

Chapter 4732 X-ray Definitions

PROPOSED REVISIONS TO 4732.0110, 5.0

Preface

This is a **DRAFT** document. None of the changes are adopted or reflect current law.

MDH's proposed changes (or new language) are <u>underscored</u>. Existing language MDH proposes to remove or repeal is stricken with a strike-out.

For each defined term, the action MDH is proposing (amend or repeal), and the rationale for the action, are included in the draft.

Summary of Changes in Version 5.0 (based on Advisory Committee meeting, 5/30/2017):

- 1. Advisory committee consensus opinions are reflected in the right margin comment box.
- 2. Advisory committee member submitted comments are added to the right margin comment box.
- 3. MDH made edits to a number of existing and proposed definitions listed under "New amendments" below. The changes and rationale are based on Advisory Committee feedback and are noted in the comment boxes in the right margin.

New definitions:

• "<u>Qualified practitioner</u>" (subp. 138c). Placeholder.

New amendments:

- "Medical event" (subp. 107)
- "Patient" (subp. 119)
- "Personal protective equipment" (subp. 123)
- "Personal supervision" (subp. 124a)
- "Protective barrier or barrier" (subp. 136)
- "Qualified medical physicist" (subp. 138a)
- "Qualified operator" (subp. 138b)
- "Quality assurance program" (subp. 139)

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- "Quality control" (subp. 140)
- "Radiation safety committee" (subp. 148a)
- "Registered radiologist assistant or RRA" (subp. 159) No longer repealing.

New repealers:

- "Licensed practitioner of the healing arts" (subp. 101)
- "Nonstochastic effects" (subp. 115)

Guiding principles in this revision:

- Defining only those terms necessary and pertinent to MDH enforcement of ionizing radiation producing equipment.
- Removing regulatory requirements from definitions.
- Eliminating definitions that are obsolete or those that are not used in the rule chapter.

Note on Radiation Therapy, Proposed Chapter 4733:

It is MDH's intent to continue work on its Radiation Therapy rulemaking (proposed Chapter 4733). With this in mind, most radiation therapy definitions are proposed for repeal from Minnesota Rules, Chapter 4732 and will be added as new definitions in the new Chapter 4733. These definitions will not be repealed if the Radiation Therapy rulemaking does not advance accordingly.

MDH encourages your review and welcomes your comments and feedback at <u>xrayrules@state.mn.us</u> or using the online <u>comment form</u> on the X-Ray rules website.

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4732.0110 DEFINITIONS

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

Subp. 2. Absorbed dose. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The special units of absorbed dose is are the rad under the conventional system of measurement and is the gray under the SI system of measurement.

Subp. 3. Absorbed dose rate. "Absorbed dose rate" means absorbed dose per unit time for machine with timers, or dose-monitor unit per unit time for linear accelerators.

Subp. 4. Accelerator. "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum <u>that discharges the</u> <u>resulting and of discharging the resultant</u> particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, linear accelerator, particle accelerator, and cyclotron are equivalent terms.

Subp. 5. Added filtration. "Added filtration" means filtration that is in addition to the

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

Subp. 6a. Advanced practice registered nurse. "Advanced practice registered nurse" has the meaning given in Minnesota Statutes, section 148.171, subdivision 3.

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Commented [JC1]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials). Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732

is consistent with ch. 4731. 4731.0100, subp. 4. Absorbed dose. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray.

Commented [JC2]: Action: Repeal. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC3]: Action: Amend to improve readability. Rationale: Plain language/improve readability. _AC: Agree, 1/31/17

Commented [JC4]: Action: Repeal. Rationale: Term is not used in rule chapter.

Commented [JC5]: Action: Amend. **Rationale:** Improve syntax/readability. **AC:** Agree, 1/31/17

Commented [JC6]: Action: Amend by adding new definition. Rationale: Needed to align with APRN authority changes in Minn. Stat. ch. 148. AC: Agree, 1/31/17

Subp. 7. Air kerma (K). "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the

initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The special name for the unit of kerma is the gray (Gy). The SI unit is ioule per kilogram.

Subp. 8. 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. 9. Annual. "Annual" means an <u>interval</u> activity is done or is performed at intervals not to exceed 12 months <u>or 365 days</u>.

Subp. 10. Appropriate <u>Allowable</u> limit or appropriate limits. "Appropriate <u>Allowable</u> 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. 11. As low as reasonably achievable or ALARA. "As low as reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposure to radiation as far below the dose limits as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvement in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

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Commented [JC7]: Action: Repeal Rationale: Common definition in industry; not needed in rule. AC: Agree, but incorporate term in affected rule part. 1/31/17

Commented [JC8]: Action: Repeal. Rationale: Term is not used in rule chapter. AC: Agree, 1/31/17

Commented [JC9]: Action: Amend. Rationale: Improve syntax/clarity. AC: Discussion on 1/31/17 included adding 365 days or 12 months. MDH: We intend to propose language, separate from the definition, to address registrant compliance within this timeframe.

Commented [JC10]: Action: Amend by striking "appropriate" and inserting "<u>allowable</u>". Rationale: Conform with usage in the rules. Term, as expressed, is not used in rule chapter, but "allowable limit" is used. AC: Agree, 1/31/17

Commented [JC11]: Action: Amend. Rationale: Improve syntax/readability. AC: Consider moving term to ALARA program rule part, 1/31/17.

Subp. 12. Attenuation. "Attenuation" means the reduction of exposure rate upon

passage of radiation through matter.

Subp. 13. Attenuation block. "Attenuation block" means a block or stack, having dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation that is large enough to intercept the entire x-ray beam.

Subp. 14. Audit. "Audit" means a planned and documented activity performed according to procedures to determine, by examination and evaluation of objective evidence, the adequacy of and extent to which applicable elements of the quality assurance program have been developed, documented, and effectively implemented.

Subp. 15. Automatic exposure control or AEC. <u>"Automatic exposure control" or "AEC"</u> means a device that automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location or locations.

Subp. 16. Base plus fog density. "Base plus fog density" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals.

Subp. 17. Beam axis. "Beam axis" means a line from the source through the centers of the x-ray fields, or for therapy the axis of rotation of the beam-limiting device.

5 DRAFT – Version 5.0 06/21/17 This document may be made accessible upon request to <u>xrayrules@state.mn.us</u>. Commented [JC12]: Action: Repeal. Rationale: Common definition in industry; not needed in rule. AC: Agree, 1/31/17

Commented [JC13]: Action: Repeal. Rationale: The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application. AC: Agree, 1/31/17

Commented [JC14]: Action: Repeal. Rationale: Repeal definition of audit. Incorporate audit/review requirements in Quality Assurance Program rule part (.0520). AC: Agree, 1/31/17

Commented [JC15]: Action: Repeal. Rationale: Common industry term; not needed in rule. AC: Agree, 1/31/17

Commented [JC16]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC17]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 18. Beam-limiting device or BLD. "Beam-limiting device" or "BLD" means a device used to restrict the dimensions of the x-ray field or useful beam.

Subp. 19. Beam-monitoring system. <u>"Beam monitoring system" means a system</u> designed and installed to detect and measure the radiation present in the useful beam.

Subp. 20. Beam-scattering filter or foil. "Beam-scattering filter" or "foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Subp. 21. Bent beam linear accelerator. "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Subp. 22. Bone densitometry system. "Bone densitometry system" means a medical device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories that uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

Subp. 23. C-arm fluoroscope system. "C-arm fluoroscope system" means an a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated by a common mechanical support system to maintain a desired

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Commented [JC18]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC19]: Action: Repeal. **Rationale:** The term is more specific to a radiation therapy application.

Commented [JC20]: Action: Repeal. Rationale: The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC21]: Action: Repeal. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC22]: Action: Amend. Rationale: Clarify by aligning with SSRCR definition, Part F, p. 2. AC: Recommend removing reference to gamma ray, 4/10/17

Commented [JC23]: Action: Amend. Rationale: Clarify by aligning with SSRCR definition, Part F, p. 2.



spatial relation relationship. Such a system allows a change in the direction of the beam axis

with respect to the patient without moving the patient.

Subp. 24. Cabinet x-ray system. "Cabinet x-ray system" means an x-ray system with the

x-ray tube installed in an enclosure independent of existing architectural structure except the

floor on which it may be placed. The cabinet x-ray system is intended to:

A. contain at least that portion of a material being irradiated;

B. provide radiation attenuation; and

C. exclude personnel from its interior during generation of radiation.

Included are all x ray systems designed primarily for the inspection of carry on baggage at airline, railroad, and bus terminals and in similar facilities. An x-ray tube used within a shielded part of a building or x-ray equipment that may temporarily or occasionally incorporate portable shielding is not considered a cabinet x ray system.

