance tests within the preceding two years. The calibration of any electronic equipment must be traceable to its calibration standard at the National Institute of Standards and Technology (NIST). Until such time that there is a NIST standard for noninvasive kVp meters, the meters must be returned to the manufacturer for calibration or to an accredited calibration laboratory.

Subp. 3. **Equipment performance measurements for all x–ray facilities.** Each registrant operating a radiographic facility must implement the quality assurance measures specified in items A to C.

A. The quality assurance manual described in subpart 2 must include the required tests and the minimum performance criteria specified in parts 4730.1691 to 4730.1695 for the registrant's radiographic or therapeutic equipment and processing equipment. The registrant is not limited to the equipment performance tests required in parts 4730.1691 to 4730.1695 but may also include tests from item C. The registrant is required to meet the minimum performance criteria specified in parts 4730.1691 to 4730.1695, when applicable. The facility must retain records showing the correction of any deficiencies until the next inspection by the commissioner.

B. The manual must specify the minimum frequency of equipment performance tests. In addition, the tests must be done after any change in the facility or equipment which might cause an increase in radiation hazard or a change in equipment that results in the minimum performance criteria not being met.

C. The registrant and the registrant's employees must be familiar with the contents and recommendations of any of the following applicable publications:

(1) NCRP report 99, "Quality Assurance for Diagnostic Imaging Equipment," (December 30, 1988);

(2) "Quality Assurance Program for Diagnostic Radiology Facilities," by Roger L. Burkhart, Ph.D., United States Department of Health, Education and Welfare, public health service, food and drug administration, publication number 80–8110 (February 1980);

(3) "A Basic Quality Assurance Program for Small Radiology Facilities," by Roger L. Burkhart, Ph.D., United States Department of Health, Education and Welfare, public health service, food and drug administration, publication number 83–8215 (1983).

The registrant may incorporate portions of the publications specified in this subpart into the facility's quality assurance manual described in subpart 2, item A. The publications are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414; 23 SR 1760*

4730.1660 [Repealed, 16 SR 485]

4730.1665 COMPUTED TOMOGRAPHY EQUIPMENT PERFORMANCE MEASUREMENTS.

Subpart 1. **Applicability.** This part applies to computed tomography facilities and must be done in addition to the requirements in part 4730.1655.

Subp. 2. **General equipment performance measurements.** The registrant must ensure that the equipment performance measurements and calibration procedures specified in this part are performed. The equipment performance measurements and calibration procedures must be in writing and include:

A. Those measurements and calibration procedures specified in part 4730.1691 for CT scanners at the frequency specified and those aspects of processing at the frequency specified. In addition, the equipment performance measurements and calibration procedures must be done after any change in the facility or equipment which might cause an increase in radiation hazard or a change in equipment that results in the minimum performance criteria not being met.

B. The computed tomography dose index in the two positions in item D, subitem (3)(b). The CT dosimetry phantom must be oriented so that the measurement point of 1.0 centimeter beneath the surface is in the angular location where the computed tomography dose index is maximum. For the purpose of determining the computed tomography dose index, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be used.

C. The procedures specified in subpart 3, item A.

D. Radiation output measurements.

(1) Measurements of radiation output from a computed tomography x–ray system must be performed as specified in part 4730.1691 and after any change or replacement of components which could cause a change in the radiation output.

(2) The measurement of the radiation output of the computed tomography x–ray system must be performed with a calibrated dosimetry system. The calibration of the dosimetry system must be traceable to its calibration standard at the National Institute of Standards and Technology (NIST). The dosimetry system must have been calibrated within the preceding two years.

(3) Computed tomography dosimetry phantoms must be used in determining the radiation output of the computed tomography x–ray system. The phantoms must comply with Code of Federal Regulations, title 21, section 1020.33.

(a) All dose measurements must be performed with the computed tomography dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(b) Computed tomography dosimetry phantoms must provide a means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

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

(4) The dose measurements must be made for the head and body technique used at the facility. The image quality measurements must be made using a typical clinical technique in the head and body scan modes of operation.

Subp. 3. **Additional operator equipment performance measurements.** In addition to the equipment performance measurements described in subpart 2, the equipment performance measurements specified in items A and B must be performed by an operator.

A. The operator's computed tomography equipment performance procedures must be those with the monthly or daily frequencies in part 4730.1691, and include all processing procedures noted in part 4730.1691.

B. The registrant or radiation safety officer must review and initial all of the operator's equipment performance measurements at least quarterly. An operator's equipment performance measurements must include acquisition of images obtained with the CT dosimetry phantoms using the same processing mode and CT conditions of operation as are used to perform the equipment performance measurements required by subpart 2.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1670 RADIATION SAFETY SURVEYS.

Subpart 1. **Applicability.** Each registrant conducting diagnostic or therapeutic x–ray procedures must ensure that the radiation safety surveys specified in this part are site–specific and in compliance with this chapter. A survey must be performed at the time of initial installation and after any change in the facility or equipment which might cause a change in radiation hazard. A report of each survey must be prepared, maintained at the facility according to the record requirements in part 4730.1520, and made available to the commissioner on request. The safety survey must include the following:

A. an evaluation of tube housing integrity;

B. calibrations;

C. equipment performance measurements;

D. maintenance and equipment modifications; and

E. shielding plans or results from radiation shielding evaluations.

Subp. 2. **Radiation monitoring equipment.** At each medical particle accelerator facility, portable monitoring equipment designed for the types of radiation produced at the facility must be available. The portable monitoring equipment must be operable and calibrated for the radiation being produced at the facility. The equipment must be tested for proper operation prior to each use and calibrated at intervals not to exceed two years and after each servicing or repair.

Subp. 3. **Written procedures.** The registrant must ensure that all radiation safety surveys are performed according to written procedures established by the radiation safety officer and are in accordance with this part.

Subp. 4. **Corrective actions.** If radiation safety survey results are not in compliance with this chapter, corrective action must be taken.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1675 CALIBRATIONS.

Subpart 1. **Diagnostic radiographic system calibrations.** The registrant must ensure that calibrations are performed on a diagnostic radiographic system whenever that system does not meet the minimum performance criteria specified in part 4730.1691 and when there is any change or replacement of components which could cause a change in the radiation output of that system.

Subp. 2. **Therapeutic x–ray system calibrations for systems of less than 1.0 MeV.** Each registrant operating a therapeutic x–ray system of less than 1.0 MeV must ensure that the calibrations specified in this subpart are performed.

A. The calibration of the radiation output of a therapeutic x–ray system must be performed:

(1) at intervals not to exceed 12 months;

(2) after any change or replacement of components which could cause a change in the radiation output; and

(3) with a calibrated dosimetry system. The calibration of the dosimeter must be traceable to its calibration standard at the National Institute of Standards and Technology (NIST). Verification of the dosimeter calibration must be performed every two years.

B. The calibration and beam characteristics of the therapeutic x–ray system must include, but not be limited to:

(1) dose rate as a function of field size, technique factors, filter, and treatment distance used;

(2) the degree of congruence between the radiation field and the field indicated by the localizing device if the device is present;

(3) an evaluation of the uniformity of the largest radiation field used;

(4) verification of the applicability of the inverse square law;

(5) verification of the accuracy of any source–to–skin distance (SSD) indicators;

(6) evaluation of timer or end effects; and

(7) verification of half value layer (HVL).

C. A copy of the current therapeutic x–ray system's dosimetry data must be available.

Subp. 3. **Calibrations for therapeutic x–ray systems greater than 1.0 MV.** Each registrant operating a therapeutic x–ray system of greater than 1.0 MV must ensure that the calibrations specified in this subpart are performed.

A. The calibration of systems subject to part 4730.2450 must be performed according to protocols TG–21 and TG–25 endorsed by the American Association of Physicists in Medicine. The protocol known as TG–21 is titled "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams" and TG–25 is titled "Clinical Electron–Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group No. 25." The protocols are published in American Association of Physicists in Medicine, Medical Physics, volume 10, number 6, pages 741 to 771 (1983) and volume 18, number 1, pages 73 to 102 (1991). The TG–21 protocol and the TG–25 protocol are incorporated by reference and are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system. The protocols are not subject to frequent change. The calibration protocol must be performed:

(1) before the system is first used for the irradiation of a patient;

(2) at time intervals which do not exceed 12 months; and

(3) after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

B. Calibration radiation measurements required by item A must be performed using a dosimetry system traceable to its calibration standard at the National Institute of Standards and Technology (NIST). The dosimetry system must:

(1) have a calibration factor for cobalt–60 gamma rays traceable to a standard maintained by the National Institute of Standards and Technology (NIST);

(2) have a calibration which has been verified every two years by an Accredited Dosimetry Calibration Laboratory (ADCL) or by intercomparison with another dosimetry system that has been calibrated by an ADCL within two years;

(3) be calibrated after any servicing that may have affected its calibration; and

(4) have constancy checks as specified in part 4730.1695, subpart 1, item B.

C. The documentation of each therapy beam must include, but not be limited to, the following determinations:

(1) verification that the equipment is operating in compliance with the design specifications for the light localizer, all readouts, the optical distance indicator, laser and cross–hairs alignment with the isocenter (when applicable), radiation isocenter variation with collimator, gantry and table support rotation, beam flatness, and symmetry at a specified depth;

(2) the variation with field size of the absorbed dose rate at a reference depth in–phantom (or air) as a fraction of its value for the field size used to determine the calibration as specified in part 4730.1675, subpart 3, item A;

(3) the uniformity of the radiation field and any dependency on the direction of the useful beam;

(4) verification that existing depth–dose data and isodose charts applicable to the specific system continue to be valid or are updated to existing system conditions; and

(5) verification of transmission for all accessories such as wedges, block trays, and compensators.

D. A copy of the most recent beam data must be available.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1680 THERAPEUTIC X–RAY SYSTEM SPOT CHECKS OF CALIBRATION.

Subpart 1. **Spot checks of calibration for therapeutic x–ray systems of less than 1.0 MV.** The registrant must ensure that spot checks of calibration are performed on therapeutic x–ray systems. Spot checks must be performed at a minimum frequency of every six months and meet the requirements specified in this subpart.

A. Spot–check procedures must be in writing, must be maintained in the facility in accordance with part 4730.1520, and must be available to the commissioner on request.

B. Parameters exceeding the tolerance specified in part 4730.1695 must be corrected to within the tolerance specified before the system is used for patient irradiation.

C. Whenever a spot check indicates a change in the operating level of a system which exceeds the minimum tolerance level specified in part 4730.1695, the system must be recalibrated as required in part 4730.1675, subpart 2.

D. Items to be spot checked include those calibrations and beam characteristics in part 4730.1675, subpart 2, items A and B.

Subp. 2. **Spot checks of calibration for therapeutic x–ray systems greater than 1.0 MV.** The registrant must ensure that spot checks of calibration are performed on systems subject to part 4730.2450 during calibrations and at intervals not to exceed one month. Spot checks must meet the requirements specified in items A to G:

A. Spot–check procedures must be in writing.

B. The spot–check procedures must specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

C. At intervals not to exceed one month, spot checks must be made of absorbed dose measurements at a minimum of two depths in a phantom.

D. Where a system has built–in devices that provide a measurement of any parameter during irradiation, the measurement must not be used as a spot–check measurement.

E. A parameter exceeding a tolerance level specified in part 4730.1695 must be corrected to within the tolerance level before the system is used for patient irradiation.

F. Whenever a spot check indicates a change in the tolerance level of a system which exceeds the minimum tolerance level as specified in part 4730.1695, the system must be recalibrated as required in part 4730.1675, subpart 3.

G. Where a spot check involves a radiation measurement, the measurement must be obtained using a dosimetry system satisfying the requirements of part 4730.1675, subpart 3, item B.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1685 MEDICAL PARTICLE ACCELERATOR RADIATION MONITORING EQUIPMENT.

At each medical particle accelerator facility, portable monitoring equipment designed for the types of radiation produced at the facility must be available. The portable monitoring equipment must be operable and calibrated for the radiation being produced at the facility. The equipment must be tested for proper operation prior to each use and calibrated at intervals not to exceed two years and after each servicing or repair.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485*

4730.1688 IN–SERVICE EDUCATION IN QUALITY ASSURANCE.

Each registrant must provide the in–service training program on quality assurance for employees specified in part 4730.1510, subpart 4. Employees must sign or initial their attendance on a record to be kept for inspection by the commissioner.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485*

4730.1690 QUALITY ASSURANCE RECORDS.

Subpart 1. **Radiographic facility records.** The registrant must ensure that radiographic equipment and processing records are maintained for each system until the next inspection by the commissioner, including:

A. all test results;

B. records for repairs and service of equipment and processors; and

C. other information specified in part 4730.1520.

Subp. 2. **Computed tomographic x–ray facility records.** The registrant must ensure that records are recorded, plotted, and maintained until the next inspection by the commissioner. The records must indicate:

A. calibrations performed;

B. quality control measures for computed tomographic systems; and

C. requests for repair and service and the repairs made.

Subp. 3. **Therapeutic x–ray facility records.** The registrant must ensure that the following records are maintained for therapeutic x–ray systems until the next inspection by the commissioner:

A. calibration records for therapeutic x–ray systems less than one MeV;

B. calibration records of measurements for therapeutic x–ray systems greater than one MeV as required under part 4730.1675, subpart 3, item A, and dosimetry system calibrations as required by part 4730.1675, subpart 3, item B;

C. spot–check measurements and any necessary corrective actions for therapeutic x–ray systems less than one MeV;

D. spot–check measurements and any necessary corrective actions for therapeutic x–ray systems greater than one MeV; and

E. requests for repair and service and the repairs made.

Subp. 4. **Medical particle accelerator facility records.** The registrant must ensure that records of all radiation safety surveys, calibrations, and instrumentation tests are maintained for a medical particle accelerator at the facility until the next inspection by the commissioner.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1691 DIAGNOSTIC EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.

