DEPARTMENT OF HEALTH

Draft MN Rules, Chapter 4732 – X-ray Revision, v3

4732.1200 [PURPOSE AND SCOPE.]

4732.1300 [DEFINITIONS.]

4732.1400 FACILITY AND X-RAY SYSTEM REGISTRATION.

Subpart 1. **Applicability**. A person or registrant is responsible for the x-ray systems under its administrative control and must comply with the requirements of this chapter.

A. A person must register a facility and an x-ray system with the commissioner according to Minnesota Statutes, section 144.121.

B. A registration for a facility or an x-ray system under this chapter is not transferable.

C. A facility fee or an x-ray system fee paid under this chapter is not transferable or refundable.

D. X-ray systems that are in transit or inoperable are exempt from the requirements of this chapter. For purposes of this part:

(1) inoperable means that the x-ray tube is removed from the x-ray system, or the x-ray system has been made physically inoperable by inactivating or dismantling the electrical circuitry such that the x-ray system is not capable of producing radiation; and

Commented [JC(1]: New definition:
Administrative control means the provisions relating to a registrant's oversight and compliance of x-ray systems, x-ray operators, quality assurance, procedures, recordkeeping, training, and all applicable requirements according to this chapter for the safe operation of a registered facility.

(2) in transit means x-ray systems that are non-operational and under the control of a registered service provider before installation are exempt from the registration and fee requirements of this part.

E. An x-ray system in storage must be registered according to this part. For purposes of this part, storage means a condition in which an operable x-ray system is not being used.

F. Electron microscopy equipment is exempt from the requirements of this chapter according to Minnesota Statutes, section 144.121, subdivision 1a, paragraph c.

G. Domestic television receivers that produce radiation incidental to its operation for other purposes are exempt from the requirements of this chapter provided the dose rate at 5 cm from any outer surface of 10 cm^2 is less than 0.5 mrem per hour.

Subp. 2. **Application; pre-registration.**

A. An applicant that is acquiring an x-ray system must pre-register with the commissioner.

B. An applicant must provide all applicable pre-registration information on a form or in a format prescribed by the commissioner including:

(1) the legal name of the facility;

(2) the name, email address, and telephone number of the responsible individual of the facility;

(3) the address of the facility physical location where the x-ray system is located; and

Commented [JC(2]: FL definition

Commented [JC(3]: Colorado:
A radiation machine that is out of service yet kept at a facility is exempt from the registration and certification evaluation provided:
1.the radiation machine has been made physically inoperable by inactivating or dismantling the electrical circuitry such that the radiation machine is not capable of producing radiation, and
2.the Department has received documentation of "Disposition of a Radiation Machine", or equivalent form, that is signed by a registered service technician

Commented [TP(4]: KY

(4) confirmation that a shielding plan for the acquired x-ray system is completed according to part 4732.#### .

Commented [JC(5]: Reference to **Shielding Plan** part (TBD)

Subp. 3. **Registration; initial.**

A. An applicant that is registering an x-ray system must submit to the commissioner:

(1) a completed application for registration under item B; and

(2) a nonrefundable fee according to Minnesota Statutes, section 144.121, subdivision 1a.

B. A registrant must apply for registration of its facility and x-ray systems within 30 days of installation and be registered before first use.

C. The application for registration under item A, subitem (1), must be on a form or in a format prescribed by the commissioner and includes:

(1) the legal name of the facility;

(2) the facility registration number, if applicable;

(3) the mailing address, email address, telephone number, and, if applicable, the website address;

(4) the name, email address, and telephone number of the responsible individual of the facility;

(5) the name, email address, and telephone number of the individual designated as the radiation safety officer for the facility;

(6) the federal tax identification number of the facility;

(7) the Minnesota tax identification number of the facility, if applicable;

(8) indication of facility type;

(9) the x-ray system type, manufacturer, serial number, model number, and installation date of the x-ray system;

(10) an unique alpha-numeric identifier that designates an x-ray system, assigned by the registrant, that is used:

a) in correspondence with the commissioner; and

b) during an inspection;

(11) the number of x-ray tubes in each x-ray system;

(12) the location of the x-ray system within the facility;

(13) the imaging receptor type, if applicable;

(14) confirmation of the facility's institutional review board according to part 4732.####, if applicable;

Commented [JC(6]: Reference to **Registrant Responsibilities** part (Subp. 22)

(15) confirmation of off-site mobile or portable services provided by the facility, if applicable;

(16) the date of the application;

(17) the signature or electronic authorization by the responsible individual certifying that the information is accurate and complete; and

(18) any additional information the commissioner deems necessary for evaluation of the application for registration.