Subp. 25. Calibration. "Calibration" means:

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

B. the determination of the radiation dose or exposure rate at a designated

distance from a radiation source under specified conditions of measurement;

CA. to check, adjust, or systematically standardize to graduations of a

quantitative measuring instrument; and

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Commented [JC24]: Action: Amend. **Rationale:** Striking requirement provisions from the definition. Propose to insert these provisions in affected rule parts. (*Cabinet x-ray system is used primarily for industrial applications but is also used in certain medical procedures involving tissue biopsy.*)

Commented [JC25]: Action: Amend. Rationale: Existing definition combines concepts of "calibration" and "equipment performance evaluation" (EPE). Create new definition for EPE, see subp. 60a.

AC: Amend "Calibration" and create new definition of EPE, 4/10/217

<u>DB</u>. to check, adjust, or systematically <u>equipment service adjustments to</u> bring radiation-producing equipment into manufacturer's specifications <u>and into</u> compliance with this chapter.

Subp. 26. Cephalometric device. "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Subp. 27. Certified cabinet x-ray system. <u>"Certified cabinet x-ray system" means an x-</u>ray system that has been certified according to Code of Federal Regulations, title 21, section 1010.2, as being manufactured and assembled pursuant to Code of Federal Regulations, title 21, section 1020.40.

Subp. 28. Certified components. <u>"Certified components" means components of x ray</u> 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. 29. Certified system. "Certified system" means an x-ray system that has one or

more certified components.

Subp. 30. Changeable filters. "Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

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Commented [JC26]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC27]: Action: Repeal. Rationale: Term is defined where it is mentioned in part 4732.1040.

Commented [JC28]: Action: Repeal. **Rationale:** Most human use components in use since 1974 are certified by FDA. MDH defines equipment performance standards in chapter 4732.

Commented [JC29]: Action: Repeal. **Rationale:** Most human use components in use since 1974 are certified by FDA. MDH defines equipment performance standards in chapter 4732.

Commented [JC30]: Action: Repeal. Rationale: Term is not used in rule chapter.

Subp. 31. 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. 32. Coefficient of variation or C. "Coefficient of variation" or "C" means the standard deviation divided by the average of the parameters measured.

Subp. 33. Collimation. <u>"Collimation" means the restriction of the useful beam to an</u>

Subp. 34. Collimator. "Collimator" means a device used to limit the size, shape, and direction of the primary beam.

Subp. 35. Commissioner. "Commissioner" means the commissioner of the Department of Health or the commissioner's designee.

Subp. 36. Computed radiography. <u>"Computed radiography" means a system of creating</u> digital radiographic images that utilizes a storage-phosphor plate instead of film in a cassette. Once the plate is exposed, a laser beam scans it to produce the digital data that is translated into an image.

Subp. 37. Computed tomography or CT. "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

9 DRAFT – Version 5.0 06/21/17 This document may be made accessible upon request to <u>xrayrules@state.mn.us</u>. **Commented [JC31]: Action:** Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC32]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC33]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC34]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC35]: Action: Amend. **Rationale:** Preferred rule definition of commissioner includes commissioner's designee.

Commented [JC36]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC37]: Rich Geise (AC): Why leave CT when the term is probably better understood than CR? MDH: We are defining equipment in the rule, not the processing of the image. This includes fluoroscopy, CBCT, etc.

Frank Zink (AC): Consider using FDA group classification.

Subp. 37a. Cone Beam Computed Tomography or (CBCT). "Cone beam computed tomography" or "CBCT" is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays, and a cone-shaped x-ray beam (instead of fan shaped) that rotates around the patient. Reconstruction algorithms may be are used to generate images of in any desired plane.

Subp. 38. Control panel. "Control panel" means the part of the x-ray control upon which where the switches, knobs, push buttons, keypads, touchscreens, and other hardware are mounted and necessary for manually setting the technique factors are mounted.

Subp. 39. CT conditions of operation. <u>"CT conditions of operation" means all selectable</u> parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors defined in subpart 195.

Subp. 40. CT dose index or CTDI. <u>"CT dose index" or "CTDI" means the integral from</u> 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:

 $\frac{\text{CTDI} = 1/\text{nT} - 7T \int +7T D(z) dz}{2}$

where:

z = position along a line perpendicular to the tomographic plane;

D(z) = dose at position z;

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Commented [JC38]: Action: Amend by adding new definition.

Rationale: CBCT is a newer imaging technology that is used in most dental facilities. See SSRCR definition, <u>Part F</u>, p.3.

AC: Consider wording changes in last sentence. (4/10/17)

Commented [JC39]: Action: Amend. Rationale: Clarify by including technological features found on most modern equipment. See SSRCR definition, Part F, p.4.

Commented [JC40]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Richard Geise (AC): Recommend including term where used in rule part. People might not be clear on which conditions apply to a specific case.

Commented [JC41]: Action: Repeal. Rationale: MDH intends to incorporate proposed definition below in affected rule part. "CT dose index means the integral 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)." (Submitted comments: Geoffrey West, Ph.D., DABR, CHP, West Physics).

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. 41. CT gantry. "CT gantry" means the tube housing assemblies, beam limiting

devices, and detectors, as well as the supporting structures and frames that hold those

components.

Subp. 42. CT number. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

Subp. 43. CT scan. <u>"CT scan" means the complete process of collecting x-ray</u> transmission data for the production of a tomogram. This includes data collected simultaneously during a single scan for the production of one or more tomogram.

Subp. 44. CT scan increment. "CT 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. 45. CT scan time. "CT scan time" means the time between the beginning and end of x-ray transmission data accumulation for a CT scan.

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Commented [JC42]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC43]: Action: Repeal. **Rationale:** MDH will incorporate definition and SSRCR definition (<u>Part F</u>, p. 4) in affected rule part.

Commented [JC44]: Action: Repeal. **Rationale:** Term is used once in the definition of "CT scan time", which is proposed to be repealed.

Rich Geise (AC): Term should be used in regard to repeat analysis for CT, but can be defined in specific rule part.

Commented [JC45]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC46]: Action: Repeal. **Rationale:** Term is not used in rule chapter. "Scan time" is used 4 times in the definition of "Technique factors" (subp. 195).

Subp. 46. 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. 47. Declared pregnant woman. "Declared pregnant woman" means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing, or is no longer pregnant.

Subp. 48. Densitometer. "Densitometer" means an instrument that measures the degree of blackening or radiographic density of a film due to radiation or light by measuring the

Subp. 49. Diagnostic radiological physicist. "Diagnostic radiological physicist" means an individual who is qualified to practice independently in the appropriate subfields for medical diagnostic physics and is:

ratio of the light intensity incident on the film to the light intensity transmitted by the film.

A. certified in radiological physics or diagnostic radiological physics by the
American Board of Radiology;
B. certified in diagnostic physics by the American Board of Medical Physics;
C. certified in diagnostic physics by the Canadian College of Medical Physics; or
D. a holder of a masters degree in medical physics, radiological sciences, or an

equivalent field involving graduate study in physics applied to the application of

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Commented [JC47]: Action: Repeal. **Rationale:** Term as expressed in not used in 4732. MDH will incorporate definition provision into affected rule part.

Commented [JC48]: Action: Repeal. Rationale: MDH will incorporate definition provisions in affected rule part (4732.0415).

Commented [JC49]: Action: Repeal. **Rationale:** Term, as expressed, term is only used once in part 4732.0505. MDH proposes to incorporate definition provisions in affected rule part.

Commented [JC50]: Action: Repeal. **Rationale:** MDH will add and define "qualified medical physicist" and repeal all other related terms.

radiation to humans from an accredited college or university and has at least two years of full-time practical training or supervised experience under an individual who meets the qualifications in item A, B, or C.

Subp. 50. Diagnostic x-ray X-ray imaging system. "Diagnostic x-ray X-ray imaging system" means an assemblage of components for the generation, emissions, and reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image which that are designed and used for irradiation of any part of a body for the purpose of diagnosis or

visualization- and does not include therapeutic imaging systems under chapter 4733.

Subp. 51. Digital radiography. "Digital radiography" means <u>an x-ray imaging method (or</u> radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography a radiographic image displayed on a video monitor after computer processing.

Subp. 52. Direct supervision. "Direct supervision" means guidance and instruction by a qualified individual who is physically present and watching the performance of the radiological operation or procedure and in such proximity that contact can be maintained and immediate assistance can be given as required.

Subp. 53. Dose or radiation dose. "Dose" or "radiation dose" means absorbed radiation dose, radiation dose equivalent, effective radiation dose equivalent, committed radiation dose equivalent, committed effective radiation dose equivalent, or total effective radiation dose equivalent. For purposes of this chapter, "radiation dose" is an equivalent term.

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Commented [JC51]: Action: Amend. Rationale: Strike "diagnostic" so that term is generally applicable.

AC: Consider excluding therapy uses. (4/10/17)

Commented [JC52]: Action: Amend. **Rationale:** Updating and clarifying definition using SSRCR definition, <u>Part F</u> p. 5.