Subpart 1. **Frequency of tests.** The tests in subparts 1a to 12 are to be made at the time of installation and at the specified intervals thereafter.

Subp. 1a. **Image receptors.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Screen–film contact	Annually	No significant areas of poor contact as measured by 8 wires/inch copper mesh, or 7 holes/inch for regular film and 40 wires/inch copper mesh for mammography
B.	Screen–film–cassette speed match	Annually	Densities within ± 0.10 O.D. for all cassettes used for each diagnostic task

Subp. 2. **Automatic processing.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Darkroom fog	Semi–annually	≤ 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on–site at the time of test. For mammography the O.D. increase must be ≤ 0.05
B.	Sensitometry and densitometry	Before processing first film of the day	Density ± 0.15 O.D. using film exposed on–site at time of test. As of July 1, 1993, veterinary facilities are not required to perform this test
C.	Temperature check	At the time of sensitometry	Follow manufacturer's recommendations

Subp. 3. **Manual processing.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Darkroom fog	Semi–annually	≤ 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on–site at time of test
B.	Sensitometry and densitometry	Before processing first film of the day	Density ± 0.15 O.D. using film exposed on–site at time of test. As of July 1, 1993, veterinary facilities are not required to perform this test
C.	Temperature check	Before processing each batch of film	Follow manufacturer's time and temperature chart

Subp. 4. **All diagnostic radiographic tubes; required when applicable.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	SID accuracy	Biennially	± 2% of measured value
B.	X–ray and light field alignment	Biennially	± 2% of SID any one direction, ± 3% of SID, both directions (total)
C.	X–ray and image receptor alignment	Biennially	± 2% of SID
D.	Collimator dial accuracy	Biennially	± 2% of SID
E.	Reproducibility	Biennially	Coefficient of variation ≤ 5%
F.	mR/mAs	Biennially	± 10% of baseline
G.	Linearity	Biennially	± 10% over clinical range
H.	Linearity–for mAs only units manufactured after May 3, 1994	Biennially	Average ratios of exposure to the indicated mAs obtained in any two consecutive mAs settings shall not differ by more than 0.10 times their sum, or at two settings differing by no more than a factor

			of two where the mAs selector provides continuous selection.
I.	Timer accuracy	Biennially	Single Phase: use Table 4730.1692 or ± 10% of setting. Three phase, high frequency, and constant potential: use ± 5% of selected time when measured ≥ than 100 milliseconds. At times shorter than 100 milli–seconds, use manufac–turers' specifications.
J.	Half–value layer	Biennially	Use part 4730.1750, subpart 6, item A
K.	kVp accuracy	Biennially	± 5% of indicated kVp for noncertified equipment. For certified equipment follow manufacturer's specified limits
L.	Phototimer reproducibility, if present	Biennially	± 5% of average exposure
M.	AEC (phototimer) increments	Biennially	± 10% of manufacturer's stated increments
N.	Illuminance of certified collimator	Biennially	≥ 15 footcandles
O.	Film density vs. thickness change on AEC	Biennially	± 0.30 O.D. of the averaged exposures over the range specified by the manufacturer
P.	Film density vs. kVp change on AEC	Biennially	± 0.30 O.D. of the averaged exposures when measured at ≥ 1.2 O.D. and over the range as specified by the manu–facturer
Q.	Spot film reproducibility (fluoro units with manual mode)	Annually	± 5% of average exposure
R.	Phototimer back–up timer cut off	At time of installation	terminates exposure at ≤ 600 mAs

S.	AEC density at normal or "0"	Biennially	≥ 1.0 O.D.

Subp. 5. **For facilities with fluoroscopes and C–arm fluoroscopes, except radiation therapy simulators, manufactured before May 19, 1995.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Maximum output at tabletop or equivalent minimum SSD	Annually and every tube change	≤ 5 R (1.3 mC kg^{-1}) per minute for manual; ≤ 10 R (2.6 mC kg^{-1}) per minute for Automatic Exposure Rate Control systems
B.	High level control maximum output at tabletop or equivalent minimum SSD	Annually and every tube change	≤ 20 R (5.0 mC kg^{-1}) per minute
C.	Fluoroscopic image size	Annually and every tube change	Error between fluorographic beam size and observed image size must be no more than ± 3% of SID for all modes and at any tower height
D.	Actual spot–film size vs indicated	Annually	Error between actual fluorographic beam size at image receptor and indicated image size must be no more than ± 3% of SID for all modes and at any tower height
E.	Spot–film reproducibility	Annually	± 5% of average exposure
F.	Phototimer reproducibility, if present	Annually	± 5% of average exposure
G.	Fluoroscopic high contrast resolution and distortion	Annually	15 centimeter (six inch) intensifier: center 30 and edge 24 (wires per inch) copper mesh; 23 centimeter (nine inch) intensifier: center 24 and edge 20 (wires per inch) copper mesh
H.	Half–value layer	Annually and after every tube change	Use part 4730.1750, subpart 6, item A

I.	kVp accuracy	Annually and after every tube change	± 5% for noncertified equipment. For certified equipment follow manufacturer's specified limits.

Subp. 5a. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured on or after May 19, 1995.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Maximum output at tabletop or equivalent minimum SSD	Annually and at every tube change	≥ 5 R/min must have Automatic Exposure Rate Control; ≥ 10 R/min must have high level control; if no high level control maximum is ≤ 10 R/min.
B.	High level control maximum output at tabletop or equivalent minimum SSD	Annually and at every tube change	≤ 20 R/min
C.	All other tests as indicated in subpart 5		

Subp. 6. **For facilities with mammography systems.** All tests on mammographic units must follow the Mammography Quality Standards Act of 1992, United States Code, title 42, section 263b, and regulations adopted thereunder.

Subp. 7. **For facilities with tomography systems other than computed tomography.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Section level	Annually	± 5 mm
B.	Level incrementation	Annually	± 2 mm
C.	Section thickness	Annually	Follow manufacturer's specifications
D.	All tests in part 4730.1691, subpart 4, if applicable		
E.	Spatial plane resolution	Annually	40 mesh screen or better

Subp. 8. **For facilities with computed tomography scanners.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Accuracy of scout localization view	Annually	± 1 mm

B.	Accuracy of distance measurements	Annually	± 1 mm
C.	CT dose index	Annually	± 20% from manufacturer's recommendations
D.	CT number dependence on slice thickness	Annually	Mean ± 3 CT numbers averaged over 100 pixels
E.	CT number calibration and noise	Daily	Water: 0 ± 5 CT numbers; Noise: ± 3 standard deviations of the mean of the baseline noise variance measurements
F.	CT number uniformity and artifacts	Monthly for mobile units. Annually for fixed base units	Variation ± 5 CT numbers between the mean values of measurements made at center and edge of phantom that is at least 20 cm. in diameter among a mean of 100 pixels. Artifacts: no noticeable artifacts
G.	Hard copy output and visual display	Daily	Luminance and contrast not significantly different

Subp. 9. **For facilities with cinefluorographic and special procedure systems.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Cinefluorographic exposure rates	Annually	Approximately 10 to 20 μR (2.6 to 5.0 nC/kg) per frame at intensifier for nine inch (23 cm) mode; approximately 20 to 30 μR (5 to 8 nC/kg) per frame at intensifier for six inch (15 cm) mode
B.	All tests in subparts 4, 5, and 5a, if applicable		
C.	Film changer screen–film contact	Annually	No significant areas of poor contact as measured by 8 wires/inch copper mesh or 7 holes/inch
D.	High contrast resolution for cinefluorographic and digital systems	Annually	No significant difference between static and dynamic conditions

E.	Optical density of films over duration of filming run	Annually	< ± 0.2 O.D. difference

Subp. 10. [Repealed, 23 SR 1760]

Subp. 11. **For facilities with dental intraoral systems.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Film processing	Before the first film of the day	Between 0.75 and 1.05 O.D. on the test tool or follow test tool manufacturer's recommendations
B.	Filtration (HVL)	Biennially	Use part 4730.1750, subpart 6, item A
C.	Radiation exposure at end of cone	Biennially	Use part 4730.1950, subpart 4, item C
D.	Timer reproducibility and accuracy	Biennially	± 10% of indicated timer setting
E.	kVp accuracy	Biennially	± 5% of indicated kVp for noncertified equipment. For certified equipment follow manufacturer's specified limits
F.	Reproducibility	Biennially	Coefficient of variation ≤ 5%
G.	Fog test	Semi–annually	Use criteria in subpart 2, item A for automatic processing; subpart 3, item A for manual processing
H.	Dental mA linearity	Biennially	± 10% over the clinical range

Subp. 12. **For facilities with dental extraoral systems including panoramic systems.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Film processing		Use automatic and manual processing as specified in subparts 2 and 3. A step wedge may be used in place of the sensitometry and densitometry test in subparts 2, item B, and 3, item B

B.	Same test types and minimum performance criteria as Diagnostic Radiographic Tubes in subpart 4		
C.	Fog test	Semi–annually	Use criteria in subpart 2, item A for automatic processing; subpart 3, item A for manual processing

Source: Derived from NCRP 99, Tables A.1 to A.10.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414; 23 SR 1760*

4730.1692 EXPOSURE TIME CONTROL LIMITS FOR SINGLE PHASE FULL–WAVE RECTIFIED GENERATORS.

Exposure time (seconds)	Acceptance limits
1/5	24 ± 1 dot
1/10	12 ± 1 dot
1/20	6 ± 0 dots
1/30	4 ± 0 dots

Note: when using a spinning top, the x–ray pulses are imaged as dots on the film as the small hole in the top is moved rapidly (rotated) over the film. Source: National Council on Radiation Protection, Report No. 99, Table 7.3, December 30, 1988.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485*

4730.1693 THERAPY EQUIPMENT PERFORMANCE TESTS AND LIMITS FOR MEASUREMENT EQUIPMENT.

Subpart 1. **Local standard (Loc. Std.).**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. AAPM – accredited Dosimetry calibration Laboratory calibration	Every two years	D
B. Linearity	Every four years	0.5 percent
C. Venting	Every four years	D
D. Extracameral signal	Initial use	0.5 percent
E. Leakage	Each use	0.1 percent
F. Recombination	Initial use	Documented
G. Collecting potential	Each use	D

Subp. 2. **Other field instruments.**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. Local standard comparison	Every 2 years	one percent
B. Linearity	Every two years	D
C. Venting	Every two years	D
D. Extracameral signal	Every two years	D
E. Leakage	Each use	0.1 percent
F. Recombination	Initial use	Documented
G. Collecting potential	Each use	D

Subp. 3. **Relative dosimetric equipment.**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. Thermoluminescent Dosimeter		
(1) Calibration	Each batch or box	D
(2) Linearity	Initial use	D
B. Film		
(1) Dose and response	Each batch or box	D
(2) Densitometer linearity	Every year	D
C. Air Ionization Chamber system		
(1) Linearity	Every year	D
(2) Extracameral signal	Initial use	1 percent
D. Diode System		
(1) Energy dependence	Initial use	D
(2) Extracameral signal	Initial use	D
(3) Linearity	Initial use	D

Subp. 4. **Survey instruments.**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. Calibration	Every year	D
B. Linearity	Every year	D
C. Constancy	Each use	5 percent
D. Battery voltage	Each use	D

Subp. 5. **Positioning equipment.**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. Accuracy	Each use	2 mm
B. Hysteresis	Each use	2 mm

Subp. 6. **Phantoms and attenuators.**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. Thickness	Initial use	D
B. Density	Initial use	D
C. Phantom stacked density	Initial use	D
D. Detector fit	Initial use	D

Subp. 7. **Accessory equipment.**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. Thermometer		
(1) Calibration	Initial use	0.1 degree/C
B. Barometer (mercury)		
(1) Calibration Hg	Initial use	1 mm Hg
C. Barometer (aneroid)		
(1) Calibration Hg	Initial use	1 mm Hg
(2) Intercomparison	Annually	1 mm Hg

D = Documented and correction applied or noted in report of measurement, when appropriate.

Source: Derived from American Association of Physicists in Medicine, Report No. 13, Table I, pp. 21–22, 1984 and TG–40, Medical Physics, volume 21, number 4, Tables I, II, and IV, pages 581 to 618 (1994).

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1695 EQUIPMENT PERFORMANCE TESTS FOR EXTERNAL BEAM TELETHERAPY AND SIMULATION SYSTEMS.