Subp. 4. **Denial of application.**

A. The commissioner shall deny an application for registration if a registrant's registration does not meet the requirements of subpart 3.

B. The commissioner shall follow the criteria for a denial of an application under Minnesota Statutes, section 144.99, subdivision 8, paragraph (a) or (b).

C. The commissioner shall notify an applicant electronically or in writing of the denial of the registration and provide the reason for the denial.

Subp. 5. **Notice of registration; issuance.**

A. The commissioner shall issue a notice of registration to a registration that meets the requirements of subpart 3.

B. A registration is valid for one year from the date of issuance.

Subp. 6. **Registration; annual renewal.** A registrant must renew a registration annually by submitting an application and the nonrefundable fee under subpart 3 within 60 days of the expiration date of the existing registration.

Subp. 7. **Registration; expiration.**

A. If a registrant does not submit an application for renewal according to subpart 4, postmarked on or before the expiration specified on the notice of registration, then the registrant must cease operation.

B. The commissioner shall apply a penalty fee for late registration according to Minnesota Statutes, section 144.121, subd. 1b.

Commented [TP(7]: Late fees are incorporated within MN Statute

Subd. 1b.Penalty fee for late registration.
Applications for initial or renewal registrations submitted to the commissioner after the time specified by the commissioner shall be accompanied by an amount equal to 25 percent of the fee due in addition to the fees prescribed in subdivision 1a.

Subp. 8. **Registration; suspension.** The commissioner shall suspend a registration issued under this chapter according to Minnesota Statutes, section 144.99 subdivision 9.

Subp. 9. **Registration; revocation.** The commissioner shall revoke a registration issued under this chapter according to Minnesota Statutes, section 144.99 subdivision 9.

Subp. 10. **Registration; additional x-ray system.**

A. A registrant that acquires an additional x-ray system outside of renewal must submit to the commissioner:

(1) a completed application for an additional x-ray system under item B; and

(2) a nonrefundable fee according to Minnesota Statutes, section 144.121, subdivision 1a.

B. A registrant must register additional x-ray systems within 30 days of installation and be registered before first use.

C. The application for an additional x-ray system registration under item A must be on a form or in a format prescribed by the commissioner and includes:

(1) the legal name of the facility;

(2) the facility registration number;

(3) the facility physical location;

(4) the x-ray system type, manufacturer, serial number, model number, and installation date of the x-ray system;

(5) an unique alpha-numeric identifier that designates an x-ray system, assigned by the registrant, that is used:

a) in correspondence with the commissioner; and

b) during an inspection;

(6) the number of x-ray tubes in each x-ray system;

(7) the location of the x-ray system within the facility;

(8) the imaging receptor type, if applicable;

(9) confirmation of the facility's institutional review board according to part 4732.####, if applicable;

Commented [JC(8]: Reference to **Registrant Responsibilities** part (Subp. 22)

(10) confirmation of off-site mobile or portable services provided by the facility, if applicable;

(11) the date of the application;

(12) the signature or electronic authorization by the responsible individual certifying that the information is accurate and complete; and

(13) any additional information the commissioner deems necessary for evaluation.

Subp. 11. **Out-of-state x-ray systems.**

Commented [TP(9]: MI language; TN, MD

A. A person that brings an x-ray system into the state for any use must:

(1) register the x-ray system with the commissioner;

(2) comply with all applicable laws and rules; and

(3) provide electronic or written notice to the commissioner of 3 working days before the x-ray system is to be used in the state.