Richard Geise (AC): Despite what is in SSRCR, DR does not include CR. CR uses photostimulable phosphore screens that are subsequently processed. DR does not. The difference between direct and indirect DR is that direct DR converts the x-ray energy directly to charge (e.g. Selenia) whereas indirect converts x-ray to light then light to charge. CR is not indirect DR.

Commented [JC53]: Action: Repeal. Rationale: Not used except in Radiation Therapy (RT) rule parts, and these RT parts will also be repealed. Also, see new proposed definition of "Personal supervision" at Subp. 124a.

Commented [JC54]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 64. "Dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent.

Subp. 54. Dose equivalent or DE_HT. "Dose equivalent" or "DE" "HT" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert a quantity used for5. 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 radiation dose and the quality factor. For x-rays and gamma rays, the dose equivalent in rem is usually assumed to be numerically equal to either the exposure in roentgens or the absorbed dose in rad. The special unit radiation dose equivalent is the rem under the conventional measurement system and is the Sievert under the SI measurement system.

Subp. 55. Dose limits or limits. "Dose limits" or "limits" means the permissible upper bounds of radiation doses.

Subp. 56. 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. 57. Dose-monitor unit. "Dose-monitor unit" means a unit response from the dose-monitoring system from which the absorbed radiation dose has been calculated.

Subp. 58. Effective dose equivalent or H_E. "Effective dose equivalent" or "HE" means the sum of the products of the dose equivalent to each organ or tissue (HT) and the weighting factors (w<u>W</u>T) applicable to each of the body organs or tissues that are irradiated. (HE = $\Sigma \alpha \mu \rho \times$ WT HT).

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Commented [JC55]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 64"Dose equivalent" or "HT" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert. **AC:** Disagree, 1/31/17. Consensus opinion: full definition should remain in ch. 4732 and remove internal reference to ch. 4731.

Commented [JC56]: Action: Repeal. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC57]: Action: Repeal. Rationale: The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC58]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 69. "Effective dose equivalent" or "HE" means the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (WT) applicable to each of the body organs or tissues that are irradiated. (HE = Σ aµp× WT HT).

Subp. 59. Electron-beam generator. <u>"Electron-beam generator" means a type of</u> electron accelerator in which the electron beam is brought out into the atmosphere for irradiation purposes.

Subp. 60. Electronic signature. "Electronic signature" has the meaning given in Minnesota Statutes, section 325L.02 (h) means an electronic sound, symbol, or process attached to or logically associated with a record, and executed or adopted by a person with the intent to sign the record according to Minnesota Statutes, chapter 325L.

Subp. 60a. Equipment performance evaluation. "Equipment performance evaluation"

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; or

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

Subp. 61. Exposure. "Exposure" means being exposed to ionizing radiation or to

radioactive material. The unit of exposure is the Roentgen in air (R). The SI unit is 2.58 x 10-4

coulombs per kilogram.

Subp. 62. 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. The Si unit is 10-4 coulombs per kilogram per hour.

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Commented [JC59]: Action: Repeal. Rationale: Term is not used in rule chapter.

Commented [JC60]: Action: Amend. Rationale: Clarify meaning by referencing the statutory definition.

Commented [JC61]: Action: Amend by adding new definition **Rationale:** Create a more precise definition of "calibration" that is specific to service providers. Based on feedback regarding definition of "calibration".

Commented [JC62]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials). Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731. 4731.0100, subp. 77. "Exposure" means being exposed to ionizing radiation or to radioactive material. Commented [JC63]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials). Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion)

If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731. 4731.0100, subp. 79. "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. 63. External beam radiation therapy. "External beam radiation therapy" means

therapeutic irradiation in which the source of radiation is at a distance from the body.

Subp. 63a. Externship. "Externship" means a temporary training program in a workplace setting offered to a student as part of a course of study.

Subp. 64. Facility. "Facility" means the location at which one or more sources of radiation are installed or located within one <u>a single</u> building <u>or</u> one <u>or more</u> vehicles, registered under at one <u>physical</u> address, <u>or a complex a set of adjoining buildings, that is and are under <u>one person's responsibility and oversight</u> the same administrative control.</u>

Subp. 65. 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. 66. Field-flattening filter. "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

Subp. 67. Filmless radiography or photostimulable storage phosphor (PSP) imaging. "Filmless radiography" or "photostimulable storage phosphor (PSP) imaging" means a system that could employ employs reusable imaging plates, associated hardware and software to acquire and display digital projection radiographs. These imaging devices are known by a number of names including computed radiography (CR), photostimulable storage phosphor (PSP) imaging, or digital radiography (DR). In the digital form, PSP images are readily put into

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Commented [JC64]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC65]: Action: Amend by adding new definition Rationale: Term is used in several parts.

Commented [JC66]: Action: Amend. Rationale: Include concept of "complex" and clarify what is meant by "administrative control".

Commented [JC67]: Action: Repeal. Rationale: Term is used once in the definition of "technique factors. Propose incorporating definition provisions in affected rule part.

Commented [JC68]: Action: Repeal **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC69]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

picture archiving and communications systems and viewed on a monitor rather than viewing an image on x-ray film.

Subp. 68. Filter or filtration. "Filter" or "filtration" means material placed in the useful beam to preferentially absorb selected radiations.

Subp. 68a. Fluoroscopically-guided interventional procedure or FGI. "Fluoroscopicallyguided interventional procedure" or "FGI" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

Subp. 69. Fluoroscopic imaging assembly. <u>"Fluoroscopic imaging assembly" means a</u> subsystem in which x-ray photons produce a set of fluoroscopic or radiographic recorded images from the fluoroscopic image receptor. Fluoroscopic imaging assembly 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. 69a. Fluoroscopy.
 "Fluoroscopy" means a technique for generating x-ray images

 and presenting them simultaneously and continuously as visible images. This term has the same

 meaning as the term "radioscopy" in the standards of the International Electrotechnical

 Commission.

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Commented [JC70]: Action: Amend by adding new definition. Rationale: FGI is a newer technology that is used in most CVT procedures. See SSRCR, Part F, p. 6.

Commented [JC71]: Action: Repeal. **Rationale:** MDH will incorporate definition provisions in affected rule parts (4732.0875 and 4732.0306).

Commented [JC72]: Action: Amend by adding new definition. **Rationale:** defining equipment in the rule, not the processing of the image. From SSRCR, <u>Part F</u>, p.6.

Subp. 70. Focal spot. "Focal spot" means the area of the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

Subp. 71. Gantry. "Gantry" means the part of the system supporting and allowing possible movements of the radiation head.

Subp. 72. 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. 73. Gonad shield. "Gonad shield" means a protective barrier for the testes or ovaries.

Subp. 74. Gray or Gy. "Gray" or "Gy" means is the SI unit of absorbed radiation dose. One gray is equal to one an absorbed dose of one joule per kilogram. The conventional system equivalent is One gray is also equal to 100 rads.

Subp. 75. Half-value layer or 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. 76. Healing arts. "Healing arts" means health professions for diagnostic or healing treatment of human and animal maladies illnesses and injury that are regulated under

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Commented [JC73]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC74]: Action: Repeal. **Rationale:** The definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application. As proposed in chapter 4733: <u>"Gantry" means that part of the radiation therapy system</u> <u>supporting and allowing movements of the radiation head</u> <u>about a center of rotation.</u>

Commented [JC75]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC76]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC77]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100. subp. 91. "Gray" or "Gy" is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram. One gray is also equal to 100 rads.

Commented [JC78]: Action: Repeal. Rationale: MDH proposes to incorporate definition provisions in affected rule part

Commented [JC79]: Action: Amend. Rationale: Plain language edit and striking erroneous statutory citation.

Rich Geise (AC): Definition also includes diagnosis and treatment of injuries.

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. 77. Healing arts screening or screening. "Healing arts screening" or "screening" means the testing of <u>human beings using</u> individuals with x-ray equipment to detect or evaluate health conditions indications when the tests are not specifically and individually ordered by a licensed practitioner of the healing arts <u>qualified practitioner</u> who is legally authorized to prescribe the tests for the purpose of diagnosis or treatment.

Subp. 78. High radiation area. "High radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a radiation dose equivalent in excess of 0.1 rem (1.0 mSv) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

Subp. 78a. Image. "Image" means a radiograph or record produced on a device such as a fluorescent screen, processed film, x-ray image intensifier tube, solid-state detector, or gaseous detector or other successor technology that transforms incident x-ray photons into a visible image.

Subp. 79. 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 intensity.

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Commented [JC80]: Action: Amend. Rationale: Conforming to SSRCF Part F definition.

SSRCR definition (Part F, p.7):

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

Commented [JC81]: Action: Amend by adding new definition. Rationale: Updating and consolidating so there is only term to express "radiograph", "x-ray", etc...