Subpart 1. **Dosimetry.**

	MINIMUM TEST INTERVAL	TOLERANCE
A. General axis dose calibration	Annually	2 percent
B. Constancy checks–photons		
(1) Dose per monitor unit along central axis	Weekly	3 percent
(2) Depth dose	Monthly	2 percent
(3) Beam uniformity	Monthly	3 percent
(4) Monitor chamber linearity	Annually	1 percent
(5) Timer linearity and error	Annually	1 percent

Subp. 2. **Geometry.**

	MINIMUM TEST INTERVAL	TOLERANCE
A. Field positioning aids		
(1) Light field and radiation field agreement	Monthly	2 mm
(2) Mechanical distance pins, lasers, and SSD lights	Monthly	2 mm
(3) Scale readouts		2 mm/1 degree angle
B. Machine alignment		
(1) Jaw symmetry	Annually	2 mm
(2) Coincidence of collimator (jaw) and gantry axes with isocenter	Annually	2 mm
(3) Stability of gantry arm and bearing under rotation	Annually	2 mm
(4) Couch motion and tabletop sag	Annually	2 mm

Subp. 3. **Constancy checks–electrons.**

	MINIMUM TEST INTERVAL	TOLERANCE
A. Beam uniformity	Monthly	5 percent
B. Depth dose	Monthly	2 mm at therapeutic depth
C. Dose per monitor unit constancy check	Weekly	3 percent

Subp. 4. **Treatment accessories.** *

	MINIMUM TEST INTERVAL	TOLERANCE
A. Wedge transmission factor	Annually	2 percent
B. Transmission factor constancy for all treatment accessories	Annually	2 percent

Subp. 5. **Simulators.**

	FREQUENCY	TOLERANCE
A. Localizing lasers	Daily	2 mm
B. Distance indicator	Daily	2 mm

C. Field size indicator	Monthly	2 mm
D. Gantry/collimator angle indicators	Monthly	1 degree
E. Cross–hair centering	Monthly	2 mm diameter
F. Focal spot–axis indicator	Monthly	2 mm
G. Fluoroscopic image quality	Monthly	Established baseline
H. Collision avoidance	Monthly	Functional
I. Light/radiation field coincidence	Monthly	2 mm or 1 percent
J. Collimator rotation isocenter	Annual	2 mm diameter
K. Gantry rotation isocenter	Annual	2 mm diameter
L. Couch rotation isocenter	Annual	2 mm diameter
M. Coincidence of collimator, gantry, couch axes, and isocenter	Annual	2 mm diameter
N. Table top sag	Annual	2 mm
O. Vertical travel of couch	Annual	2 mm
P. Exposure rate	Annual	Established baseline
Q. Table top exposure with fluoroscopy	Annual	Established baseline
R. Kvp and mAs calibration	Annual	Established baseline
S. High and low contrast resolution	Annual	Established baseline

Subp. 6. [Repealed, 23 SR 1760]

* Attenuation in blocks, wedge factors, and compensator data must be checked annually. A visual inspection of the mechanical integrity of these accessories must be done monthly.

Source: Derived from American Association of Physicists in Medicine, Report No. 13, Table II, page 29 (1984) and TG–40, Medical Physics, volume 21, number 4, Tables I, II, III, and IV, pages 581 to 618 (1994).

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1700 [Repealed, 16 SR 485]

X–RAY USES

4730.1750 GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIOGRAPHIC SYSTEMS.

Subpart 1. **Applicability.** All diagnostic radiographic systems must meet the requirements in this part.

Subp. 2. **Warning label.** The control panel containing the main power switch must bear the warning statement which is 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."

Subp. 3. **Battery charge indicator.** On battery–powered x–ray generators, visual means must be provided on the control panel to indicate whether the battery is adequately charged for proper operation.

Subp. 4. **Leakage radiation from the diagnostic source assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one meter (39.4 inches) in any direction from the source must not exceed 100 milliroentgens (25.8 uC/kg) in one hour when the x–ray tube is operated at its leakage technique factors. Compliance must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Subp. 5. **Radiation from components other than the diagnostic source assembly.** The radiation emitted by a component other than the diagnostic source assembly must not exceed two milliroentgens (0.516 uC/kg) in one hour at five centimeters (1.97 inches) 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 must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Subp. 6. **Beam quality, half–value layer.** The half–value layer of the useful beam for a given kVp must not be less than the values shown in item A. If it is necessary to determine a half–value layer at a kVp which is not listed in item A, linear interpolation or extrapolation may be made.

A. Values for half–value layer of useful beam for x–ray tube:

Design operating range (kVp)	Measured kVp	Half–value layer (millimeter of aluminum) Other x–ray Systems	Specified Dental Systems
Below 50	30	0.3	1.5
	40	0.4	1.5
	50	0.5	1.5
51–70	51	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
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

B. All intraoral dental radiographic systems installed on and after December 1, 1980, must have a minimum half–value layer not less than 1.5 millimeters aluminum.

C. For capacitor energy storage equipment, compliance with the requirements of this subpart must be determined with the capacitors fully charged and with a technique which discharges at least half of the energy stored in the capacitors (half of the maximum milliampere–second).

D. The half–value layer of the useful beam must be measured with all the materials in the beam which are always present between the source and the patient.

Subp. 7. **Beam quality, filtration controls.** For x–ray systems which have variable kVp and variable filtration for the useful beam, means must be provided to prevent an exposure unless the filtration required to obtain the half–value layer specified in subpart 6, item A, is in the useful beam for the given kVp which has been selected.

Subp. 8. **Multiple tubes.** Where two or more x–ray tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated before initi-

ation of the exposure. The indication must be both on the x–ray control panel and at or near the tube housing assembly which has been selected.

Subp. 9. **Mechanical support of tube head.** The tube housing assembly supports must be adjusted so it remains stable during an exposure unless tube housing movement is a designed function of the x–ray system.

Subp. 10. **Technique factors.** The technique factors in items A to C apply to all diagnostic radiographic systems.

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

B. If automatic exposure controls are used in a system installed after September 10, 1991, in addition to the requirements of item A:

(1) the exposure time or milliampere–second must be displayed for x–ray generators with a constant milliamperage; and

(2) the milliampere–second must be displayed for falling load generators.

C. The requirement of item A may be met by permanent markings on systems having fixed technique factors. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist.

Subp. 11. **Timers.** The requirements in this subpart for timers apply to all general radiographic, intraoral dental, and veterinary medicine radiographic systems.

A. A means must be provided to terminate the exposure at a preset time interval, a preset product of milliamperage and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

B. An exposure must not be possible when the timer is set to a zero or off position, if either position is provided.

C. Except for dental panoramic systems, termination of the exposure must cause automatic resetting of the timer to its initial setting or to zero.

Subp. 12. **Reproducibility.** With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) must be less than or equal to 20 percent of the average exposure time (T) when four timer tests are performed:

$(T_{max} - T_{min}) \leq 0.2\ T$.

Subp. 13. **X–ray control.** The x–ray control must meet the requirements in this subpart.

A. The exposure control switch must be a dead–man type which requires continuous pressure to complete the exposure.

B. Each x–ray control console other than dental intraoral systems must be located in such a way as to meet the requirements in this item.

(1) Stationary x–ray systems must have the x–ray control permanently mounted behind the protective barrier so the operator remains behind that barrier during the entire exposure.

(2) Portable x–ray systems that produce more than 25 milliamperes–minutes per week at the same location must meet the requirement of subitem (1).

(3) Portable x–ray systems that produce less than 25 milliamperes–minutes per week at the same location, must meet the requirement of subitem (1), or be provided with a 6.5 foot (2.0 m) high protective barrier which is placed at least six feet (1.8 m) from the tube housing assembly and at least six feet (1.8 m) from the patient.

C. The x–ray control console must provide visual indication observable at or from the operator's protected position whenever x–rays are produced.

D. All x–ray control console panel indicator lights must be operational.

Subp. 14. **Exposure reproducibility.** The coefficient of variation must not exceed 0.05 when all technique factors are held constant.

Subp. 15. **Additional requirements applicable only to certified x–ray components.** Only diagnostic radiographic systems incorporating one or more certified components must comply with the requirements in this subpart which relate to those certified components.

A. The radiographic system must be operated on an adequate power supply as specified by the manufacturer. The coefficient of variation of radiation exposures must be no greater than 0.05 for any specific combination of selected technique factors.

B. When the radiographic system allows a choice of x–ray milliamperage settings and is operated on a power supply as specified by the manufacturer according to the requirements of applicable federal performance standards for any fixed kVp within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the milliampere–seconds product obtained at any two consecutive milliamperage settings must not differ by more than 0.10 times their sum:

$$(\overline{X}_1 - \overline{X}_2) \leq 0.10\ (\overline{X}_1 + \overline{X}_2),$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs values obtained at each of two consecutive milliamperage settings.

C. Deviation of technique factors for kVp must be those the manufacturer has specified for that system. For other technique factors, the deviation must have a coefficient of variation of no more than five percent.

D. The x–ray control console must provide a signal audible to the operator that the exposure has terminated.

E. A certified diagnostic radiographic system and its associated certified components used on humans must be maintained in compliance with applicable requirements of the Federal X–ray Equipment Performance Standard, Code of Federal Regulations, title 21, chapter 1, subchapter J, in effect at the time of manufacture.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414; 23 SR 1760*

4730.1800 [Repealed, 16 SR 485]

4730.1850 DIAGNOSTIC RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, VETERINARY MEDICINE, OR COMPUTED TOMOGRAPHY SYSTEMS.

Subpart 1. **Applicability.** This part applies to all diagnostic x–ray systems certified according to standards provided by United States Code, title 42, section 263f, and to diagnostic x–ray systems installed before those standards were established. This part does not apply to fluoroscopic, dental intraoral, veterinary medicine, or computed tomography x–ray systems. The requirements in this part are in addition to the requirements in parts 4730.0100 to 4730.1750.

Subp. 2. **Beam limitation.** The useful beam must be limited to the patient's area of clinical interest.

Subp. 3. **General purpose stationary x–ray systems.** General purpose stationary x–ray systems must meet the standards in items A to E.

A. A means for stepless adjustment of the size of the x–ray field must be provided.

B. A method must 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 must not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x–ray beam.

C. Except when spot–film devices or special attachments for mammography are in service, a method must be provided to:

(1) indicate when the axis of the x–ray beam is perpendicular to the plane of the image receptor;

(2) align the center of the x–ray field with respect to the center of the image receptor to within two percent of the SID; and

(3) indicate the SID to within two percent.

D. The beam–limiting device must numerically indicate the field size at the plane of the image receptor to which it is adjusted.

E. The indication of field size dimensions and SIDs must be:

(1) specified in inches or centimeters; and

(2) such that aperture adjustments result in x–ray field dimensions at the plane of the image receptor which correspond to those indicated by the beam–limiting device to within two percent or less of the SID when the beam axis is perpendicular to the plane of the image receptor.

Subp. 4. **Diagnostic radiographic systems designed for one image receptor size.** Diagnostic radiographic systems designed for only one image receptor size at a fixed SID must 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 must align the center of the x–ray field with the center of the image receptor to within two percent of the SID. Alternatively, such systems must be provided with means to both size and align the x–ray field so the x–ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

Subp. 5. [Repealed, 23 SR 1760]

Subp. 6. **Other noncertified general purpose x–ray systems.** A facility with a noncertified general purpose x–ray system must comply with items A to C.

A. Means must be provided to limit the x–ray field in the plane of the image receptor so the field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x–ray beam is perpendicular to the plane of the image receptor.

B. Means must be provided to align the center of the x–ray field with the center of the image receptor to within two percent of the SID, or means must be provided to both size and align the x–ray field so the x–ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

C. The requirements of items A and B may be met with a system that meets the requirements for a general purpose x–ray system as specified in subpart 3. When alignment means are also provided, the requirements of items A and B may be met with either:

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

(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 system is designed. Permanent, clearly legible markings must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.

Subp. 7. **Radiation exposure, x–ray controls.** An x–ray control must be incorporated into each x–ray system so an exposure can be terminated by the operator at any time during exposures of greater than one–half second. During serial radiography means must be provided to permit completion of any single exposure of the series in process before terminating the series.

Subp. 8. **Radiation exposure, automatic exposure controls.** When an automatic exposure control is provided:

A. indication must be made on the control panel when this mode of operation is selected;

B. the minimum exposure time for all radiographic systems, other than that specified in item E, must be equal to or less than 1/60 second or a time interval required to deliver five milliampere–seconds, whichever is greater;

C. either the product of the kVp, milliamperage, and exposure time must be limited to not more than 60 kWs per exposure, or the product of x–ray milliamperage and exposure time must be limited to not more than 600 mAs per exposure;

D. a visible signal must indicate when an exposure has been terminated at the limits required by item C, and manual resetting must be required before further automatically timed exposures can be made; and

E. if the kVp is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation must be equal to or less than a time interval equivalent to two pulses.

Subp. 9. **Source–to–skin distance.** All portable x–ray systems must be provided with means to maintain a minimum source–to–skin distance equal to or greater than 30 centimeters (11.8 inches).

Subp. 10. **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 must not exceed a rate of two milliroentgens (0.5 uC/kg) per hour at five centimeters (1.97 inches) from any accessible surface of the diagnostic source assembly, with the beam–limiting device fully open.

Subp. 11. **Additional requirements for certified systems only.** The standards in items A to E are applicable to certified x–ray systems only.

A. Stationary and portable general purpose x–ray systems must have means to limit the useful beam.

(1) There must be provided a means of stepless adjustment of the size of the x–ray field. The minimum field size at a SID of 100 centimeters (39.4 inches) must be equal to or less than five by five centimeters (1.97 by 1.97 inches).

(2) When a light localizer is used to define the x–ray field, it must provide an average illumination of not less than 160 lux (15.0 foot candles) above ambient at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less. The average illumination must be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems installed on and after May 27, 1980, are exempt from this requirement.

(3) The edge of the light field at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam–limiting devices designed for use on stationary x–ray systems, and a contrast ratio of not less than three in the case of beam–limiting devices designed for use on portable x–ray systems. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three millimeters (0.12 inches) from the edge of the light field toward the center of the field; and I_2 is the illumination three millimeters (0.12 inches) from the edge of the light field away from the center of the field. Compliance must be determined with a measuring instrument aperture of one millimeter (0.04 inches) in diameter.

B. The useful beam limitation for portable x–ray systems must meet the beam limitation requirements of item A and subpart 3.

C. This item applies to those general purpose x–ray systems which contain a tube housing assembly, an x–ray control, and a table (if so equipped). The system must be certified according to Code of Federal Regulations, title 21, section 1020.30(c). The system must meet the standards in subitems (1) to (6).

(1) When positive beam limitation is provided, it must meet the criteria in units (a) to (f).

(a) The image receptor must be inserted into a permanently mounted cassette holder.

(b) The image receptor length and width must each be less than 50 centimeters (19.7 inches).