B. The notice under item A, subitem (3) must be on a form or in a format prescribed by the commissioner and includes:

(1) the facility registration number;

(2) the name of registrant;

(3) the type of x-ray system including manufacturer, model, and serial number;

(4) the name of the individual operating the registrant's x-ray system;

(5) the nature, duration, and scope of use;

(6) the facility physical location or locations where the x-ray system will be used;

(7) the name, email, and telephone number of contact person at the facility physical location where the x-ray system will be used; and

(8) any additional information the commissioner deems necessary for evaluation.

C. For purposes of this subpart, working days has the meaning given in part 1400.2030, subpart 1.

Subp. 12. **Demonstration of x-ray systems.**

A. A registrant that intends to use a registered service provider's x-ray system for demonstration must:

(1) provide electronic or written notice to the commissioner of 3 working days prior to first demonstration use;

(2) register according to this part after 15 days;

(3) submit the nonrefundable fee according to Minnesota Statutes, section 144.121, subdivision 1a, after 15 days; and

(4) comply with the applicable requirements of this chapter.

B. For purposes of this subpart, working days has the meaning given in part 1400.2030, subpart 1.

Subp. 13. **Changes to registration**. A registrant must notify the commissioner electronically or in writing within 30 days of any change that invalidates the following registration information:

A. the legal name of the facility;

Commented [JC(10]: **New definition:**
Facility physical location means a single physical location where a registrant conducts business, x-ray systems are located, and at which the registrant or an employee of the registrant is available.

Commented [JC(11]: https://www.revisor.mn.gov/rules/1400.2030/

Commented [TP(12]: MD

Commented [KM(13]: Similar:
AR, CO, DE, FL, IA, LA, ME, MI, NC, ND, NM, OR, TX

B. the mailing address;

C. the facility physical location;

D. the facility email address;

E. the responsible individual and contact information;

F. the radiation safety officer and contact information;

G. the federal tax identification number; and

H. any additional information the commissioner deems necessary for evaluation.

Subp. 14. **Disposition of x-ray systems**. A registrant must notify the commissioner, on a form or format prescribed by the commissioner, within 30 days of disposition of a registrant's registered x-ray system.

A. The disposition notification includes:

(1) the legal name of the facility;

(2) the facility registration number;

(3) the facility physical location;

(4) the mailing address;

(5) the x-ray system type, manufacturer, model number, and serial number of the x-ray system;

(6) the number of x-ray systems remaining;

(7) the method of disposition of a registered x-ray system by:

a) sale or transfer;

b) disposal or recycle; or

c) rendering inoperable;

(8) the registration number of the person taking possession of the x-ray system, if applicable; and

(9) any additional information the commissioner deems necessary for evaluation.

B. A registrant that is removing an x-ray system from its registration by selling or transferring must submit documentation including:

(1) the name, mailing address, telephone number, and email address of the recipient; and

(2) the date the recipient takes possession.

C. A registrant that is removing an x-ray system from its registration by disposing or recycling must submit documentation that the x-ray system is physically inoperable including:

(1) the method of disposal;

(2) the date of disposal;

(3) the name and address of the recycling company; and

(4) documentation of disposal or recycling.

D. A registrant that indicates its x-ray system is out of service yet kept at a facility is exempt from registering the x-ray system only if:

(1) the x-ray system is inoperable; and

(2) the commissioner receives a service report under item E.

E. A registrant that is removing an x-ray system from its registration by rendering it inoperable must submit documentation from a registered service provider or a

licensed electrician indicating the x-ray system is inoperable and is no longer capable of producing radiation.

Subp. 15. **Registration not implied**. No person, in any advertisement, public notice, or other media posting, shall refer to the fact that their facility is registered with the commissioner, and no person shall state or imply that any activity under such registration has been approved by the commissioner.

Commented [JC(14]: Same: AL, DE, IA, KY, LA, ME, MI, NC, NM, OR, PA
SSRCR; 4732.0200, subp. 2, item C

Registrant Responsibilities

Subp. 16. **Registrant checklist responsibilities.** Before a registrant's first use of an x-ray system on individuals or before first use of an x-ray system in an academic institution, industrial, research, forensic science, or veterinary setting, a registrant must complete and maintain the checklist under subpart 17.