Commented [JC82]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 80. Image quality. "Image quality" means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

Subp. 81. Image receptor. "Image receptor" means a device such as a fluorescent screen or radiographic film, solid-state detector, or gaseous detector 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. 82. Individual. "Individual" means a living human being.

Subp. 83. Individual monitoring. "Individual monitoring" means the assessment of dose equivalent by the use of individual monitoring devices or by the use of radiation survey data.

Subp. 84. Individual monitoring devices. "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this chapter, "personal monitoring dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are include a such as film badges, thermoluminescent dosimeters devices, pocket ionization chambers, or personal air sampling

devices and optically stimulated luminescence devices.

Subp. 85. Industrial cabinet baggage system. "Industrial cabinet baggage system" has

the meaning given for cabinet x-ray systems in subpart 24.

20 DRAFT – Version 5.0 06/21/17 This document may be made accessible upon request to <u>xrayrules@state.mn.us</u>. **Commented [JC83]: Action:** Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC84]: Action: Amend. **Rationale:** Revise so that definition is consistent for irradiation purposes.

Commented [JC85]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731. *Discuss impact to subp. 124. 4731.0100, Subp. 103. "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters, pocket ionization chambers, or personal air sampling devices.

Michael Lewandowski (AC): Is the definition of individual monitoring devices intended to include personal dose monitoring or dose of record monitoring? Inclusion of pocket ionization chambers as an example indicates devices that may not be suitable for dose of record monitoring. TLD, OSL and some electronic dosimeters are NVLAP accredited, but pocket ionization chambers may not be NVLAP accredited.

AC: Additional work needed. Ch. 4731 definition may not be best suited for X-ray rule definition. (4/10/17)

Commented [JC86]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 86. Industrial vault radiography. <u>"Industrial vault radiography" means industrial</u> radiography conducted in an enclosure, shielded so that radiation levels at every location on the exterior meet the unrestricted limitations in this chapter.

Subp. 87. 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 ensuring compliance with this chapter.

Subp. 88. Industrial radiographer's assistant. "Industrial radiographer's assistant" means an individual who uses radiographic exposure devices or radiation survey instruments in

industrial radiography under the supervision of an industrial radiographer.

Subp. 89. Industrial radiography. "Industrial radiography" means an examination of the structure of materials by the nondestructive methods of utilizing ionizing radiation to make images. Industrial radiography does not include cabinet x-ray or the use of ionizing radiation-producing equipment to measure thickness, to identify levels and material in containers, or to analyze the chemical compositions. Industrial x-ray does not include the use of ionizing radiation-producing equipment in forensic, medical, or veterinary research.

Subp. 90. Inherent filtration. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Subp. 91. Inspection. "Inspection" means an official examination or observation of equipment, facilities, and procedures that includes, including but not limited to tests, radiation 21 DRAFT - Version 5.0 06/21/17

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Commented [JC87]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC88]: Action: Repeal. Rationale: Term is used once in rule. Propose to replace with "qualified operator".

Commented [JC89]: Action: Repeal. Rationale: Term is not used in rule chapter.

Commented [JC90]: Action: Amend. **Rationale:** Clarification.

Michael Lewandowski (AC): The definition of industrial radiography appears to include an undefined term "industrial x-ray" and other undefined terms "forensic, medical, or veterinary research". The last sentence in Subp. 89 does not appear to add clarity to the definition of industrial radiography. The second sentence in Subp. 89 should end "... or to analyze the chemical composition".

Commented [JC91]: Action: Repeal. Rationale: Used in two definitions "Added filtration" and "Changeable filters", both of which are proposed to be repealed.

Commented [JC92]: Action: Amend. Rationale: Clarify that inspection is of "equipment, facilities, and procedures" and also includes "records review". MDH will add a new subpart with inspection requirements.

surveys, and monitoring <u>and records review</u> to determine compliance with <u>this chapter</u> rules, and requirements of the commissioner.

Subp. 91a. Install or installed. Install" or "installed" means deliver, assemble, or place Xray equipment or X-ray machines so that the machines and equipment are: (1) in a registrant's possession; and (2) ready for use by a registrant.

Subp. 92. Instrument traceability. "Instrument traceability" for ionizing radiation measurements means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a program that requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology (NIST), or other equivalent national or international programs.

Subp. 93. Interlock. "Interlock" means a device that automatically causes a reduction of the exposure rate upon entry by personnel into a high radiation area. An interlocking device must prevent the start or continued operation of equipment unless certain predetermined conditions prevail.

Subp. 94. Ionizing radiation <u>or radiation</u>. "Ionizing radiation" <u>or "radiation"</u> means any radiation capable of producing displacing electrons from atoms or molecules, thereby producing ions. Examples: <u>include</u> alpha, beta, gamma, x-ray, and neutron radiation.

Subp. 95. Irradiation. "Irradiation" means the exposure of a living being or matter to

ionizing radiation.

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Commented [JC93]: Action: Amend by adding new definition. Rationale: Clarify equipment responsibilities and possession for a registrant.

Commented [JC94]: Action: Amend. **Rationale:** Striking requirement provisions that are currently in part 4732.0710.

Rationale: MDH proposes to incorporate definition provisions in affected industrial rule part.

Commented [JC95]: Action: Repeal.

Commented [JC96]: Action: Amend. Rationale: Form edits.

Commented [JC97]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Michael Lewandowski (AC): Irradiation is a common tern and is not needed. If retained, it should be defined to be exposure of matter to radiation. There is no need to include "living being" as matter is more general.

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. Kilovolt peak or kVp. "Kilovolt peak" or "kVp" has the meaning given for peak tube potential in subpart 120.

Subp. 98. Lead equivalence or lead equivalent <u>thickness</u>. "Lead <u>equivalent thickness</u>" equivalence" or "lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Subp. 99. Leakage radiation. "Leakage radiation" means radiation emanating from the radiation source assembly except for other than the useful beam and radiation produced when the exposure switch or timer is not activated.

Subp. 100. 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.

Subp. 101. 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 illnesses or injury, 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.

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Commented [JC98]: Action: Possible repeal. **Rationale:** Term is only used in Radiation Therapy rule parts. If term is added as part of revisions to fluoroscopy, then it will remain.

Rich Geise (AC): Term is important in fluoroscopic imaging and not strictly limited to radiation therapy.

Commented [JC99]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC100]: Action: Amend. **Rationale:** Clarification.

Rich Geise (AC): Recommends "lead equivalent thickness". The lead equivalent thickness of a protective barrier (or PPE) is the thickness of lead that provides the same attenuation as the barrier.

Commented [JC101]: Action: Amend. Rationale: Syntax edits.

Commented [JC102]: Action: Repeal. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC103]: Action: Repeal. **Rationale:** MDH intends to replace definition with "qualified practitioner".

Subp. 102. 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. 103. 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 (Vn - V1)/V1

where:

Vn = no-load line potential; and

V1 = load line potential.

Subp. 104. mA. "mA" means milliampere.

Subp. 105. mAs. "mAs" means milliampere-second.

Subp. 106. 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. 107. Medical event. "Medical event" means an unintentional diagnostic

administration of radiation for human use where a registrant is performing a fluoroscopically-

guided interventional or CT procedure that exceeds the maximum dose limits and requires a

report under part 4732.0610.

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Commented [JC104]: Action: None. **AC:** Prefer to leave definition as is, which is consistent with SSRCR, 5/30/17.

Commented [JC105]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC106]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC107]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC108]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC109]: Action: Amend. Rationale: Strike regulatory language and propose to add new medical event procedures in part 4732.0610. AC: Add "unintentional" to definition, 5/30/17.



the administration of radiation received from radiation-producing equipment and

includes:

A. therapeutic administration involving:

(1) the wrong patient;

(2) the wrong treatment modality;

(3) a dose to tissue other than the treatment site that is 50 percent or

more of the dose expected from the administration defined in the

written directive;

(4) a total radiation dose delivered that differs from the prescribed dose

by 20 percent or more;

(5) a total radiation dosage delivered that differs from the prescribed

dosage by 20 percent or more or falls outside the prescribed dosage

range; or

(6) a fractionated radiation dose delivered that differs from the

prescribed dose, for a single fraction, by 50 percent or more; and

B. when the patient radiation dose during a fluoroscopic procedure exceeds 600

rads for an adult.

Subp. 108. Medical particle accelerator. "Medical particle accelerator" has the meaning

given for accelerator in subpart 4.

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Commented [JC110]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Subp. 109. Medical physicist. "Medical physicist" has the meaning given for diagnostic radiological physicist in subpart 49, or therapeutic radiological physicist in subpart 200.

Subp. 110. Medical uses use. "Medical uses use" means the intentional internal or external administration of radiation to human and animal patients or human research subjects.

Subp. 111. Megavolt (MV) or mega electron volt (MeV). "Megavolt," "MV," or "mega electron volt," "MeV," means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000,000 volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

Subp. 112. Moving beam radiation therapy. "Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, and rotational therapy.