(c) The x–ray beam axis must be within plus or minus three degrees of vertical and the SID must be 90 centimeters to 130 centimeters (35.4 inches to 51.2 inches) inclusive; or the x–ray beam axis must be within plus or minus three degrees of horizontal and the SID must be 90 centimeters to 205 centimeters (35.4 inches to 80.7 inches) inclusive.

(d) The x–ray beam axis must be perpendicular to the plane of the image receptor to within plus or minus three degrees.

(e) Neither tomographic nor stereoscopic radiography is being performed.

(f) The positive beam limitation system must not be intentionally overridden. This override provision is subject to the provisions of item C, subitem (3).

(2) Positive beam limitation must prevent the production of x–rays when:

(a) the length or width of the x–ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three percent of the SID except as permitted by subitem (4); or

(b) the sum of the length and width differences as stated in unit (a) without regard to sign exceeds four percent of the SID.

(3) If a method of overriding the positive beam limitation system exists, that method must be designed for use only in the event of positive beam limitation system failure or if the system is being serviced. If the positive beam limitation system is in a position that the operator considers part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator:

(a) a key must be used to override the positive beam limitation;

(b) the key must remain in place during the entire time the positive beam limitation system is overridden; and

(c) that the key or key switch must be clearly and durably labeled as follows: "FOR X–RAY FIELD LIMITATION SYSTEM FAILURE."

(4) Compliance with item C, subitem (2), must be determined when the equipment indicates the beam axis is perpendicular to the plane of the image receptor and the provisions of item C, subitem (1), are met. Compliance must be determined no sooner than five seconds after insertion of the image receptor.

(5) The positive beam limitation system must be capable of operation, at the discretion of the operator, so that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters (39.4 inches) must be equal to or less than five centimeters by five centimeters (1.97 inches by 1.97 inches).

(6) The positive beam limitation system must be designed so that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in item C, subitem (2), then any change of image receptor size of SID must cause the automatic return.

D. For x–ray systems installed after September 5, 1978, designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system must be limited so the exposure five centimeters (1.97 inches) from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure must be measured with the system operated at the minimum SID for which it is designed. Compliance must be determined at the maximum kVp for the system and at the maximum rated product of milliamperage and exposure time (milliampere–seconds) for that kVp. Compliance must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

E. If the facility chooses, automatic or semiautomatic collimators (PBL) may be permanently changed to a manual mode. This requires the automatic system to be permanently disabled. The collimator must be relabeled with a durable material "manual operation required" so that it is clearly observable to the operator.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.1900 [Repealed, 16 SR 485]

4730.1950 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.

Subpart 1. **Applicability.** This part applies to x–ray systems used for intraoral dental radiography. Requirements for extraoral dental radiographic systems are covered in part 4730.1850. This part applies in addition to the requirements in parts 4730.0100 to 4730.1750.

Subp. 2. **Source–to–skin distance.** X–ray systems designed for use with an intraoral image receptor must be provided with a position–indicating–device to limit source–to–skin distance to not less than 18 centimeters (7.1 inches).

Subp. 3. **Field limitation.** Radiographic systems designed for use with an intraoral image receptor must be provided with and used with collimation to limit the x–ray field such that:

A. if the minimum source–to–skin distance is 18 centimeters (7.1 inches) or more, the x–ray field, at the minimum, must be containable in a circle having a diameter of no more than seven centimeters (2.76 inches); or

B. with rectangular position–indicating–devices, the longer side must not exceed 5.1 centimeters (two inches); and

C. the x–ray system must be operated so the useful beam at the patient's skin does not exceed the requirements of this subpart.

Subp. 4. **Safety controls.** The registrant must ensure that the safety controls in this subpart are followed.

A. Intraoral film holders and bite blocks must be used except when endodontic procedures do not permit. Film must not be routinely held by hand.

B. The tube housing and the position–indicating–device must not be hand–held during an exposure and must be stable before the exposure is initiated and during the exposure.

C. The exposure at the end of the cone for a bitewing technique must not exceed the values listed in Table 4730.1950:

TABLE 4730.1950

kVp	"D" Speed Film ESE (milliroentgens)	"E" Speed Film ESE (milliroentgens)	"D/E or E+" Speed Film ESE (milliroentgens)
50	425 – 575	220 – 320	220 – 320
55	350 – 500	190 – 270	190 – 270
60	310 – 440	165 – 230	165 – 230
65	270 – 400	140 – 200	140 – 200
70	240 – 350	120 – 170	120 – 170
75	170 – 260	100 – 140	100 – 140
80	150 – 230	90 – 120	90 – 120
85	130 – 200	80 – 105	80 – 105
90	120 – 180	70 – 90	70 – 90
95	110 – 160	60 – 80	60 – 80
100	100 – 140	50 – 70	50 – 70

Notes:

(1) Exposures are specified as free–in–air exposures without backscatter.

(2) The indicated kVp is often significantly different from the actual kVp. The kVp must be tested at the time the output per film is measured to determine the correct exposure range to be applied.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414; 23 SR 1760*

4730.2000 [Repealed, 16 SR 485]

4730.2050 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS.

Subpart 1. **Applicability.** This part applies to x–ray systems used for diagnostic veterinary medicine radiography and applies in addition to the requirements in parts 4730.0100 to 4730.1750.

A. Requirements for fluoroscopic veterinary medicine systems are covered in part 4730.2150.

B. Requirements for therapeutic veterinary medicine shall be the same as those in parts 4730.2350, 4730.2450, and 4730.2475.

C. Requirements for dental intraoral veterinary medicine shall be the same as those in part 4730.1950.

Subp. 2. **Beam limitation.** Collimators must be provided to restrict the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the tube housing.

A. If a variable-aperture beam limiting collimator is used, the projected light and x-ray field must not exceed the smallest dimension of the x-ray film cassette by greater than two percent of the distance of the x-ray tube to the film (SID) in any direction.

B. A method must be provided to:

(1) indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(2) align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID; and

(3) indicate the SID to within two percent.

C. If a fixed dimension beam limiting collimator is used, it must meet the additional requirements in this item.

(1) The collimator must be labeled to indicate the field size and the SID for which it is designed.

(2) The collimator must be used only for the field size and the SID for which it is designed.

(3) The x-ray field must not exceed the x-ray film cassette by greater than two percent of the distance of the x-ray tube to the film SID in the x-ray film cassette's smallest dimension.

(4) The requirements in part 4730.1850, subpart 3, items D and E.

D. In the case of horizontal beam x-rays, a mechanical cassette holding device must be used to ensure that no part of the body of the individual steadying the cassette is exposed to primary beam x-rays.

E. If necessary, and any involved individual is properly attired in protective apron and gloves of at least 0.5 mm lead equivalency, this does not preclude the operation of the radiographic system by one of the individuals holding the animal patient using a foot switch.

Subp. 3. **Operating procedures.** The registrant must ensure that the operating procedures in this subpart are applied.

A. The operator must not stand in the path of the useful beam during radiographic exposures.

B. No individual other than the operator must be in the radiographic room while exposures are being made unless the individual's assistance is required.

C. When an animal must be held in position by an individual during radiography, that individual must wear protective gloves and apron of at least 0.5 mm lead equivalency, and the individual must be positioned so no part of the body, protected or unprotected, will be struck by the useful beam.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414*

4730.2100 [Repealed, 16 SR 485]

4730.2150 FLUOROSCOPIC X-RAY SYSTEMS EXCEPT RADIATION THERAPY SIMULATORS.

Subpart 1. **Applicability.** This part applies to all fluoroscopic x-ray systems in addition to the requirements in parts 4730.0100 to 4730.1750.

Subp. 2. **Limitation of useful beam, primary barrier.** For all fluoroscopes, the requirements in items A and B must be met.

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

B. The x–ray tube used for fluoroscopy must not produce x–rays unless the barrier is in position to intercept the entire useful beam.

Subp. 3. **Limitation of useful beam, x–ray field.** All fluoroscopes must be provided with image intensification equipment to view the fluoroscopic images.

A. For image–intensified fluoroscopic equipment, neither the length nor the width of the x–ray field in the plane of the image intensifier may exceed that of the visible area of the image intensifier by more than three percent of the SID during fluoroscopy or digital imaging. The sum of the excess length and the excess width must be no greater than four percent of the SID. In addition, means must be provided to permit further limitations of the field:

(1) Beam–limiting devices installed after May 22, 1979, and incorporated in equipment with either a variable SID or a visible area of greater than 300 square centimeters (46.5 square inches), must be provided with means for the stepless adjustment of the x–ray field.

(2) All equipment with a fixed SID and a visible area of 300 square centimeters (46.5 square inches) or less must 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 (19.4 square inches) or less. Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five by five centimeters (1.97 by 1.97 inches) or less.

(3) For fluoroscopic x–ray systems manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x–ray beam is perpendicular to the plane of the image receptor.

(4) Compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x–ray fields used with circular image reception, the error in alignment must be determined along the length and width dimensions of the x–ray field which pass through the center of the visible area of the image receptor.

B. Spot–film devices which are certified components must meet the additional requirements in subitems (1) to (4):

(1) Means must 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 must 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 installed 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 must be only at the operator's option.

(2) It must 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 must be equal to, or less than, five by five centimeters (1.97 by 1.97 inches).

(3) The center of the x–ray field in the plane of the film must be aligned with the center of the selected portion of the film to within two percent of the SID.

(4) On spot–film devices installed after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x–ray beam is perpendicular to the plane of the image receptor. Compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

C. If a means exists to override any of the automatic x–ray field size adjustments required in this subpart, that means must:

(1) be designed for use only in the event of system failure;

(2) incorporate a signal visible at the fluoroscopist's position which indicates whenever the automatic field size adjustment is overridden; and

(3) be clearly and durably labeled as follows: "FOR X–RAY FIELD LIMITATION SYSTEM FAILURE."

Subp. 4. **Activation of the fluoroscopic tube.** X–ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the fluoroscopist

for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the x–ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

Subp. 4a. **Entrance exposure rate allowable limits on fluoroscopic systems manufactured before May 19, 1995.** The registrant must ensure that the entrance exposure rate allowable limits in this subpart are met.

A. 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 results in an exposure rate in excess of ten roentgens per minute (10 R/min) or 2.58 x 10^{-3} coulomb per kilogram (C/kg) per minute at the point where the center of the useful beam enters the patient, except:

(1) during recording of fluoroscopic images when using photographic film; or

(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 results in an exposure rate in excess of 5 R/min (1.29 x 10^{-3} C/kg per minute) 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 is required. The high–level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high–level control is being employed.

B. 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 results in an exposure rate in excess of 5 R/min (1.29 x 10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient, except:

(1) during the recording of fluoroscopic images; or

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

C. 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 results in an exposure rate in excess of 10 R/minute (2.58 x 10^{-3} C/kg per minute) in either mode at the point where the center of the useful beam enters the patient, except:

(1) during the recording of fluoroscopic images when using photographic film; or

(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 results in an exposure rate in excess of 5 R/minute (1.29 x 10^{-3} C/kg per minute) 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 is required. The high–level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high–level is being employed.

D. Compliance with this subpart shall be determined as follows:

(1) movable grids and compression devices shall be removed from the useful beam during the measurement;

(2) if the source is below the x–ray table, the exposure rate shall be measured at one centimeter above the tabletop or cradle;

(3) if the source is above the x–ray 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;

(4) in a C–arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam–limiting device or spacer

is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly; and

(5) in a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the x–ray table and in the direction of the x–ray source with the end of the beam–limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x–ray source, with the end of the beam–limiting device or spacer no closer than 15 centimeters to the center line of the x–ray table.

Subp. 5. **Entrance exposure rate allowable limits on fluoroscopic systems manufactured after May 19, 1995.** The registrant must ensure that the entrance exposure rate allowable limits in this subpart are met.

A. Fluoroscopic equipment operable at any combination of tube potential and current that results in an exposure rate greater than 5 R/minute (1.29×10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control (AERC). Provision for manual selection of technique factors may be provided.

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

(1) during the recording of images from an x–ray image–intensifier tube using photographic film; or

(2) when an optional high–level control is activated. When the high–level control is activated, the equipment shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 20 R/minute (5.16×10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient. Special means of activation of high–level control is required. The high–level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high–level control is being employed.

C. Compliance with item B, subitem (2), shall be determined as follows:

(1) movable grids and compression devices shall be removed from the useful beam during the measurement;

(2) if the source is below the x–ray table, the exposure rate shall be measured at one centimeter above the tabletop or cradle;

(3) if the source is above the x–ray 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;

(4) in a C–arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam–limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly; and

(5) in a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the x–ray table and in the direction of the x–ray source with the end of the beam–limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x–ray source, with the end of the beam–limiting device or spacer no closer than 15 centimeters to the center line of the x–ray table. Variable SID units shall not exceed 10 R/minute at any SID.

D. During fluoroscopy and cinefluorography, x–ray tube potential and current must be continuously indicated. Deviation of x–ray tube potential and current from the indicated values must not exceed the maximum deviation as stated by the manufacturer according to Code of Federal Regulations, title 21, section 1020.30, paragraph (h), item (3).

E. Periodic measurement of the maximum exposure rate must be performed in the manual mode, automatic exposure rate control, and high–level control mode, if applicable.

(1) The measurements must be made annually and after any maintenance of the system which might affect the exposure rate.

(2) The results of these measurements must be in the record required in part 4730.1520, subpart 1, item D. The measurement results must be stated in Roentgens per minute or mC/kg per minute and must include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed must be included in the results.

(3) Materials must be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

(4) The periodic measurement of the maximum entrance exposure rate must be made under the conditions that satisfy the requirements of item D. For x–ray systems that do not incorporate an automatic exposure rate control, the kilovoltage and milliamperage must be manually adjusted to produce the maximum entrance exposure rate.