Commented [JC(15]: CO 2.7 Service company registrant responsibilities
TX (O)(2)

A. This subpart applies to a registrant's:

(1) initial installation of an x-ray system in a new facility;

(2) initial installation of an additional x-ray system in an existing facility; or

(3) replacement of an x-ray system according to part 4732.####.

Commented [JC(16]: Reference to **Shielding Plan** part (TBD)

B. A checklist must be completed initially for each x-ray system in a registrant's facility.

C. A registrant must not use an x-ray system if the required registered service provider signatures are not on the checklist under subpart 17, item A.

D. A registrant must have a copy of the checklist under subpart 17 available for review by the commissioner upon request.

Subp. 17. **Checklist requirements.** A registrant is responsible for verifying the required signatures on the checklist for each registrant's x-ray system on a form or in a format prescribed by the commissioner.

A. The checklist must be verified and signed, electronically or in writing, by the registered service provider who performs the initial equipment performance evaluation.

B. For each installed x-ray system, a registrant must obtain the manufacturer's guidance documents, instructions manuals, and manufacturer specifications from a service company or service provider.

Subp. 18. **Designation of radiation safety officer.**

A. A registrant must designate a radiation safety officer, with the written agreement of the registrant, who meets the requirements under part 4732.####.

B. A registrant must attest in writing that the radiation safety officer who meets the qualifications under 4732.####, subpart 5, has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer.

C. A registrant, through the designated radiation safety officer, is responsible for the radiation safety activities according to registrant-approved specific activities and this chapter.

D. The radiation safety officer, with written agreement of the registrant, may assign and document in the agreement specific activities to each radiation safety delegate.

Commented [JC(17]: Reference to **Radiation Safety Officer** part

Commented [JC(18]: Reference to RSO qualifications

E. A registrant must attest in writing that the radiation safety delegate who meets the qualifications under 4732.####, subpart 5, has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer.

F. A registrant may designate one or more radiation safety delegate to support the radiation safety officer.

Subp. 19. **Individuals qualified to operate x-ray systems on humans.**

A. A registrant must only allow individuals to operate an x-ray system if they meet the requirements under:

(1) part 4732.#### for a CT qualified operator;

(2) part 4732.#### for a fluoroscopic qualified operator;

(3) part 4732.#### for a radiographic qualified operator;

(4) part 4732.#### for a dental qualified operator;

(5) part 4732.#### for a breast biopsy qualified operator;

(6) part 4732.#### for a bone densitometry qualified operator; and

(7) part 4732.#### for a security screening qualified operator.

B. A registrant must review and maintain the following written or electronic documentation for a registrant's qualified operator for each x-ray system modality a list identifying all qualified operators including:

(1) first and last name; and

(2) qualifications.

Commented [JC(19]: Reference to RSO qualifications

Commented [BB(20]: Similar: TX, IL

Commented [TP(21]: MDH intends to revisit x-ray system modality and possibly define.

Subp. 20. **Personal protective equipment.** A registrant must provide personal protective equipment with a minimum of 0.25 mm lead equivalency.

Commented [BB(22]: Similar: TX

A. A registrant must evaluate protective garments for integrity initially, and at intervals not to exceed 24 months for breaks, tears, holes, missing material, or gaps, by:

(1) visual inspection;

(2) performing a tactile test; and

(3) imaging using a computed tomography excluding CBCT, fluoroscopy, or radiographic x-ray system if the registrant has such an x-ray system.

B. A registrant must document the evaluation results for each protective garment including:

(1) the name of the individual who performed the evaluation;

(2) the date of the evaluation;

(3) the pass or fail result;

(4) any saved images under item B, subitem (3), if applicable.

C. A registrant must remove from service any protective garment that fails the integrity evaluation.

D. For purposes of this subpart, protective garments means a full apron, a half apron, a vest, gloves, a thyroid collar, and any radiation-absorbing material used for protection.