Subp. 113. 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. 114. Nominal treatment distance.-"Nominal treatment distance" means:

A. for electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam;

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Commented [JC111]: Action: Repeal. Rationale: MDH will add and define "qualified medical physicist" and repeal all other related terms.

Commented [JC112]: Action: Amend. **Rationale:** Writing in the singular is a best practice and the preferred form by the Revisor.

Rich Geise (AC): Could not find this phrase used other than in reference to radiation therapy.

Commented [JC113]: Action: Repeal. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC114]: Action: Repeal. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC115]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Rich Geise (AC): Don't think term is commonly understood except by physicists, but it probably should not be used in the text. Just use definition in the text of part .0860.

Commented [JC116]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term has no X-ray application and is more specific to a radiation therapy application.

B. for x-ray irradiation, the virtual source or target to isocenter distance along

the entral axis of the useful beam; and

C. for nonisocentric equipment, the distance specified by the manufacturer.

Subp. 115. Nonstochastic effects. "Nonstochastic effects" means health effects the severity of which varies with the radiation dose, and for which a threshold is believed to exist. Radiation induced cataract formation is an example of a nonstochastic effect.

Subp. 116. Occupational dose. "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the registrant involve exposure to radiation-producing equipment, whether or not the radiation-producing equipment is in the possession of the registrant. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with chapter 4731, from voluntary participation in medical research programs, or as a member of the public.

Subp. 117. Open-beam configuration. <u>"Open-beam configuration" means an analytical</u> 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 normal operation.

Subp. 118. Optical density or O.D. <u>"Optical density" or "O.D." means the logarithm of</u> the incident light intensity minus the logarithm of the transmitted light intensity.

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Commented [JC117]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Rich Geise (AC): Term is not restricted to radiation therapy. These can occur in patients in CT and fluoroscopy and have occurred in physicians performing fluoroscopy. However, the phrase is out of date. Current terminology is "tissue reactions" (cf. e.g. NCRP Statement No. 11, December 31, 2014).

Commented [JC118]: Action: Repeal. Rationale: MDH proposes to incorporate definition provisions in affected rule parts.

Commented [JC119]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC120]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 119. Patient. "Patient" means an individual or animal subjected to healing arts examination, and diagnosing diagnosis, or treatment.

Subp. 120. Peak tube potential. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

Subp. 121. Permanent radiographic installation. "Permanent radiographic installation" means a shielded enclosed room, cell, vault, or structure that is not moved and is not located at a temporary job site. The installation is designed or intended for radiography, and in which radiography is regularly performed.

Subp. 122. 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, excluding federal government agencies.

Subp. 123. Personal protective <u>equipment or PPE</u> garments. "Personal protective equipment" or "PPE garments" mean garments, including <u>full</u> aprons, <u>vests</u>, and <u>half aprons</u>, gloves, <u>lead glasses</u>, and thyroid collars made of radiation absorbing materials used to reduce radiation exposure <u>to an individual</u>.

Subp. 124. Personal monitoring dosimeter. "Personal monitoring dosimeter" has the meaning given for individual monitoring devices in subpart 84.

28 DRAFT – Version 5.0 06/21/17 **This document may be made accessible upon request to <u>xrayrules@state.mn.us</u>.** **Commented [JC121]: Action:** Amend. **Rationale:** Modifying definition so that it applies to ionizing radiation use only.

AC: Keep "treatment" concept. Change "diagnosis" to "<u>diagnosing</u>", 5/30/17.

Rich Geise (AC): Recommends leaving in "or treatment". Interventional fluoroscopy often involves a treatment such as placement of stents, coils, etc.

Michael Lewandowski (AC): The definition of patient should also include treatment.

Commented [JC122]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC123]: Action: Repeal. Rationale: MDH proposes to incorporate definition provisions in affected rule parts.

Commented [JC124]: Rich Geise (AC): Recommends changing "contact person" in .0565 to "contact individual".

Commented [JC125]: Action: Amend. Rationale: Update definition from "garment" to "equipment" to reflect current usage. Change "absorbing" to "<u>attenuating</u>" because it is more technical and precise.

AC: Keep "absorbing" (instead of "attenuating"), 05/30/17.

Rich Geise (AC): Recommends "absorbing" be left in because it is more commonly understood than attenuating. Attenuating is not defined. It is the absorbing quality of the material that makes it useful. A material that attenuates radiation purely by scatter production would certainly not be protective. Also consider adding "to an individual" to the end of the definition. [See discussion in Subp. 136]

Commented [JC126]: Action: Repeal. Rationale: Term is defined in subpart 84. *Discuss 4/4/17 changes to subp. 84.

Subp. 124a. Personal supervision. "Personal supervision" means a qualified practitioner in attendance in the room or viewing from an adjacent control area where a qualified practitioner can visually observe during the performance of the imaging procedure.

Subp. 125. Phantom. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. <u>This requires that</u> both the atomic number (Z) and the density of the material be similar to that of tissue.

Subp. 126. Phototimer. "Phototimer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation that reaches a radiation monitoring device. A radiation monitoring device is part of an electronic circuit that controls the duration of time the x ray tube is activated. "Phototimer" includes the meaning given for automatic exposure control in subpart 15.

Subp. 126a. Physician assistant. "Physician assistant" means a person registered according to an individual who is licensed under Minnesota Statutes, chapter 147A, who is qualified by academic training, practical training, or both to provide patient services as specified in the physician-physician assistant agreement under Minnesota Statutes, section 147A.20 recognized by the Minnesota Board of Medical Practice.

Subp. 127. Pixel or picture element. "Pixel" or "picture element" means an elemental area of a digital image.

29 DRAFT – Version 5.0 06/21/17 **This document may be made accessible upon request to <u>xrayrules@state.mn.us</u>.** Commented [JC127]: Action: Amend by adding new definition. Rationale: Relevant to radiation safety practices for fluoroscopy.

AC: Change "physician" to "<u>qualified practitioner</u>" and add "<u>or viewing from an adjacent control area</u>", 05/30/17.

Commented [JC128]: Action: Amend. Rationale: Proposed language is consistent SSRCR part F definition.

Commented [JC129]: Action: Repeal. Rationale: Term is addressed by definition of "automatic exposure control" under subpart 84.

Commented [JC130]: Action: Amend. **Rationale:** Update definition because PA's are now licensed, not registered. MDH proposes to cite the statute instead of naming Board of Medical Practice.

Commented [JC131]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 128. Port film or portal imaging. <u>"Port film" or "portal imaging" means a</u> radiographic film or electronic image taken with a therapeutic x-ray system to verify proper setup of the treatment field.

Subp. 129. Positive beam limiting or limitation or PBL, <u>Positive beam limiting or</u> limitation" or "PBL" means the automatic or semiautomatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without this adjustment.

Subp. 130. Position-indicating device or PID. "Position-indicating device" or "PID"

means a device on dental x-ray equipment used to indicate the beam position and to establish the source to skin distance.

Subp. 131. Prescribed dose. "Prescribed dose" means the total radiation dose and radiation dose per fraction as documented in the written directive or therapeutic order.

Subp. 132. Primary beam. "Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation-producing equipment housing.

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

Subp. 134. Primary protective barrier. "Primary protective barrier" means the material,

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Commented [JC132]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC133]: Action: Repeal. Rationale: Propose to incorporate definition provisions in affected rule parts.

Commented [JC134]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC135]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC136]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC137]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC138]: Action: Repeal. **Rationale:** Define primary and secondary barrier under the definition protective barrier.



excluding filters, placed in the useful beam for protection purposes to reduce the radiation

exposure.

Subp. 135. Protective apron. "Protective apron" see personal protective garments in subpart 123.

Subp. 136. Protective barrier or barrier. "Protective barrier" or "barrier" means a

structural barrier of radiation-absorbing materials used to reduce radiation exposure and

includes:

1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

2. "Secondary protective barrier" means a barrier sufficient to absorb the stray radiation

to the required degree.

Subp. 137. Protective glove. "Protective glove," see personal protective garments in subpart 123.

Subp. 138. 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. 138a. Qualified medical physicist or QMP. "Qualified medical physicist or QMP"

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Commented [JC139]: Action: Repeal. Rationale: Contained within definition of PPE, subp. 123.

Commented [JC140]: Action: Amend. Rationale: Clarify by defining primary and secondary protective barrier. Based on Iowa rules.

Michael Lewandowski (AC): Attenuating is a better adjective than absorbing. Reduction in radiation exposure may be achieved through absorption of radiation or scattering of radiation. See #2 under Subp. 136. [See discussion in Subp. 123] AC: Recommend using "absorbing" instead of "attenuating", 05/30/17. Note: MDH will consider a Cathpax as PPE.

Commented [JC141]: Action: Repeal. Rationale: Added to the definition of personal protective equipment.

Commented [JC142]: Action: Repeal. Rationale: Term is not used in rule chapter.