Subp. 6. **Barrier transmitted radiation rate limits.** 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, must not exceed 3.34×10^{-3} percent of the entrance exposure rate at ten centimeters (3.9 inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute (0.25 mC/kg) of entrance exposure rate.

Subp. 7. **Measuring compliance of barrier transmission.** Compliance with subpart 6 shall be determined according to this subpart.

A. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

B. If the source is below the tabletop or cradle, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (11.8 inches) above the tabletop or cradle.

C. If the source is above the tabletop or cradle and the SID is variable, the measurement must 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 must not be closer than 30 centimeters (11.8 inches).

D. The attenuation block must be positioned in the useful beam ten centimeters (3.9 inches) from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Subp. 8. **Indication of kilovoltage and milliamperage.** For fluoroscopic x–ray systems manufactured and installed after February 25, 1978, during fluoroscopy and cinefluorography, the kilovoltage and the milliamperage must be continuously indicated.

Subp. 9. **Source–to–skin distance.** The source–to–skin distance must not be less than:

A. 38 centimeters (15 inches) on stationary fluoroscopes;

B. 35.5 centimeters (14 inches) on stationary fluoroscopes manufactured prior to August 1, 1974;

C. 30 centimeters (11.8 inches) on all portable fluoroscopes; and

D. 20 centimeters (7.9 inches) for image intensified fluoroscopes used for specific surgical applications. The written safety procedures must provide precautionary measures to be adhered to when image intensified fluoroscopes are used for specific surgical applications.

The 20 centimeter (7.9 inch) spacer cone must be replaced with the 30 centimeter (11.8 inch) spacer cone immediately after the end of the fluoroscopic surgical procedure.

Subp. 10. **Fluoroscopic timer.** Means must be provided to preset the cumulative on–time of the fluoroscopic x–ray tube. The maximum cumulative time of the timing device must not exceed five minutes without resetting. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative on–time. The signal must continue to sound while x–rays are produced, until the timing device is reset.

Subp. 11. **Control of scattered radiation.** The procedures in this subpart must be used to control scattered radiation from all fluoroscopes.

A. When a fluoroscopic table with an undertable x–ray tube is used, the bucky opening must be shielded to attenuate the scattered radiation by at least 70 percent. Lead

drapes must be attached to the intensifier tower to attenuate scattered radiation by at least 70 percent.

B. For other undertable configurations, provisions must be made through equipment design or radiation protection measures to ensure that individuals do not receive a dose in excess of the allowable dose limits listed in part 4730.0310.

(1) Any individual who must be in the room during a fluoroscopic procedure must wear a protective apron of not less than 0.5 millimeter lead equivalence.

(2) All fluoroscopic x–ray equipment must be provided with a bucky–slot cover panel, if applicable, and either lead drapes attached to the intensifying tower or self–supporting shields of not less than 0.5 millimeter lead equivalent material.

C. For single–tube above table combination radiographic and fluoroscopic x–ray systems used in the fluoroscopic mode, protective aprons of not less than 0.5 millimeter lead equivalence must be used to ensure that any individual who must be in the room during a fluoroscopic procedure does not receive a dose greater than the allowable dose limits listed in part 4730.0310. In addition, portable lead shields, barriers, or aprons of not less than 0.5 millimeter lead equivalence must be used.

D. For portable C–arm fluoroscopes, provision must be made through the use of protective aprons of not less than 0.5 millimeter lead equivalence to ensure that any individual other than the patient who may be exposed during a fluoroscopic procedure does not receive a dose in excess of the allowable dose limits listed in part 4730.0310.

Subp. 12. **Radiation therapy simulation systems.** A radiation therapy simulation system is exempt from the requirements of subpart 5, provided:

A. the system is designed and used so no individual other than the patient is in the simulation room when the system is producing x–rays; and

B. a system which does not meet the requirements of subpart 10 has a means to indicate the cumulative time that an individual patient has been exposed to x–rays. Procedures must require in such cases that the timer be reset between examinations.

Statutory Authority: *MS s 144.05; 144.12; 144.121; L 1992 c 444 s 1*

History: *16 SR 485; 17 SR 3414; 23 SR 1760*

4730.2200 [Repealed, 16 SR 485]

4730.2250 COMPUTED TOMOGRAPHY SYSTEMS.

Subpart 1. **Applicability.** This part applies to all computed tomography systems in addition to the requirements in parts 4730.0100 to 4730.1750.

Subp. 2. **Termination of exposure.** A visible signal must indicate when the x–ray exposure has been terminated. The operator must 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.

Subp. 3. **Tomographic plane indication and alignment.** The provisions in items A to C apply.

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

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

C. If a device using a light source is used to satisfy either item A or B, the light source must provide illumination levels of not less than 160 lux (15.0 foot candles) above the room ambient illumination level.

Subp. 4. **Beam–on and shutter status indicators.** The x–ray control and gantry must visually indicate whenever x–rays are produced and, if applicable, whether the shutter is open or closed. All emergency buttons or switches must be clearly labeled as to their functions.

Subp. 5. **Indication of computed tomography conditions of operation.** The computed tomography x–ray system must be designed so the computed tomography conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of the 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 computed tomography conditions of operation must be visible from any position from which scan initiation is possible.

Subp. 6. **Extraneous radiation.** When data is not being collected for image production, the radiation adjacent to the tube port must not exceed the leakage radiation from the diagnostic source assembly that is measured at a distance of one meter (39.4 inches) in any direction from the source. That leakage must not exceed 100 milliroentgens (26 uC/kg) in one hour when the x–ray tube is operated at its leakage technique factors. Compliance must be determined by a measurement averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Subp. 7. **Maximum surface computed tomography dose index identification.** The angular position where the maximum surface computed tomography dose index occurs must be identified to allow for reproducible placement of a computed tomography dosimetry chamber.

Subp. 8. **Additional requirements.** Items A to D are applicable to computed tomography x–ray systems containing a gantry manufactured after September 3, 1985.

A. The total error in the indicated location of the tomographic plane or reference plane must not exceed five millimeters (0.2 inches).

B. If the x–ray production period is less than one–half second, the indication of x–ray production must be actuated for at least one–half second. Indicators at or near the patient side of the gantry must be discernible to the operator.

C. The deviation of indicated scan increment versus actual increment must not exceed plus or minus one millimeter (0.04 inches) with a mass of 100 kilograms (220 pounds) resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or 30 centimeters (11.8 inches), whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this incremented distance.

D. Premature termination of the x–ray exposure by the operator must necessitate resetting of the computed tomography conditions of operation before the initiation of another scan.

Subp. 9. **Audio communication.** Within the computed tomography area, provision must be made for two–way audio communication between the patient and operator at the control panel.

Subp. 10. **Patient observation.** Within the computed tomography area, provision must be made for a shielded window containing the same lead equivalence as the adjoining walls so the operator at the control panel may directly observe the patient, any other individual in the room, and any doorways into the room. A closed circuit television system may be used as a secondary means of observing the patient.

Subp. 11. **Location of control panel and x–ray control.** The control panel and x–ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

Subp. 12. **Operating procedure information.** Information about the operation, radiation safety surveys, and equipment performance measurements of the system must be available at the control console. This information must contain:

A. the dates of the last radiation safety survey and equipment performance measurements;

B. written results of the most recent radiation safety survey and equipment performance measurements including:

(1) those specified in part 4730.1665, subparts 2 and 3;

(2) photographic images obtained from the photographic image recording device; and

(3) images stored in digital form.

C. instructions on the use of the computed tomography phantoms, including a schedule of equipment performance checks appropriate for the system, allowable variations for the indicated measurements, and the results of the last two years' equipment performance measurements in addition to the original equipment performance and acceptance test measurements, images, and digital data; and

D. the distance in millimeters between the tomographic plane and the reference plane if a reference plane is used.

Subp. 13. **Corrective action.** If the equipment performance measurements required by part 4730.1665, subparts 2 and 3, of the computed tomography systems identify that a measurement has exceeded a tolerance specified in part 4730.1691, the registrant must correct the measurement to within the tolerances specified in part 4730.1691. Correction of the problem must take place within five working days and must be verified by performing the equipment performance measurements specified in part 4730.1665, subparts 2 and 3.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.2300 [Repealed, 16 SR 485]

4730.2350 THERAPEUTIC X-RAY SYSTEMS OF LESS THAN 1.0 MV.

Subpart 1. **Applicability.** In addition to the requirements in parts 4730.0100 to 4730.1695, this part applies to all therapeutic x-ray systems of less than 1.0 MV.

Subp. 2. **Leakage radiation.** When the tube is operated at its leakage technique factors, the instantaneous exposure rate leakage radiation must not exceed the value specified at the distance specified in this subpart for the classification of that x-ray system.

A. Leakage radiation for contact therapeutic x-ray systems must not exceed 100 milliroentgens (25.8 uC/kg) per hour at five centimeters (1.97 inches) from the surface of the tube housing assembly.

B. Zero to 150 kVp systems installed prior to September 10, 1991, must have a leakage radiation which does not exceed 1.0 roentgen (0.258 mC/kg) in one hour at one meter (39.4 inches) from the source.

C. Zero to 150 kVp systems installed on or after September 10, 1991, must have a leakage radiation which does not exceed 100 milliroentgens (25.8 uC/kg) in one hour at one meter (39.4 inches) from the source.

D. 151 to 999 kVp systems must have leakage radiation which does not exceed one roentgen (0.258 mC/kg) in one hour at one meter (39.4 inches) from the source. However, systems that operate in excess of 500 kVp may have a leakage radiation rate at one meter (39.4 inches) from the source not to exceed 0.1 percent of the useful beam one meter (39.4 inches) from the source.

Subp. 3. **Leakage from permanent beam limiting devices.** Permanent fixed diaphragms or cones used for limiting the useful beam must provide the same or a higher degree of protection as required for the tube housing assembly in subpart 2.

Subp. 4. **Removable beam limiting devices.** Removable beam limiting devices must, for the portion of the useful beam to be blocked by these devices, transmit not more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

Subp. 5. **Adjustable beam limiting devices.** Adjustable beam limiting devices installed after September 10, 1991, must meet the requirements of subpart 4. Adjustable beam limiting devices installed before September 10, 1991, must, for the portion of the x-ray beam to be blocked by these devices, not transmit more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

Subp. 6. **Filter system.** The filter system must be designed so:

A. the filters cannot be accidentally displaced at any possible tube orientation;

B. the radiation at five centimeters (1.97 inches) from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating condition; and

C. each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

Subp. 7. **Tube immobilization.** The tube housing assembly must be capable of being immobilized for stationary treatments.

Subp. 8. **Focal spot marking.** The tube housing assembly must be marked so it is possible to determine the location of the focal spot to within five millimeters (0.2 inches), and such marking must be readily accessible for use during calibration procedures.

Subp. 9. **Beam block.** If the x–ray tube of a contact therapeutic x–ray system is hand–held during irradiation, the operator must wear protective gloves and apron. When practical, a cap of at least 0.5 millimeters lead equivalence must cover the aperture window of the tube housing of such apparatus when the apparatus is not being used.

Subp. 10. **Timer.** A timer which has a display must be provided at the treatment control panel. The timer must:

A. have a preset time selector and an elapsed time indicator;

B. be a cumulative timer which activates with the production of radiation and retains its reading after the irradiation is interrupted or terminated;

C. terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;

D. permit accurate presetting and determination of exposure times within an accuracy of one second;

E. not permit an exposure if set at zero; and

F. not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

Subp. 11. **Control panel functions.** The control panel must have:

A. an indication of whether electrical power is available at the control panel and if activation of the x–ray tube is possible;

B. an indication of whether x–rays are being produced;

C. meters that indicate kVp and mA;

D. means for terminating an exposure at any time;

E. a locking device which will prevent unauthorized use of the x–ray system; and

F. for x–ray systems installed after September 10, 1991, a positive display of all specific filters in the beam.

Subp. 12. **Multiple tubes.** A control panel may energize more than one x–ray tube if the x–ray tubes are located in the same room. In this situation, the following must apply:

A. it must be possible to activate only one x–ray tube at any time;

B. there must be an indication at the control panel identifying which x–ray tube is energized; and

C. there must be an indication at the tube housing assembly when that tube is energized.

Subp. 13. **Source–to–skin distance.** There must be means of determining the source–to–skin distance to within two millimeters (0.08 inches).

Subp. 14. **Shutters.** Unless it is possible to bring the x–ray output to the prescribed exposure parameters within five seconds, the beam must be automatically attenuated by a shutter having a lead equivalence of not less than that of the tube housing assembly. In addition:

A. after the system is at operating parameters, the shutter must be controlled electrically by the operator from the control panel; and

B. an indication of the shutter position must appear at the control panel.

Subp. 15. **Low–filtration x–ray tubes.** Each x–ray system equipped with a beryllium or other low–filtration window must be clearly labeled as "beryllium window" or "low–filtration window" on the tube housing assembly and at the control panel.

Subp. 16. **Entrance interlocks.** For therapeutic x–ray systems capable of operation above 150 kVp, interlocks or safety devices must be provided so all access to the radiation therapy rooms are blocked before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening or tripping of a safety device, it must not be possible to restore the system to operation without reactivating the safety device and reinitiating irradiation by manual action at the control panel. When any entrance door is opened while the x–ray tube is activated, the exposure at a distance of one meter (39.4 inches) from the source must be reduced to less than 100 milliroentgens (0.001 sieverts or one millisievert) per hour.

Subp. 17. **Operating procedures.** The tube housing assembly of contact therapeutic equipment must not be held by hand during operation unless the system is designed to require such holding and the kVp of the system does not exceed 50 kVp. In such cases, the holder must wear protective gloves and apron of not less than 0.5 millimeter lead equivalence at 100 kVp.