Subp. 21. **Annual audit.**

A. A registrant must develop and implement a radiation program audit of its quality management system according to part 4732.#### or part 4732.#### for industrial x-ray systems.

B. A registrant must perform, sign, and date a radiation program audit at intervals not to exceed 12 months.

C. A registrant must document and correct any noncompliance issues found during an audit.

Subp.22. **Living human research; institutional review board.** Nothing in this subpart relieves a registrant from complying with the applicable requirements in this chapter and applicable federal regulations governing the use of x-ray systems when conducting research involving living human subjects.

A. A registrant may conduct research involving living human subjects using x-ray systems if the research is conducted according to federal regulations for the protection of living human subjects in research under Code of Federal Regulations, title 21, part 56 and Code of Federal Regulations, title 45, part 46.

B. Before imaging a living human subject, a registrant must:

(1) obtain prior review and approval of the research activities by an institutional review board;

(2) implement the requirements of The Federal Policy for the Protection of Human Subjects under Code of Federal Regulations, title 45, part 46; and

(3) obtain prior informed consent from the living human subjects.

Commented [JC(23]: Reference to **Quality Management System** part

MDH intends to revisit annual audit at the end of rule development and possible parts to be included.

Commented [JC(24]: CO

C. A registrant's research involving living human subjects must be conducted using x-ray systems authorized for medical use.

D. For purposes of this part, human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

4732.#### [SERVICE PROVIDERS.]

4732.#### LIMITED SCOPE X-RAY OPERATORS.

Subpart 1. **Applicability.** An individual who operates x-ray systems on living human beings in the discipline of limited medical radiography according to Minnesota Statutes, section 144.121, subdivision 5, must meet the training requirements of this part.

Subp. 2. **Limited scope x-ray operator examination registration.**

A. An applicant for the limited scope x-ray operator examination must register by completing a form, or in a format prescribed by the commissioner, including:

(1) legal name;

(2) date of birth;

(3) social security number;

(4) mailing address;

(5) phone number;

(6) email address;

(7) training course attended;

(8) training and classes completed;

(9) modules;

Commented [JC(25]: Dakota County Technical College; Inver Hills Community College https://minnesotatraining.com/programs/healthcare/limited-scope-x-ray-certification/

(10) electronic signature and date; and

(11) any additional information the commissioner deems necessary.

B. To be eligible for a limited scope x-ray operator registration, an applicant must:

(1) be eighteen years of age or older; and

(2) have a high school diploma or a GED certificate.

C. An applicant for limited scope x-ray operator registration must provide all information required by the commissioner including:

(1) certificate of completion from a training course provider approved by the commissioner;

(2) documentation of completing and passing the required training course according to subpart 6; and

(3) the nonrefundable registration fee according to Minnesota Statutes, section 144.121, subdivision 5, paragraph (d).

Subp. 3. **Denial of application.** The commissioner shall deny an application for a limited scope x-ray operator according to Minnesota Statutes, section 144.99 subdivision 8.

Subp. 4. **Limited scope x-ray operator practice.** Pursuant to Minnesota Statutes, section 144.121, subdivision 5, an individual may only operate x-ray systems on humans after passing the core module examination and is limited to the regions of the human anatomy for which the individual has passed the module examination.

A. Before operating an x-ray system on humans, an individual must pass:

(1) the core module examination with a score of 70 percent or greater; and

Commented [BB(26]: Similar: WI, TN, DE, TX

Commented [BB(27]: Multiple states limit the specific views and prohibit specific x-ray exams from being completed by limited scope x-ray operators.

Commented [BB(28]: 75% - AK, CO, ME, NJ, UT, WY, TX
70% - AR, IA, NE, ND, OR,
65%- TN, IL,

(2) at least one of the module examinations for the region of the anatomy to be imaged under items B to F.

B. A limited scope x-ray operator who has passed the module examination for chest allows an operator to image the:

(1) chest;

(2) ribs; and

(3) sternum.