Commented [JC143]: Action: Amend by adding new definition. Rationale: QMP is a nationally recognized industry term for

individuals who perform medical physics on diagnostic x-ray equipment.

Notes: 1) MDH deleted originally proposed "<u>means a service</u> provider who meets each of the following credentials for diagnostic medical physics under part 4732.XXXX." 2) MDH will incorporate QMP requirements from SSRCR, Part F, into rule part.

means an individual trained in evaluating the performance of CT scanners x-ray systems, related equipment and facility quality assurance programs and who meets the requirements under part 4732.XXXX.

Subp. 138b. Qualified operator or operator. "Qualified operator" or "operator" means an individual who is authorized to operate diagnostic x-ray equipment for human use.

Subp. 138c. Qualified practitioner.

Subp. 139. Quality assurance program. "Quality assurance program" means <u>a</u> registrant's site-specific set of activities that includes policies and procedures designed to reduce unnecessary radiation exposure by optimizing the performance of facility personnel and equipment an all encompassing program including quality control that extends to administrative, education, and preventive maintenance methods. It includes a continuing evaluation of the adequacy and effectiveness of the overall imaging program, with a view to initiating corrective measures when necessary. The nature and extent of this program will vary with the size and type of the facility, and the type of activities conducted.

Subp. 140. Quality control. "Quality control" means a series of <u>standardized tests</u> <u>developed to detect changes in x-ray equipment-system and imaging receptor system function</u> <u>from its original level of performance</u> distinct technical procedures that ensure the production of a satisfactory product. The objective of these tests, when performed routinely, allows prompt, corrective action to maintain x-ray image quality and equipment performance. **Commented [JC144]: Action:** Amend by adding new definition.

Rationale: Placeholder. MDH would like to propose one term to define all operators of x-ray equipment for human and non-human use.

AC: Recommend removing reference to MS 144.121, subd. 5a, 05/30/17.

Commented [CJ(145]: Action: Amend by adding new definition.

Rationale: Placeholder. MDH will develop term to replace and encompass licensed practitioner of the healing arts.

Commented [JC146]: Action: Amend. Rationale: Concept of radiation safety is missing in current definition. Proposed language is based NCRP Report No. 99

 Quality Assurance for Diagnostic Imaging. By National Council on Radiation Protection and Measurements, p 1-3.
 MDH proposes to incorporate highlighted language in the rule part governing quality assurance.

Rich Geise (AC): Better left defined in .0520 which describes the QAP. If it stays, recommend "means activities identified by policies and procedures designed...etc". The program is not the manual. Alternatively, it might mean activities defined in a manual.

Commented [JC147]: Action: Amend. Rationale: Proposed language is based NCRP Report No. 99 – Quality Assurance for Diagnostic Imaging. By National Council on Radiation Protection and Measurements NCRP 99.

There is no definition of "quality control" in SSRCR.

Commented [CJ(148]: Added "equipment performance".

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is to provide quality that is not only satisfactory but also dependable and economic. The quality control procedures are concerned directly with the equipment.

Subp. 141. Quarter or quarterly. "Quarter" or "quarterly" means at an intervals that not to exceed 12 consecutive weeks. is not less than 12 consecutive weeks and not more than 14 consecutive weeks.

Subp. 142. Rad. "Rad" means is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 Gy). The SI equivalent is 0.01 gray.

Subp. 143. Radiation. "Radiation" means ionizing radiation.

Subp. 144. Radiation area. "Radiation area" means an area accessible to individuals in which the radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Subp. 145. 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. 146. Radiation head. "Radiation head" means the structure from which the useful beam emerges has the meaning given in part 4733.0105, subpart ##.

Subp. 147. Radiation-producing equipment. "Radiation-producing equipment" means

any device capable of producing radiation.

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Commented [JC149]: Action: Amend. Rationale: Recommend adding "<u>or quarterly</u>" and making syntax edit.

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731. 4731.0100, subp. 186. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 Gy).

Commented [JC150]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive

Materials).

Commented [JC151]: Action: Repeal. **Rationale:** Redundant. Amended definition of "ionizing radiation" definition to include "ionizing radiation <u>or</u> radiation".

Commented [JC152]: Action: Amend. Rationale: Not the full meaning of radiation detector needed for CT.

Commented [JC153]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 148. Radiation protection. "Radiation protection" means the use of time,

distance, shielding, and other personnel protective garments.

Subp. 148a. Radiation safety committee. "Radiation safety committee" means a representative group of qualified individuals in a CT or fluoroscopic facility responsible for the ongoing review and management of CT or FGI protocols, quality control, and quality assurance program.

Subp. 149. Radiation safety officer. "Radiation safety officer" means an individual who is responsible for administering has the knowledge and training to apply appropriate radiation protection standards in a registered facility, and has been assigned such responsibility by the registrant.

Subp. 150. Radiation therapy simulation system. "Radiation therapy simulation system" means a radiographic, fluoroscopic, or CT x-ray system including all software applicable to the process intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Subp. 151. Radiograph. "Radiograph" means an image produced on a radiosensitive surface, such as a photographic film or digital plate, by radiation other than visible light, such as by x-rays passed through an object or by photographing a fluoroscopic image that results in a permanent record.

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Commented [JC154]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC155]: Action: Amend by adding a new definition. Rationale: Missing from rule chapter.

AC: Recommend removing additional language from SSRCR definition and changing FGI to "fluoroscopic", 5/30/2017.

Rich Geise (AC): Presents an unrealistic expectation of a committee. To ensure the desired image quality at the lowest possible dose was achieved in FGI, one would have to observe and constantly second-guess the fluoroscopy operator. This only referred to in .0600 in relation to fluoroscopic events. Duties and responsibilities should be defined there.

Commented [JC156]: Action: Amend. **Rationale:** Syntax edits to clarify and improve readability.

Commented [JC157]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). Term is specific to radiation therapy application.

Commented [JC158]: Action: Repeal. **Rationale:** Added to the definition of "image".

Subp. 152. Radiographic imaging system. "Radiographic imaging system" means any system where a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

Subp. 152a. Radiology practitioner assistant or RPA. <u>"Radiology practitioner assistant"</u> or "RPA" means an individual who is an advanced level radiographer registered with the American Registry of Radiologic Technologists and certified by the Certification Board for Radiology Practitioner Assistants. The individual is qualified by completion of an educational program recognized by the Board of Directors of the Certification Board for Radiology Practitioner Assistants. The RPA may provide patient services as specified in an agreement with a supervising radiologist.

Subp. 153. Rated line voltage. "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the radiation-producing equipment is designed to operate.

Subp. 154. Rating. "Rating" means the operating limits as specified by the component manufacturer.

Subp. 155. Recording. "Recording" means producing a retrievable form of an image resulting from x-ray photons.

Subp. 156. Reference man. "Reference man" means a hypothetical aggregation of human physical and physiological characteristics. These characteristics may be used by

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Commented [JC159]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC160]: Action: Repeal. **Rationale:** MDH proposes to incorporate highlighted provision into affected rule part. MDH will review at a later time when we review who is qualified to supervise for fluoroscopy.

Commented [CJ(161]: Is this language still going into the rule part?

Commented [JC162]: Action: Repeal. Rationale: Term is not used in rule chapter.

Commented [JC163]: Action: Repeal. Rationale: Term is not used in rule chapter.

Commented [JC164]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC165]: Action: Repeal. Rationale: Term is not used in rule chapter.

researchers and public health workers to standardize results of experiments and to relate

biological insult to a common base.

Subp. 157. Reference plane. "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

[There is no Subpart 158 in M. Rules, part 4732.0110.]

Subp. 159. Registered radiologist assistant or RRA. "Registered radiologist assistant" or "RRA" means a person who is an advanced level radiographer certified and who is registered as a radiologist assistant in radiography by the American Registry of Radiologic Technologists_ and has successfully completed all elements of a radiologist assistant educational program recognized by the ARRT. The RRA would be able to provide patient services as specified in an agreement with a supervising radiologist.

Subp. 160. Registrant. "Registrant" means:

A. a person having administrative control of any radiation-producing equipment except those specifically exempted under this chapter and who is legally obligated to register with the commissioner according to this chapter; or
B. a person who is legally obligated to register with the commissioner as a service provider.

Subp. 161. Registration. "Registration" means registration with the commissioner according to this chapter.

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Commented [JC166]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC167]: Action: Amend. Rationale: Changes are consistent with ARRT. ARRT does not "certify" radiologist assistants; it is only a registration.

Commented [CJ(168]: End of 5/230/2017 AC meeting review.

Subp. 162. Rem. "Rem" means a special unit of <u>any of the quantities expressed as dose</u> <u>equivalent</u> equivalence. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). The SI equivalent is 0.01 sievert.

Subp. 163. Restricted area. "Restricted area" means any an area, to which access to which is or egress may be limited by the <u>a licensee or</u> registrant for purposes of protection of to protect individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but includes separate rooms in a residential building that are set apart as a restricted area.