Subp. 18. **Additional requirements.** The x–ray system must not be used in the administration of radiation therapy unless the requirements of parts 4730.1675, subpart 2, and 4730.1680, subpart 1, items C and D, have been met.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.2400 [Repealed, 16 SR 485]

4730.2450 X–RAY AND ELECTRON THERAPY SYSTEMS WITH ENERGIES OF 1.0 MV/1.0 MEV AND ABOVE.

Subpart 1. **Applicability.** In addition to the requirements in parts 4730.0100 to 4730.1695, the requirements in this part shall apply to the use of therapeutic x–ray systems with energies of 1.0 MV and above.

Subp. 2. **System requirements; leakage radiation to the patient area.** All x–ray and electron therapy systems or any part of a system must meet the requirements in this subpart.

A. Systems or any part of a system installed after September 10, 1991, must meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (cGy) due to any leakage radiation component, including x–rays, electrons, and neutrons, at any point in a circular plane of two meters (78.7 inches) radius centered on or perpendicular to the central axis of the beam at the isocenter (patient plane), or nominal treatment distance and outside the maximum useful beam size must not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane surface.

Measurements, excluding those for neutrons, must be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the positions specified in this item. Measurements of the portion of the leakage radiation dose contributed by neutrons must be averaged over an area up to but not exceeding 200 square centimeters (31 square inches).

(2) For each system, the registrant must determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subitem (1) for the operating conditions specified in that subitem.

B. Systems installed before September 10, 1991, must meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (cGy) due to leakage radiation, excluding neutrons, at any point in a circular plane of a two meter (78.7 inch) radius centered on a plane perpendicular to the central axis of the beam two meters (78.7 inches) from the virtual source, and outside the maximum size useful beam, must not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements must be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the positions specified in this item.

(2) For each system, the registrant must determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subitem (1) for the operating conditions specified in that subitem.

Subp. 3. **Leakage of radiation outside the patient area for systems or any part thereof installed after September 10, 1991.** For systems or any part of a system installed after September 10, 1991, the system must meet the requirements in this subpart.

A. The absorbed dose in rads (cGy) due to leakage radiation, except in the area specified in subpart 2, item A, subitem (1), when measured at any point one meter (39.4 inches) from the path of the charged particle, before the charged particle strikes the target or window, must not exceed 0.1 percent of the maximum absorbed dose in rads (cGy) of the neutrons and must not exceed 0.1 percent of the maximum absorbed dose in rads (cGy) of the photons of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in subpart 2, item A, subitem (1).

B. The registrant must determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in item A for specified operating conditions. Radiation measurements, excluding neutrons, must be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches). Neutron measurements must be averaged over an area up to but not exceeding 200 square centimeters (31 square inches).

Subp. 4. **Beam limiting devices.** Adjustable or interchangeable beam limiting devices must be provided, and the devices must transmit no more than five percent of the useful beam at the nominal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient. The neutron component of the useful beam must be excluded from the calculation of the five percent limitation.

Subp. 5. **Filters.** All x–ray and electron therapy systems must have filters that meet the requirements in this subpart.

A. All compensating removable filters must be clearly identified. Documentation available at the control panel must contain a description of the filter. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

B. If the absorbed dose rate data required by subpart 17 relates exclusively to operation with a field flattening or beam scattering filter in place, the filter must be removable only with the use of tools.

C. For systems or any part of a system installed after September 10, 1991, which uses a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(1) irradiation must not be possible until a selection of a filter has been made at the treatment control panel;

(2) an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;

(3) a display must be provided at the treatment control panel showing the filters in use; and

(4) an interlock must be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

Subp. 6. **Electron beam quality.** The registrant must determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, when electrons and photons are being generated.

Subp. 7. **Radiation monitors.** All therapeutic x–ray systems must be provided with radiation monitors in the radiation head.

A. Systems or any part of a system installed after September 10, 1991, must measure all therapeutic radiation beams with at least two radiation monitors. The radiation monitors must be incorporated into two separate dose monitoring systems.

B. Systems installed prior to September 10, 1991, must be provided with at least one radiation monitor. This radiation monitor must be incorporated into a primary dose monitoring system.

C. The radiation monitor and the dose monitoring system into which that radiation monitor is incorporated must meet the following requirements:

(1) Each radiation monitor must be removable only with tools and must be interlocked to prevent incorrect positioning.

(2) Each radiation monitor must form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(3) Each dose monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation.

(4) For dose monitoring systems installed after September 10, 1991, the design of the dose monitoring system must assure that:

(a) the malfunctioning of one dose monitoring system does not affect the correct functioning of the second dose monitoring system; and

(b) the failure of any element common to both dose monitoring systems which could affect the correct function of both dose monitoring systems terminates irradiation.

(5) Each dose monitoring system must have a legible display at the treatment control panel. For dose monitoring systems installed after September 10, 1991, each display must:

(a) maintain a reading until intentionally reset to zero;

(b) have only one scale and no scale multiplying factors;

(c) use a design so that any increased dose is displayed by increasing numbers and must be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

(d) display the dose monitoring information required by this subitem at the control panel and be retrievable in at least one dose monitoring system for a five–minute period of time in the event of a power failure.

(6) The internal dose monitoring system must be capable of delivering a dose that varies by less than two percent over a 12–hour period.

Subp. 8. **Beam symmetry.** For any system installed after September 10, 1991, that has the capacity to produce useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions must be monitored before the beam passes through the beam limiting device. The asymmetry must be measured for a 30 square centimeter (4.65 square inch) field at a depth of ten centimeters (3.9 inches) at the points that correspond to 80 percent of the full width half maximum (FWHM) of central axis value.

Capabilities must be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam in the same plane exceeds five percent of the central axis dose rate, indication of the dose rate difference is made at the control panel; and if the dose rate difference exceeds five percent, the irradiation is terminated.

Subp. 9. **Selection and display of dose monitor units.** All x–ray and electron therapy systems must provide for the selection and display of dose monitor units according to this subpart.

A. Irradiation must not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

B. The preselected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation.

C. On systems installed after September 10, 1991, following an irradiation terminated by the dose monitoring system, it must be necessary to manually reset the preselected dose monitor units after irradiation is terminated and before irradiation can be reinitiated.

Subp. 10. **Termination of irradiation by the dose monitoring system or systems during stationary beam therapy.** All x–ray and electron therapy systems must meet the re-

quirements in this subpart regarding termination of irradiation by dose monitoring systems during stationary beam therapy.

A. Each primary system must terminate irradiation when the preselected number of dose monitor units has been detected by the system.

B. If original design of the system included a second dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the treatment control panel has been detected by the second dose monitoring system.

C. Systems installed after September 10, 1991, must have a second dose monitoring system which terminates irradiation when not more than ten percent or 25 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the treatment control panel has been detected by the second dose monitoring system.

D. Systems installed after September 10, 1991, must have an indicator on the control panel that shows which dose monitoring system has terminated irradiation.

Subp. 11. **Interruption switches.** All x–ray and electron therapy systems must have switches that allow the interruption of irradiation and meet the requirements in this subpart.

A. It must be possible to interrupt irradiation and equipment movement at any time from the operator's position at the treatment control panel.

B. Emergency off switches must be placed on or near the treatment console. Inside the treatment room, emergency off switches must be placed on or near both sides of the treatment couch, and on or near both sides of the gantry stand.

Subp. 12. **Termination switches.** All x–ray and electron therapy systems must have termination switches that make it possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

Subp. 13. **Timer.** All x–ray and electron therapy systems must have a timer that meets the requirements in this subpart.

A. A timer which has a visual display must be provided at the treatment control panel. The timer must have a preset time selector and an elapsed time indicator.

B. The timer must be a cumulative timer which activates with the production of radiation and returns its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator to zero.

C. For systems installed after September 10, 1991, after termination of irradiation and before irradiation can be reinitiated, it must be necessary to manually reset the preset time selector.

D. The timer must terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

E. For systems installed after September 10, 1991, if the backup timer is automatically set by control circuitry, the additional time must not be more than ten percent above the time determined by dividing the number of monitor units (MU) by the monitor unit irradiation rate.

Subp. 14. **Selection of radiation type.** Therapy systems capable of emitting both x–rays and electrons must allow for the selection of the radiation type according to the requirements in this subpart.

A. Irradiation must not be possible until a selection of radiation type has been made at the treatment control panel.

B. An interlock system must be provided to ensure that the equipment can emit only the radiation type which has been selected.

C. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

D. An interlock system must be provided to prevent irradiation with x–rays except to obtain a port film when electron applicators are fitted.

E. An interlock system must be provided to ensure electron beam irradiations do not take place with inappropriate beam modifiers such as wedges in the beam.

F. The radiation type selected must be displayed at the treatment control panel before and during irradiation.

Subp. 15. **Selection of energy.** Systems capable of generating radiation beams of different energies must allow for the selection of the energy value according to the requirements in this subpart.

A. Irradiation must not be possible until a selection of energy has been made at the treatment control panel.

B. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

C. The nominal energy value and photon or electron modality selected must be displayed at the treatment control panel before and during irradiation.

Subp. 16. **Selection of stationary beam therapy or rotational beam therapy.** Systems capable of both stationary beam therapy and rotational beam therapy must allow for the selection of stationary beam therapy or rotational beam therapy according to the requirements in this subpart.

A. Irradiation must not be possible until a selection of stationary beam therapy or rotational beam therapy has been made at the treatment control panel.

B. An interlock system must be provided to ensure that the equipment can operate only in the mode which has been selected.

C. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

D. The mode of operation must be displayed at the treatment control panel.

E. For systems installed after September 10, 1991, an interlock system must be provided to terminate irradiation if:

(1) movement of the gantry occurs during stationary beam therapy; or

(2) movement of the gantry stops during rotational beam therapy unless such stoppage is a preplanned function.

F. Rotational beam therapy must be controlled to provide accurate total dose and arc angle.

(1) For systems installed after September 10, 1991, where the angle of rotation terminates the radiation, the maximum difference between the delivered and expected monitor units (MU) must not exceed three percent or one monitor unit, whichever is greater. The expected MU is calculated by multiplying the set value of MU/degree by the set value of total gantry rotation angle. The observed terminal gantry angle must be within plus or minus three degrees of expected. This requirement applies for all arcs of 45 degrees or more at all MU/degree values indicated as "clinically usable" by the manufacturer.

(2) For systems installed after September 10, 1991, where the dose monitoring system terminates the irradiation, the maximum difference between the observed and expected angle of rotation of the gantry shall not exceed plus or minus three degrees. The expected angle of rotation is calculated by dividing the set value of monitor units by the set value of MU/degree. The agreement of elapsed MU to MU set must be three percent, or 1.0 MU, whichever is greater. This requirement applies for all arcs of 45 degrees or more at all MU/degree values indicated as "clinically usable" by the manufacturer.

Subp. 17. **Absorbed dose rate.** Systems installed after September 10, 1991, must have a component from which readings of the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors in subpart 7 may form a portion of this system. The requirements in items A and B also apply.

A. The dose monitor unit rate must be displayed at the treatment control panel.

B. If the system can deliver under any conditions an absorbed dose rate at the nominal treatment distance of more than ten percent above the value specified by the manufactur-

er for any equipment parameters used, a device must be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated must be in a record maintained by the registrant.

Subp. 18. [Repealed, 23 SR 1760]

Subp. 19. **System checking facilities.** Capabilities shall be provided so all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

Subp. 20. **Operating procedures.** Any therapy system with energies greater than one MV shall not be used in the administration of radiation therapy unless the requirements of parts 4730.1670; 4730.1675, subpart 3; and 4730.1680, subpart 2, have been met.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.2475 RADIATION SAFETY REQUIREMENTS FOR THE USE OF MEDICAL PARTICLE ACCELERATORS.

Subpart 1. **Applicability.** In addition to the requirements of parts 4730.0100 to 4730.1695, this part applies to medical particle accelerators used in the treatment of humans.

Subp. 2. **Medical committee to evaluate and approve medical particle accelerators.** The registrant shall appoint a medical committee of at least four members to evaluate and approve uses of a medical particle accelerator for research on a person. Membership of the committee must include the facility radiation safety officer, a physician expert in therapeutic radiology, and a therapeutic radiological physicist. Membership may include physicians who are experts in internal medicine and hematology.

Subp. 3. **Controls and interlock systems.** All medical particle accelerators used in the treatment of humans must meet the requirements for controls and interlock systems or safety devices in this subpart.

A. Instrumentation, readouts, and controls on the medical particle accelerator control console must be clearly identified and easily discernible.

B. Each entrance into a treatment room or other high radiation area must be provided with a safety device or interlock that shuts down the system under conditions of barrier penetration.

C. Each safety device or interlock must be on a circuit which allows it to operate independently of all other safety interlocks.

D. All safety devices or interlocks must be designed so any defect or component failure in the safety interlock system prevents operation of the medical particle accelerator.

E. When a safety device or interlock system has been triggered, it must be possible to resume operation of the medical particle accelerator only by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

F. Emergency "off" switches must be placed on or near the treatment console. Inside the treatment room, emergency "off" switches must be placed on or near the treatment couch, and on or near both sides of the gantry stand.

Subp. 4. **Warning devices.** All medical particle accelerators used in the treatment of humans must meet the requirements for warning devices in this subpart.

A. Each location designated as high radiation area, and each entrance to such location, must be equipped with easily observable warning lights that operate when, and only when, radiation is produced.

B. Barriers and pathways leading to high radiation areas must be posted according to part 4730.0300.

Subp. 5. **Operating procedures.** All medical particle accelerators used in the treatment of humans must be operated according to the procedures in this subpart.

A. Medical particle accelerators, when not in operation, must be secured to prevent unauthorized use.

B. All safety and warning devices, including interlocks, must be checked for proper operation at intervals not to exceed one month. Results of such tests must be recorded in writing and be available at the medical particle accelerator facility for inspection by the commissioner. These records must be maintained until the next inspection by the commissioner.