C. An limited scope x-ray operator who has passed the module examination for extremities allows an operator to image the:

(1) fingers;

(2) hand;

(3) wrist;

(4) forearm;

(5) elbow;

(6) humerus;

(7) shoulder;

(8) clavicle;

(9) scapula;

(10) toes;

(11) foot;

(12) ankle;

(13) lower leg;

Commented [BB(29]: Similar: NE, IL, KY,

Commented [BB(30]: Similar: NE, IL, KY

(14) knee;

(15) patella;

(16) femur; and

(17) hip.

D. An limited scope x-ray operator who has passed the module examination for skull and sinuses allows an operator to image the:

(1) skull;

(2) paranasal sinuses;

(3) mandible; and

(4) facial bones.

E. An limited scope x-ray operator who has passed the module examination for spine allows an operator to image the:

(1) cervical spine;

(2) thoracic spine;

(3) lumbar spine;

(4) pelvis;

(5) sacroiliac joints;

(6) sacrum and coccyx;

(7) abdomen; and

(8) full spine for scoliosis.

F. An limited scope x-ray operator who has passed the module examination for podiatric allows an operator to image the:

Commented [BB(31]: Similar: NE, IL

Commented [BB(32]: Similar: NE, IL

Commented [BB(33]: Similar: IL, NE, KY

(1) foot;

(2) ankle; and

(3) distal third of lower leg.

G. If an applicant does not pass a module under items B to F with a score of 70 percent or greater, then the individual is prohibited from imaging that region of the human anatomy.

H. An applicant is limited to three attempts to pass any module examination. The three attempts must be completed within a 3-year period that starts when an initial application is approved by the commissioner.

I. An applicant who does not pass any of the module examinations within a three-year period is no longer eligible to take the module examinations. To regain eligibility to take a module examination, an applicant must repeat and pass a commissioner-approved limited scope x-ray operator training course under subpart 7.

Commented [BB(34]: **NJ**: after fourth attempts, redo LSXO training course
SC: after three attempts, redo LSXO training course
NE: after three attempts, wait one year and redo LSXO training to become eligible again for exam
OR: three years to pass all exam modules
OH: after one attempt, redo LSXO training course
TN: after fourth attempts, redo LSXO training course
DE: two attempts per calendar year
VA: after three attempts, redo LSXO training course
WY: after failed attempt, a 6 month waiting period before next attempt
FL: after five attempts, additional training is required

Commented [JC(35]: Reference to training approval

Subp. 5. **Prohibited uses.** Pursuant to Minnesota Statutes, section 144.121, subdivision 5, an individual who is registered with the commissioner as a limited scope x-ray operator is prohibited from operating:

A. fluoroscopy x-ray systems;

B. mammography x-ray systems;

C. computed tomography x-ray systems; and

D. x-ray systems during procedures using contrast media.

Subp. 6. **Required training course.** An applicant for a limited scope x-ray operator registration must complete and pass an training course under subpart 7 that is approved by the commissioner according to part 4732.#### and meets the requirements of this part.

Subp. 7. **Training course content.** An training course for a limited scope x-ray operator must have a minimum of 120 instruction hours and cover the subjects in this subpart.

A. Patient care:

(1) ethical and legal aspects;

(2) modes of communication including verbal, non-verbal, eye contact, and touching;

(3) challenges in communication;

(4) physical assistance and monitoring;

(5) medical emergencies;

(6) patient education, safety, and comfort;

(7) medical terminology; and

(8) infection control.

B. Radiation physics:

(1) structure of matter and the atom;

(2) general description of production of x-rays;

(3) x-ray emission, quantity and quality;

(4) function of filtration and effects it has on x-ray beam;

(5) types of function of beam limiting devices;

(6) collimation;

(7) design, features, and functions of x-ray tubes; and

Commented [TP(36]: 201 KAR: an applicant must complete an approved postsecondary educational program that meets the ASRT limited x-ray ray machine operator curriculum requirements. An individual must complete a formal education program for limited x-ray machine operators approved by the board. (KY)

Commented [JC(37]: Didactic training hours:
KY-240,
TN-90,
MT-min 104,
ND -80, IA-160+24 peds,
TX-125 (all modules) + 20 DR,
CO-80 hours,
WI – 336 hours

Clinical training hours:
KY-360,
TN-230,
MT-min 48,
ND – 3 months or 120 hrs (only under direct supervision +3 months additional probationary clinical hours,
IA- 140 clinical practice exams, + 60 ped exams,
WI – 96-340 hours,
CO- 480 hours,

(8) circuitry of the x-ray system.