Subp. 164. Retake or reject. <u>"Retake" or "reject" means any diagnostic radiographic</u> imaging that had to be retaken, reexposing the patient to radiation because of some error, failure, or degradation in the radiographic imaging process.

Subp. 165. Retake or reject analysis program. "Retake or reject analysis program" means an ongoing analysis of retakes or rejects that provides information about existing imaging problems in a radiology department.

Subp. 166. Roentgen or R. "Roentgen" or "R" means is a special unit of exposure. The roentgen is equal to 2.58 x 10-4 coulombs per kilogram of air. One milliroentgens (mR) equals

0.001 roentgen.

Subp. 167. Scattered radiation or secondary radiation. "Scattered radiation" has the meaning given in part 4733.0105, subpart ## or "secondary radiation" means radiation that,

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Commented [JC169]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 201. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

Commented [JC170]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 205. Restricted area means an area, access to which is limited by a licensee or registrant to protect individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but includes separate rooms in a residential building that are set apart as a restricted area.

Commented [JC171]: Action: Repeal. Rationale: Term is addressed in part 4732.0535 (retake or reject analysis program).

Commented [JC172]: Action: Repeal. Rationale: Definition is not needed. Part 4732.0535 describes and governs the retake or reject analysis program.

Commented [JC173]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 206. Roentgen or R. "Roentgen" is a special unit of exposure equal to 2.58 x 10-4 coulomb per kilogram of air. One milliroentgens (mR) equals 0.001 roentgen.

Commented [JC174]: Action: Amend. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy).Term is specific to radiation therapy application.

As proposed in new new chapter 4733: "Scattered radiation" means radiation that, during its passage through a substance, has been changed in direction and may also have been modified by a decrease in energy."

during passage through matter, has been deviated in direction and may have also been

modified by a decrease in energy.

Subp. 168. Secondary dose-monitoring system. "Secondary dose monitoring system"

means a system that will terminate irradiation if the primary dose-monitoring system fails.

Subp. 169. Secondary protective barrier. "Secondary protective barrier" means a

barrier sufficient to attenuate stray radiation.

Subp. 170. Sensitometer. "Sensitometer" means an instrument designed to

reproducibly expose a piece of film to a number of different levels of light intensity.

Subp. 171. Sensitometric strip. "Sensitometric strip" means a film exposed by a

sensitometer, resulting in a gray scale range. The strips are used to measure the range of densities from minimum to maximum.

Subp. 172. Sensitometry. <u>"Sensitometry" means a quantitative measurement of the</u> response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

Subp. 173. Service provider. "Service provider" means a person engaged in the business of assembling, installing, repairing, or replacing one or more components into <u>a</u> diagnostic or <u>an</u> industrial radiation-producing equipment system or subsystem, or conducting equipment performance evaluations on diagnostic or industrial equipment. Service providers must be registered with the commissioner under part 4732.0275.

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Commented [JC175]: Action: Repeal. **Rationale:** The definition proposed to be part of new chapter 4733 (Radiation Therapy). Term is specific to radiation therapy application.

Commented [JC176]: Action: Repeal. Rationale: Term is not used in rule chapter. Incorporate term in "Primary Protective Barrier", subp. 136.

Commented [JC177]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC178]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

Commented [JC179]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC180]: Action: Amend. **Rationale:** Striking requirement provision as it is already contained in rule part.



Subp. 174. Shadow tray. "Shadow tray" means a device attached to the radiation head

to support auxiliary beam-limiting material.

Subp. 175. Shutter. "Shutter" has the meaning given in part 4733.0105, subpart ## 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 or Sv. "Sievert" or "Sv" means is the SI unit of any quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor identified in subpart 183 (1 Sv = 100 rems). The

conventional system equivalent is the rem.

Subp. 178. Source. "Source" means the target or focal spot of the x-ray tube or

accelerator radiation-producing equipment.

Subp. 179. Source of radiation. "Source of radiation" means a device or equipment that emits or is capable of producing radiation. For purposes of this chapter, this is equivalent to radiation-producing equipment.

Subp. 180. Source-to-image distance or SID. "Source-to-image distance" or "SID" means

the distance from the source to the center of the input surface of the image receptor.

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Commented [JC181]: Action: Repeal. **Rationale:** Term not used in rule chapter.

Commented [JC182]: Action: Amend. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC183]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731.

4731.0100, subp. 215. SI equivalent means the international system of units.

Commented [JC184]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731

4731.0100, subp. 215. Sievert or Sv is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor identified in subpart 183 (1 Sv = 100 rems).

Commented [JC185]: Action: Amend. Rationale: Clarification.

Commented [JC186]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC187]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Subp. 181. Source-to-skin distance or SSD. - "Source-to-skin distance" or "SSD" means

the distance between the source and the skin of the patient.

Subp. 182. Spot check. <u>"Spot check" means a procedure that is performed to ensure</u>

Subp. 183. Spot film. "Spot film" means a radiograph that is made during a fluoroscopic procedure to permanently record conditions that exist during that fluoroscopic procedure.

Subp. 184. Spot-film device. "Spot-film device" means a device intended to transport and position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. Spot-film device includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor to produce 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. Step wedge. <u>"Step wedge" means a quality control test tool made of type</u>

Subp. 187. Stepless adjustment. "Stepless adjustment" means a method of adjusting collimator blades continuously rather than in fixed increments.

Subp. 188. Stochastic effects. "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is

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Commented [JC188]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC189]: Action: Repeal. Rationale: Essentially an EPE (equipment performance evaluation). Common industry definition; not needed in rule.

Commented [JC190]: Action: Repeal. Rationale: Common industry definition; not needed in rule.

Commented [JC191]: Action: Repeal. **Rationale:** Obsolete as used in rule chapter.

Commented [JC192]: Action: Repeal. **Rationale:** The definition proposed to be part of new chapter 4733 (Radiation Therapy). Term is specific to radiation therapy application.

Commented [JC193]: Action: Repeal. **Rationale:** Term is already defined in rule part.

Commented [JC194]: Action: Repeal. **Rationale:** Used once in definition of "variable-aperture beam-limiting device" which is proposed to be repealed.

Commented [JC195]: Action: Repeal. **Rationale:** Term is not used in rule chapter.

assumed to be a linear function of dose without threshold. Hereditary effects and cancer

incidence are examples of stochastic effects.

Subp. 189. Storage. <u>"Storage" means a condition in which a device or radiation-</u> producing equipment is not being used for an extended period of time and has been made inoperable.

Subp. 190. Storage area. "Storage area" means a location, facility, or vehicle that is locked or has a physical barrier to prevent accidental exposure to, tampering with, or unauthorized removal of the device, container, or source.

Subp. 191. Stray radiation. "Stray radiation" has the meaning given in part 4733.0105, subpart ## means the sum of leakage radiation and scattered radiation.

Subp. 192. Supervising physician. "Supervising physician" means a Minnesota licensed physician who accepts full medical responsibility for the performance, practice, and activities of a physician assistant according to Minnesota Statutes, section 147A.20, a registered radiologist assistant, or a radiology practitioner assistant.

Subp. 193. Survey or radiation survey. "Survey" or "radiation survey" means an evaluation of the radiological conditions and potential hazards incident to the use of radiationproducing equipment. When appropriate, such evaluation <u>and</u> includes, but is not limited to, tests, using physical examinations, and measurements of measuring levels of radiation.

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Commented [JC196]: Action: Repeal. Rationale: MDH will address definition and requirements for storage in rule part.

Commented [JC197]: Action: Repeal. **Rationale:** Term is not used in rule chapter. MDH will add to proposed industrial provisions.

Commented [JC198]: Action: Amend. **Rationale:** The definition will be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application. As proposed in new chapter 4733: <u>"Stray radiation" means the sum of leakage and scattered</u>

Commented [JC199]: Action: Repeal. Rationale: There is no requirement in rule currently that addresses written agreement for RRA or RPA.

radiation including x-ray, electron, and neutron.

Commented [JC200]: Action: Amend. Rationale: Clarifying to improve readability.



Subp. 194. Target. "Target" has the meaning given in part 4733.0105, subpart ## means

the part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

Subp. 195. Technique factors. "Technique factors" means the conditions of operation for a specific procedure including source to image distance, kVp, mA, time, patient size, and image receptor type., 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 the 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;

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Commented [JC201]: Action: Repeal. Rationale: The term is more specific to a radiation therapy application. As proposed in new chapter 4733: *"Target" means the part of a radiation-producing system used to intercept a beam of accelerated particles and cause emission of other radiation.*

Commented [JC202]: Action: Amend. **Rationale:** Condensing definition and will incorporate specific procedure requirements in affected rule parts.

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. 196. Television receiver. "Television receiver" means an electronic product designed to receive and display a television picture through broadcast, cable, or closed-circuit

television.

Subp. 197. Temporary job site. "Temporary job site" means a location where

radiography is performed, other than a location listed in a registration.