C. Electrical circuit diagrams of the medical particle accelerator and the associated safety device or interlock systems must be kept current and maintained at each medical particle accelerator facility.

D. If, for any reason, it is necessary to intentionally bypass a safety device or interlock when treating a patient, such action must require:

(1) prior authorization by the radiation safety committee or radiation safety officer or individuals given such authorization in writing by the radiation safety officer;

(2) a record in a permanent log and a notice posted at the medical particle accelerator control console; and

(3) termination as soon as possible.

E. A copy of the current operating and the emergency procedures must at all times be available at the medical particle accelerator control panel.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *16 SR 485; 23 SR 1760*

4730.2500 [Repealed, 22 SR 314]

4730.2510 INDUSTRIAL USES OF IONIZING RADIATION PRODUCING EQUIPMENT AND NONMEDICAL ACCELERATORS.

Subpart 1. **Applicability.** This part establishes standards for the use of ionizing radiation producing equipment and nonmedical accelerators in industrial settings. The requirements of this part are in addition to the requirements of parts 4730.0100 to 4730.1640.

Subp. 2. **Classes.** Industrial facilities using ionizing radiation producing equipment and nonmedical accelerators must be classified as using either Class A, Class B, Class C, Class D, Class E, or Class F equipment. The class of the equipment must be specified by the registrant at the time of registration.

A. Class A registration is for unlimited use of industrial ionizing radiation producing equipment and nonmedical accelerators used for industrial radiography at maximum capacity in a permanent, shielded enclosure.

B. Class B registration is for time–limited use and temporary operation of industrial radiography.

C. Class C registration is for use of industrial cabinet and industrial cabinet baggage radiography.

D. Class D registration is for use of analytical ionizing radiation producing equipment.

E. Class E registration is for use of a nonmedical accelerator in a nonmedical setting.

F. Class F registration is for use of x–ray equipment or nonmedical accelerators for manufacturing processes, including curing, polymer linking, thickness measurements or coating weight, and quality control on continuously moving webs.

Subp. 3. **Operating and emergency procedures.** A copy of a registrant's written operating and emergency procedures must be supplied to the registrant's employees and must include:

A. methods for handling and using each source of radiation so no individual is exposed to radiation doses in excess of the limits established in parts 4730.0310 to 4730.0380;

B. methods and frequency for conducting radiation safety surveys, as required under subpart 5, item F, so radiation doses do not exceed the limits established in parts 4730.0310 to 4730.0380;

C. methods for controlling access to industrial ionizing radiation producing equipment and nonmedical accelerator areas;

D. methods and conditions for locking and securing sources of radiation;

E. methods and conditions for personnel monitoring and using personnel monitoring dosimeters under part 4730.1510, subpart 11, item C;

F. procedures and notifications that must be undertaken immediately by industrial radiography personnel when a direct reading pocket dosimeter is found to be off–scale;

G. emergency procedures for the registrant's employees to minimize exposure of individuals in the event of an accident;

H. procedures for the registrant's employees to notify the registrant in the event of an accident;

I. procedures to be followed by the registrant and the registrant's employees for notifying the commissioner and state duty officer, as required in parts 4730.1110 to 4730.1140, in the event of an accident;

J. methods for maintaining personnel monitoring records as required by subpart 12 and part 4730.1520;

K. procedures for inspecting and maintaining industrial ionizing radiation producing equipment and nonmedical accelerators; and

L. procedures for calibrating and testing radiation survey instruments and alarming ratemeters.

Subp. 4. **Instruction and training.** The registrant must provide a worker who operates or maintains industrial ionizing radiation producing equipment or nonmedical accelerator equipment with a copy of and instruction in the operating and emergency procedures for the industrial ionizing radiation producing equipment or nonmedical accelerator equipment used. The registrant must ensure that the worker receives and maintains training in the following areas:

A. the operating procedures for industrial ionizing radiation producing equipment or nonmedical accelerator equipment;

B. identifying radiation hazards associated with the use of industrial ionizing radiation producing equipment or a nonmedical accelerator;

C. the significance of the various radiation warning signs, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on a certain piece of industrial ionizing radiation producing equipment or nonmedical accelerator and the extra precautions required in such a case;

D. recognizing the symptoms of an overexposure; and

E. the procedures for reporting an actual or suspected overdose.

Subp. 5. **Inspection and maintenance of equipment.** The registrant must ensure that:

A. checks for defects in industrial ionizing radiation producing equipment and nonmedical accelerators are performed before each day or each shift of use;

B. industrial ionizing radiation producing equipment and nonmedical accelerators are inspected quarterly for proper functioning of warning devices, control devices, and components important to safety, in compliance with part 4730.0300, subparts 5 and 6, and the results of the inspections are recorded and maintained according to part 4730.1520, subparts 5 and 6;

C. tests of alarming ratemeters are conducted and recorded according to part 4730.0300, subpart 8;

D. equipment parts are maintained according to the manufacturer's specifications;

E. when an inspection required by this subpart reveals damage to a component critical to radiation safety or the function of the equipment, the component is removed from service and labeled as defective until repairs are made; and

F. a radiation safety survey is performed, at intervals not to exceed one year, to determine compliance with parts 4730.0310 to 4730.0380.

Subp. 6. **Industrial radiation safety survey.** The registrant must ensure that a radiation safety survey is performed initially and when change occurs in shielding, operation, or equipment.

Subp. 7. **Calibrated and operable radiation survey instruments.** The registrant must have sufficient calibrated and operable radiation survey instruments accessible to make a radiation safety survey as required by subparts 5 and 6 at each facility.

A. Each radiation survey instrument must be calibrated according to the procedures in part 4730.0300, subpart 7.

B. Records of radiation survey instrument calibrations must be maintained according to subpart 12 and part 4730.1520, subpart 5.

Subp. 8. **Use logs.** Each registrant must maintain use logs until the next inspection by the commissioner. For each nonmedical accelerator or piece of industrial ionizing radiation producing equipment other than Class C equipment, Class F equipment, and Class D electron microscopes that by design preclude personnel monitoring, the log must specify:

A. a serial number or other unique identification;

B. the identity of the operator assigned to the equipment;

C. the locations and dates where the equipment was used; and

D. the technique factors specifying the voltage, current, exposure time for each radiographic exposure, and number of exposures.

Subp. 9. **Bypassing a safety device.** The registrant must ensure that a safety device or interlock is not bypassed unless written approval has been obtained from the radiation safety officer or an alternate person designated by the radiation safety officer. The approval must be for a specified period of time. When a safety device or interlock is to be bypassed, a readily discernible sign stating "SAFETY DEVICE NOT WORKING" must be posted on the radiation source housing. A radiation safety survey must be performed after the safety device is removed.

Subp. 10. **Beam stop.** A device that prevents the entry of any portion of an individual's body into the primary x–ray beam path or causes the beam to be shut off when an object enters its path must be provided on all open–beam configurations. This subpart does not apply when beam alignment is being performed.

Subp. 11. **Security.** For radiation sources other than Class C and Class F industrial x–ray equipment and Class D electron microscopes designed to work without personnel dosimetry, the registrant must ensure that security systems are designed and used so that:

A. no operable industrial ionizing radiation producing equipment or nonmedical accelerator is left unattended unless:

(1) the industrial ionizing radiation producing equipment or nonmedical accelerator is locked in an inoperable condition; or

(2) the room or building in which the industrial ionizing radiation producing equipment or nonmedical accelerator is located is locked to prevent its use, tampering, or removal by unauthorized personnel; and

B. in a high and very high radiation area, the operator maintains direct surveillance of the operation to protect against unauthorized entry into a high or very high radiation area, unless:

(1) the high or very high radiation area is equipped with a control device or alarm system as described in part 4730.0300, subpart 5, 6, or 8; or

(2) the high or very high radiation area is locked to protect against unauthorized or accidental entry.

Subp. 12. **Records.** The registrant must ensure that the records in this subpart are maintained for each piece of industrial ionizing radiation producing equipment and nonmedical accelerator, except electron microscopes. A copy of the records must be kept with the operating and emergency procedures for the equipment.

A. Except as provided in item B, the following must be maintained for inspection by the commissioner until the time of the next inspection:

(1) records of the inspection and maintenance of equipment as required by subpart 5;

(2) records of industrial radiation safety surveys as required by subpart 6;

(3) records of radiation survey instrument tests and calibrations as required by subpart 7. Acceptable records include tags or labels affixed to the device or survey meter; and

(4) use logs as required by subpart 8.

B. If the results of a radiation safety survey under item A, subitem (2), are used to determine an individual's dose of radiation, the record of the radiation safety survey must be maintained according to part 4730.1520, subpart 4, item B.

C. For records at temporary jobsites, each registrant conducting industrial radiography must have available at the temporary jobsite:

(1) a copy of current registration;

(2) a copy of operating and emergency procedures;

(3) industrial radiation safety survey records as required by subpart 6;

(4) direct reading pocket dosimeter records for the period of operation at the site; and

(5) the latest instrument calibration records for instruments in use at the site.

Subp. 13. **Personnel monitoring and radiation survey requirements; Class A, Class B, and Class E.** The registrant must ensure that at a permanent or temporary jobsite, the personnel monitoring and radiation survey requirements specified in this subpart are met for Class A, Class B, and Class E industrial radiographic equipment.

A. In areas that require warnings as specified in part 4730.0300, subpart 1a, items A to C, there must be a current thermoluminescent dosimeter, film badge, or other whole body personnel monitoring device for each operator and all workers present.

B. For each operator, there must be a calibrated direct reading pocket dosimeter with a range of at least 0 to 200 milliroentgens (5.16×10^{-5} C/kg), and an alarming ratemeter that will alarm at an exposure of up to 500 mR/hr (1.29×10^{-4} C/kg/hr) or an alarming ratemeter that also integrates the total exposure up to 5,000 milliroentgens (1.29×10^{-3} C/kg). A hand–held portable radiation survey meter with an audible and visible readout of exposure rate or a fixed area radiation exposure rate monitor with a visible or audible alarming indicator may be substituted for the alarming ratemeter.

C. A yellow barrier rope with a purple, magenta, or black stripe and the warning signs specified in part 4730.0300, subpart 1a, items A to C, must be in place.

D. An exposure rate survey must be made after each industrial radiographic exposure to determine that the machine is "off."

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *22 SR 314; 23 SR 1760*

4730.2520 CLASS A INDUSTRIAL EQUIPMENT.

Subpart 1. **Applicability.** This part applies to Class A industrial ionizing radiation producing equipment used for industrial radiography. The requirements of this part are in addition to the requirements of parts 4730.0100 to 4730.1640, and 4730.2510.

Subp. 2. **Permanent enclosure.** An x–ray source and the objects exposed must be contained in a permanent enclosure. Except as provided in subpart 6, the enclosure must attenuate primary and secondary radiation so that the exposure rate at any accessible external point does not exceed two milliroentgens (5.16×10^{-7} C/kg) per hour when:

A. the beam is adjusted to give maximum exposure rate with the generator at maximum; and

B. the equipment is placed in the shortest equipment–to–wall radiographically usable position.

Subp. 3. **Interlocks.** Interlocks must be provided that either prevent entering a source enclosure while the x–ray generator is in operation or terminate the generation of x–rays if the enclosure is opened.

A. Interlocks must be provided so that all entrance doors close before industrial radiographic or nonmedical accelerator operations are initiated or continued.

B. If a useful radiation beam is interrupted by a door opening, it must not be possible to restore the system to operation without closing the door and reinitiating irradiation by manual action at the control panel.

C. Nonmedical accelerators must comply with part 4730.2560, subpart 2.

Subp. 4. **Enclosure requirements.**

A. A person must be able to exit a source enclosure at all times.

B. No person is permitted to remain within a source enclosure while the x–ray generator is in operation.

Subp. 5. **Visible and audible signals.** A source enclosure must be equipped with internal and external visible and audible signals.

A. Visual signals must be activated on generation of x–rays and remain continuously activated while x–rays are generated.

B. Audible signals must be activated if an interlock is interrupted or opened during operation.

Subp. 6. **Ceiling barrier.** If a ceiling barrier does not attenuate the exposure rate as specified in subpart 2, a posted fence or other barrier must be used to restrict access to the area above the ceiling.

Subp. 7. **Nonmedical accelerators used for industrial radiography.** If a nonmedical accelerator is used to perform industrial radiography, the registrant must comply with this part and parts 4730.2510 and 4730.2560.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *22 SR 314; 23 SR 1760*

4730.2530 CLASS B INDUSTRIAL EQUIPMENT.

Subpart 1. **Applicability.** This part applies to Class B industrial radiation equipment used for the time–limited and temporary operation of industrial radiography. The requirements of this part are in addition to the requirements of parts 4730.0100 to 4730.1640, and 4730.2510.

Subp. 2. **Restricted areas.** In all areas in which the exposure rate exceeds two milliroentgens (5.16×10^{-7} C/kg) per hour, a fence, rope, or other suitable personnel barrier must be used outside the two milliroentgens (5.16×10^{-7} C/kg) per hour iso–line to restrict entry.

Subp. 3. **Nonmedical accelerators used for industrial radiography.** If a nonmedical accelerator is used for industrial radiography, the registrant must comply with this part and parts 4730.2510 and 4730.2560.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *22 SR 314; 23 SR 1760*

4730.2540 CLASS C INDUSTRIAL EQUIPMENT.

Subpart 1. **Applicability.** This part applies to Class C industrial cabinet radiography and Class C industrial cabinet baggage systems.

A. A registrant who performs industrial radiography using certified cabinet radiography or certified cabinet baggage systems must comply with all requirements of this part and Code of Federal Regulations, title 21, part 1020, section 1020.40, as amended through April 1, 1996, and as subsequently amended. The requirements of Code of Federal Regulations are in addition to the requirements of parts 4730.0100 to 4730.1640, and part 4730.2510, except subparts 6 and 13.