Subp. 198. 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. 199. Therapeutic radiation machine. <u>"Therapeutic radiation machine" means x-</u>

Subp. 200. Therapeutic radiological physicist. "Therapeutic radiological physicist" means an individual qualified to practice independently in the subfields for medical therapeutic physics who:

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Commented [JC203]: Action: Repeal. Rationale: Obsolete.

Commented [JC204]: Action: Repeal. Rationale: MDH will incorporate provision in affected rule part 4732.1058.

Commented [JC205]: Action: Repeal. **Rationale:** Definition is proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC206]: Action: Repeal. **Rationale:** Definition is proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC207]: Action: Repeal. **Rationale:** Definition is proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

A. is certified in radiological physics or therapeutic radiological physics by the

American Board of Radiology;

B. is certified in therapeutic radiological physics by the American Board of

Medical Physics;

C. is certified in therapeutic radiological physics by the Canadian College of

Medical Physics; or

D. holds a masters degree or doctor's degree in medical physics, radiological sciences, or an equivalent field involving graduate study in physics applied to the application of radiation to humans from an accredited college or university and have at least one year of full time practical training and experience involving work in a radiation therapy facility under an individual who meets the qualifications in this item or item A, B, or C.

Subp. 201. Therapeutic-type protective tube housing. "Therapeutic type protective tube housing" means the definitions in items A to C.

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 rad (0.01 Gy) in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

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Commented [JC208]: Action: Repeal. **Rationale:** The definition is proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

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 rad (0.01 Gy) 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 in items A and B.

Subp. 202. Tomogram. "Tomogram" means an x-ray image of a thin section of the body.

Subp. 203. Tomographic plane. <u>"Tomographic plane" means the geometric plane that is</u> identified as corresponding to the output tomogram.

Subp. 204. Tomographic section. <u>"Tomographic section" means the volume of an object</u> whose x-ray attenuation properties are imaged in a tomogram.

Subp. 205. 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.

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Commented [JC209]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC210]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC211]: Action: Repeal. **Rationale:** Common industry definition; not needed in rule.

Commented [JC212]: Action: Repeal. **Rationale:** Definition is contained within definition of "instrument traceability".

Subp. 206. Tube housing assembly. "Tube housing assembly" means the tube housing with tube installed. It includes high voltage and filament transformers and other appropriate elements when contained within the tube housing.

Subp. 207. 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. 208. Type 1100 aluminum alloy. <u>"Type 1100 aluminum alloy" means an alloy of</u> aluminum that has a nominal chemical composition of 99 percent minimum aluminum and 0.12 percent copper.

Subp. 209. Useful beam. "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Subp. 210. Utilization log. "Utilization log" means a record of procedures conducted in a certain time frame and following a set of requirements:

A. medical in part 4732.0545;

B. fluoroscopic in part 4732.0825; and

C. industrial in part 4732.1040.

Subp. 211. 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.

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Commented [JC213]: Action: Repeal. **RECONSIDER Rationale:** Common industry term; not needed in rule.

Commented [JC214]: Action: Repeal. **Rationale:** Obsolete term, not needed.

Commented [JC215]: Action: Repeal. Rationale: Common industry term. MDH will incorporate in rule

Commented [JC216]: Action: Repeal. **Rationale:** The term is more specific to a radiation therapy application and proposed to be added new chapter 4733. As proposed in new chapter 4733: *"Useful beam" means the radiation that emanates from the activated tube-housing port or radiation head and passes*

Commented [JC217]: Action: Repeal. Rationale: Definition provisions already contained in affected rule part.

through the aperture of the beam-limiting device.

Commented [JC218]: Action: Repeal. Rationale: Term is not used in rule chapter.

Subp. 195a. Verbal order. "Verbal order" means an order for an imaging procedure that

is issued orally by an individual authorized under this chapter.

Subp. 212. Very high radiation area. "Very high radiation area" means an area accessible to individuals, where in which radiation levels from radiation-producing equipment sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rad (5 Gy) in one hour at one meter from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (rads and grays) are appropriate, rather than units of dose equivalent (rems and sieverts).

Subp. 213. Virtual source.-"Virtual source" means a point from which radiation appears to originate.

Subp. 214. 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. 215. Wedge filter. <u>"Wedge filter" means an added filter effecting continuous</u> change in transmission on all or part of the useful beam.

Subp. 216. 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. 217. Written directive or written order. "Written directive" or "written order" means a dated order either in writing or electronically for <u>a</u> specific patient, a specific <u>imaging</u>

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Commented [JC219]: Action: Amend by adding a new definition.

Rationale: Missing from rule chapter. Additional requirement to be added in rule chapter: *A person authorized to order must authenticate a verbal order within 48 hours of an imaging procedure.*

Commented [JC220]: Action: Amend by conforming definition to Minn. Rules chapter 4731 (Radioactive Materials).

Rationale: Advisory committee recommends keeping full definition in ch. 4732. (1/31/17, AC consensus opinion) If the definition differs in wording, amend so that ch. 4732 is consistent with ch. 4731

4731.0100, subp. 259. Very high radiation area means an area accessible to individuals in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 Gy) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (rads and grays) are appropriate, rather than units of dose equivalent (rems and sieverts).

Commented [JC221]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC222]: Action: Repeal. Rationale: MDH to incorporate provision in the affected rule part governing veterinary medical radiographic systems.

Commented [JC223]: Action: Repeal. **Rationale:** Definition proposed to be part of new chapter 4733 (Radiation Therapy). The term is more specific to a radiation therapy application.

Commented [JC224]: Action: Amend. **Rationale:** Striking "written directive" since that pertains to radiation therapy.



procedure, and has an indication of and identifies the licensed practitioner of the healing arts

<u>qualified practitioner</u> ordering the <u>imaging</u> procedure.

Subp. 218. X-ray control. "X-ray control" means a device, switch, or other similar means

by which an operator <u>a qualified operator</u> initiates and terminates the radiation exposure. The x-ray exposure control may include associated equipment such as timers and back-up timers.

Subp. 219. X-ray equipment or X-ray machines. "X-ray equipment" or "X-ray machines" means an x-ray system, subsystem, or component. Types of x-ray equipment are listed in items

A to D that includes:

A. "Mobile x-ray equipment" means x-ray equipment mounted <u>on a permanent</u> <u>base with wheels or casters for moving while completely assembled</u> in a selfcontained transport vehicle.

B. "Portable industrial x-ray equipment" means industrial x-ray equipment designed to be brought to a temporary job site to perform temporary industrial radiography.

<u>CB</u>. "Portable x-ray equipment" means x-ray equipment <u>designed to be hand-</u> <u>carried</u> on wheels or casters and designed to be brought to a patient when the patient's condition does not permit transfer to a fixed location.

 \underline{PC} . "Stationary x-ray equipment" means x-ray equipment <u>that is</u> installed in a fixed location within a facility.

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Commented [JC225]: Action: Amend. Rationale: Modifying "operator" because MDH is defining "<u>qualified operator</u>".

Michael Lewandowski (AC): Definition of x-ray control should not include "qualified operator" since "qualified operator" (Subp. 138a) is restricted to operating diagnostic equipment for human use. X-ray control should also apply to industrial and research x-ray equipment.

Commented [JC226]: Action: Amend. **Rationale:** Revising to be consistent with SSRCR, Part F, definition of "x-ray equipment". Adding "<u>or x-ray machines</u>" to be consistent with Minn. Stat. 144.121.

D. "Hand-held x-ray equipment" means x-ray equipment that is designed to be

hand-held during operation.

Subp. 220. 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. 221. 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. 222. 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. 223. 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, <u>image receptor, x-ray table</u>, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

Subp. 223a. X-ray table. "X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during 49

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Commented [JC228]: Action: Repeal. Rationale: Term in not used in rule chapter.

Commented [JC229]: Action: Repeal. Rationale: Common industry term; not needed in rule.

Commented [JC230]: Action: Amend. **Rationale:** Specifying "<u>image receptor</u>" and "<u>x-ray table</u>" as additional components.

Michael Lewandowski (AC): Definition of X-ray system should include, but not require, "x-ray table" since "x-ray table" (Subp. 223a) is defined as a patient support device. X-ray system should also include industrial and research xray devices.

Commented [JC231]: Action: Amend by adding a new definition. Rationale: Missing from rule chapter, based on SSRCR Part F. Also added to definition of "x-ray system".



radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a

radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel,

fluoroscopic image receptor, or spot-film device beneath the tabletop.

Subp. 224. 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.

Subp. 225. Year. "Year" means a period of time consisting of 12 consecutive months.

Commented [JC232]: Action: Repeal. Rationale: Common industry term; not needed in rule.

Commented [JC233]: Action: Repeal. **Rationale:** Not all instances of "year" in rule chapter align with this definition. May need to specify in each rule part where we mean 12 consecutive months.

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