B. A registrant who performs industrial radiography using noncertified cabinet radiography or noncertified cabinet baggage systems must comply with all requirements of this part and the requirements of parts 4730.0100 to 4730.1640, and 4730.2510, except subparts 6 and 13.

Subp. 2. **Personnel monitoring.** When a cabinet radiography system allows an individual to enter the interior of the cabinet, the individual must wear an alarming ratemeter and either a film badge or a thermoluminescent dosimeter.

Subp. 3. **Certified cabinet radiography systems.** Certified cabinet radiography systems must be maintained in compliance with Code of Federal Regulations, title 21, part 1020, section 1020.40, April 1, 1996, and as subsequently amended.

Statutory Authority: *MS s 144.05; 144.12*

History: *22 SR 314*

4730.2550 CLASS D INDUSTRIAL EQUIPMENT.

Subpart 1. **Applicability.** This part applies to Class D analytical ionizing radiation producing equipment. The requirements of this part are in addition to the requirements of parts 4730.0100 to 4730.1640, and 4730.2510.

Subp. 2. **Ports.** Unused ports on radiation source housings must be closed to prevent opening by an individual other than the operator.

Subp. 3. **Shutters.** For equipment with an open–beam configuration installed on or after March 1, 1998, each port on the radiation source housing must be equipped with a shutter that cannot be operated unless either a collimator or a coupling has been connected to the port.

Subp. 4. **Radiation shielding of components.** The registrant must ensure that:

A. an x–ray tube housing or port cover is constructed so that, with all shutters closed, the radiation measured at a distance of five centimeters (1.97 inches) from the x–ray tube housing or port cover surface does not produce a dose in excess of 2.5 millirems (0.025 mSv) in one hour;

B. for systems using x–ray tubes, the 2.5 millirems (0.025 mSv) dose limit is not exceeded at any specified tube rating; and

C. each x–ray generator has a protective cabinet that limits radiation leakage measured at a distance of five centimeters (1.97 inches) from the protective cabinet surface so that the x–ray generator does not produce a dose in excess of 0.5 millirem (0.005 mSv) in one hour.

Statutory Authority: *MS s 144.05; 144.12*

History: *22 SR 314*

4730.2560 CLASS E INDUSTRIAL EQUIPMENT.

Subpart 1. **Applicability.** This part applies to Class E accelerators in nonmedical settings. The requirements of this part are in addition to the requirements of parts 4730.0100 to 4730.1640, and 4730.2510.

Subp. 2. **Nonmedical accelerator controls and interlock systems.** The registrant must ensure that the nonmedical accelerator has:

A. clearly identified and easily discernible instrumentation, readouts, and controls on the control console;

B. a safety interlock at each entrance into a high or very high radiation area, including a target room, chamber, or other area, that shuts down the nonmedical accelerator when the entrance barrier is penetrated;

C. safety interlocks on a circuit that allows an interlock to operate independently of all other safety interlocks;

D. a safety interlock system designed to prevent operation of the nonmedical accelerator in the event of a defect or component failure in the system;

E. a safety interlock system that, once triggered, makes it possible to resume operation of the nonmedical accelerator only by first manually resetting the controls at the position where the safety interlock was tripped and then resetting the controls at the main control console; and

F. easily identifiable emergency "off" switches located in all high and very high radiation areas, with a manual reset that does not allow the nonmedical accelerator to be restarted from the control console without resetting the emergency "off" switch.

Subp. 3. **Electrical circuit diagrams.** Electrical circuit diagrams of the nonmedical accelerator and the associated safety interlock system must be current and maintained at each nonmedical accelerator facility.

Subp. 4. **Radiation monitoring requirements.** The registrant must ensure that the radiation levels in all high and very high radiation areas in a nonmedical accelerator facility are continuously monitored. The monitoring devices must be electrically independent of the nonmedical accelerator control and safety interlock system and must provide means to view the readout at the control panel.

Subp. 5. **Warning lights.** The entry door to a nonmedical accelerator room must be equipped with readily observable warning lights that indicate when the useful beam is in the "on" position.

Statutory Authority: *MS s 144.05; 144.12*

History: *22 SR 314*

4730.2570 CLASS F INDUSTRIAL EQUIPMENT.

Subpart 1. **Applicability.** This part applies to Class F manufacturing process equipment. The requirements of this part are in addition to the requirements of parts 4730.0100 to 4730.1640, and 4730.2510.

Subp. 2. **Permanent enclosure.** The ionizing radiation source and the materials exposed to ionizing radiation must be contained within a permanent enclosure.

Subp. 3. **Shielding.** The enclosure construction must attenuate the primary and secondary radiation beam so that the exposure rate through any portion of the shielding is less than 0.5 milliroentgen (1.29×10^{-7} C/kg) per hour and the exposure rate through openings in the shielding is less than five milliroentgens (1.29×10^{-6} C/kg) per hour at any accessible external point when the equipment is being operated at its maximum potential.

Subp. 4. **Interlocks.** Reliable interlocks must be provided on access doors in the primary and secondary shielding. The interlocks must terminate the generation of ionizing radiation or attenuate the radiation exposure rate to five milliroentgens (1.29×10^{-6} C/kg) per hour if an access door is opened.

Subp. 5. **Visible signals.** The enclosure must be equipped with visible signals that activate when ionizing radiation is generated and remain activated continually while ionizing radiation is generated.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *22 SR 314; 23 SR 1760*

4730.2580 [Repealed, 29 SR 755]

4730.2600 [Repealed, 29 SR 755]

4730.2700 [Repealed, 22 SR 314]

4730.2710 [Repealed, 29 SR 755]

4730.2750 [Repealed, 29 SR 755]

4730.2800 [Repealed, 29 SR 755]

4730.2900 [Repealed, 22 SR 314]

4730.3000 [Repealed, 23 SR 1760]

4730.3300 [Repealed, 16 SR 485]

4730.3400 [Repealed, 29 SR 755]

4730.3500 [Repealed, 29 SR 755]

4730.3600 [Repealed, 16 SR 485]

4730.3605 [Repealed, 22 SR 314]

4730.3610 [Repealed, 29 SR 755]

4730.5000 APPLICABILITY.

Except for an individual licensed under Minnesota Statutes, chapter 147, 150A, or 153, or sections 148.01 to 148.106, and rules adopted thereunder, after January 1, 1997, an indi-

vidual operating x–ray equipment for use on humans must pass an examination as specified in parts 4730.5000 to 4730.5200 or part 4730.5400.

Statutory Authority: *MS s 144.121*

History: *20 SR 2777; 21 SR 916*

4730.5050 DEFINITION.

For purpose of parts 4730.5000 to 4730.5500, "individual operating x–ray equipment on humans" means an individual who exposes humans to ionizing radiation by being directly involved with any part of the x–ray procedure from setting the equipment exposure factors through processing the x–ray.

Statutory Authority: *MS s 144.121*

History: *20 SR 2777*

4730.5100 EXAMINATION REQUIREMENTS.

Subpart 1. **General.** To be approved by the commissioner, an examination must test an individual's knowledge of:

A. basic radiation safety;

B. proper use of x–ray equipment;

C. darkroom and film processing; and

D. quality assurance procedures.

Subp. 2. **Examination approval.** A set of examination questions based on the areas listed in subpart 1 must be submitted to the commissioner for approval:

A. at least 60 calendar days before the examination is held;

B. before the initial examination is used; and

C. whenever question content is changed or additional questions are added to the question pool.

Subp. 3. **Availability of examinations.** An examination must be offered at least three times each calendar year.

Subp. 4. **Reporting examination results.** Within 30 calendar days after an examination has been administered, a list of all individuals who have passed the examination and those who have failed the examination must be submitted by the organization administering the examination to the commissioner.

Subp. 5. **Notice to individual.** Written notice to the individual who took the examination on a specific date must be provided by the organization administering the examination within 30 calendar days:

A. indicating whether the individual passed or failed the examination; and

B. listing the areas in which the individual failed.

Subp. 6. **Examination security.** The identity of an individual taking the examination must be verified by requiring a picture identification at the time the individual takes the examination.

Subp. 7. **Passing level.** The passing level for an examination must be 70 percent.

Subp. 8. **Closed book examination.** An examination must be a closed book examination.

Subp. 9. **Validity standards.** An examination must meet validity standards for educational and psychological testing specified in the American Psychological Association's "Standards for Educational and Psychological Testing" (1986). The "Standards for Educational and Psychological Testing" are incorporated by reference, are not subject to frequent change, and are available at the Minnesota State Law Library.

Subp. 10. **Examination questions.** An examination must:

A. consist of at least 75 multiple choice questions;

B. include the highest percent of questions on radiation safety; and

C. vary and reorder questions each time an examination is held.

Subp. 11. **Examination content.** An examination must adequately address the topic areas listed in subpart 1. Questions for each of the topic areas listed in subpart 1 must include the information specified in items A to D:

A. radiation safety, including:

(1) the biological effects of radiation:

(a) somatic and genetic effects; and

(b) long–term and short–term effects;

(2) operator protection:

(a) patient protection; and

(b) gonad and room shielding and the use of lead aprons and gloves;

(3) beam restriction methods;

(4) personnel monitoring:

(a) types of monitors available; and

(b) how to wear monitors;

(5) dose:

(a) maximum permissible dose for patient and operator; and

(b) the concept of "as low as reasonably achievable" (ALARA);

(6) radiation terminology:

(a) meanings; and

(b) proper use; and

(7) restraint and holding procedures and precautions;

B. the proper use of x–ray equipment, including:

(1) radiographic equipment;

(2) the parts of the x–ray machine and x–ray tube;

(3) the electronics and physics of x–ray generation;

(4) grids and buckys;

(5) automatic exposure controls;

(6) identification of imaging failures;

(7) proper maintenance of x–ray equipment;

(8) image production;

(9) technique factors:

(a) kVp, mA, mAs time and distance;

(b) function and interaction of kVp, mA, mAs time; and

(c) density, detail, contrast;

(10) cassettes and film compatibility; and

(11) technique conversion factors;

C. darkroom and film processing, including:

(1) both automatic or manual chemistry;

(2) fog;

(3) temperature and time relationship;

(4) identification of artifacts;

(5) handling and storage of film, chemistry, and replenishing;

(6) safelights types, wattage, and compatibility with film; and

(7) darkroom maintenance;

D. quality assurance procedures, including:

(1) the importance of quality assurance procedures;

(2) how to do quality assurance procedures for sensitometry and densitometry, screen tests, and fog test; and

(3) what corrective measures are appropriate.

Statutory Authority: *MS s 144.121*

History: *20 SR 2777*

4730.5200 REQUIREMENTS FOR FACILITIES USING X-RAY EQUIPMENT.

A registrant in a facility with x-ray equipment used on humans must ensure that:

A. only an individual who has met the requirements in parts 4730.5000 to 4730.5200 or 4730.5400 is allowed to operate x-ray equipment; and

B. on request of the commissioner, written verification that the individual who operates x-ray equipment has met the requirements in parts 4730.5000 to 4730.5200 or 4730.5400 is available for inspection.

Statutory Authority: *MS s 144.121*

History: *20 SR 2777*

4730.5400 EQUIVALENT EXAMINATIONS.

Subpart 1. **General.** An individual shall be determined by the commissioner to have met the requirements in parts 4730.5000 to 4730.5200 if the individual has passed any of the examinations listed in this part.

Subp. 2. [Repealed, 21 SR 916]

Subp. 3. [Repealed, 21 SR 916]

Subp. 4. [Repealed, 21 SR 916]

Subp. 5. **Radiologic technologist registration examination.** If an individual has passed the radiography examination of the American Registry of Radiologic Technologists, the individual shall be determined to have met the requirements in parts 4730.5000 to 4730.5200.

Subp. 6. **Chiropractic radiologic technologist registration examination.** If an individual has passed the radiography examination of the American Chiropractic Registry of Radiologic Technologists, the individual shall be determined to have met the requirements in parts 4730.5000 to 4730.5200.

Subp. 7. **Radiologic technologist license from other United States jurisdictions.** If an individual has passed a full or limited license examination in radiography from other United States jurisdictions, the individual may request that the commissioner review the license examination to determine if the license examination is equivalent to the examination described in parts 4730.5000 to 4730.5200. If the examination meets the requirements of part 4730.5100, the individual shall be determined by the commissioner to have met the requirements of part 4730.5000.

Subp. 8. **Other professional registrations.** If an individual has passed a registration examination other than one specified in this part, or an examination not approved under part 4730.5100, the individual may request a determination of equivalency according to the procedures and criteria in parts 4717.7000 to 4717.7050.

Statutory Authority: *MS s 144.121*

History: *20 SR 2777; 21 SR 916*

4730.5500 INDIVIDUALS OPERATING X-RAY EQUIPMENT DURING TRAINING.

Subpart 1. **Exemptions from x-ray machine operator's exam.** An individual participating in a training course for physicians, dentists, chiropractors, podiatrists, radiologic technologists, chiropractic radiologic technologists, dental hygienists, or dental assistants is exempt from the requirements of part 4730.5000 for the duration of the training course. The exemption applies to activities conducted within the scope of the training course. If an individual is operating x-ray equipment for use on humans outside the scope of the training course, the individual must comply with the requirements of part 4730.5000.

Subp. 2. **Exemption status following training.** An individual who successfully completes a training course under subpart 1 is exempt from part 4730.5000 until the next applicable national examination is given. The exemption ends on the date that the examination results are released. An individual who fails the examination is no longer exempt from part 4730.5000.

Statutory Authority: *MS s 144.05; 144.12; 144.121*

History: *20 SR 2777; 23 SR 1760*