C. Radiobiology:

(1) effects of ionizing radiation on the human body;

(2) molecular and cellular radiobiology; and

(3) factors that cause somatic and genetic damage.

D. Radiation protection:

(1) ALARA;

(2) shielding materials;

(3) radiation quantity and units of measurement;

(4) basic interactions of x-rays with matter;

(5) primary and secondary scatter;

(6) importance of time, distance, and shielding;

(7) maximum permissible doses for occupational workers and the public; and

(8) patient protection.

E. Principles of exposure:

(1) factors that control and influence radiographic quality;

(2) properties of x-rays;

(3) size distortion;

(4) shape distortion;

(5) kVp, mAs, and time;

(6) automatic exposure control (AEC) and manual settings;

(7) grids;

(8) collimation;

(9) intensifying screens;

(10) x-ray films and holders;

(11) artifacts; and

(12) inverse square law.

F. Procedures and processing:

(1) film storage and handling;

(2) manual, automatic processing film processing, and troubleshooting;

(3) computed radiography (CR);

(4) digital radiography (DR);

(5) picture archiving and communication system (PACS);

(6) quality assurance and quality control.

G. Anatomy and positioning:

(1) chest;

(2) extremities, including podiatry;

(3) spine; and

(4) skull and sinuses.

H. The limited scope x-ray operator examination from the American Registry of Radiologic Technologists website available at www.arrt.org. This website and the operator examination contents are updated periodically.

Subp. 8. **Personal supervision required.** An individual who has passed the core limited scope x-ray operator module and at least one additional module must be under the personal supervision of a qualified limited scope x-ray operator or a certified ARRT radiologic

technologist until the individual demonstrates clinical competency for each region of human anatomy passed.

Subp. 9. **Suspension of registration.** The commissioner shall suspend an individual's limited scope x-ray operator registration according to Minnesota Statutes, section 144.99 subdivision 9.

Commented [BB(38]: Similar: AK, IL, SC

Subp. 10. **Revocation of registration.** The commissioner shall revoke an individual's limited scope x-ray operator registration according to Minnesota Statutes, section 144.99 subdivision 9.

Commented [BB(39]: Similar: AK, IL, SC

4732.#### QUALITY MANAGEMENT SYSTEM.

Subpart 1. **Applicability.**

A. A registrant is responsible for developing, documenting, implementing, and maintaining written or electronic site-specific safety procedures, with the radiation safety officer that meet the requirements of this part.

Commented [BB(40]: Ohio 3701:1-66-04

B. A registrant's industrial x-ray systems are exempt from this part.

Commented [JC(41]: Industrial x-ray systems must follow procedures in the Industrial rule parts and will have a similar layout/framework.

Subp. 2. **Quality assurance program.** Each registrant must implement a quality assurance program that includes safety procedures for:

Commented [JC(42]: **Our proposed Definition:** Subp. 62. Quality assurance program. "Quality assurance program" means a registrant's site-specific set of activities that includes written procedures designed to reduce unnecessary radiation exposure by optimizing the performance of facility personnel and equipment.

A. interval requirements for the equipment performance evaluations and preventative maintenance of all x-ray systems to comply with applicable rules of this chapter and manufacturer specifications;

B. when x-ray system failures occur or when test results fall outside the tolerance limits;

C. facility-specific and system-specific operating procedures for each type of x-ray system that includes:

(1) projections where holding devices cannot be used;

(2) any restriction of the operating technique or parameter required for the safe operation of the particular x-ray systems; and

(3) operating procedures listed in each x-ray system modality.

D. emergency procedures for responding to malfunctioning x-ray systems;

E. training ancillary personnel initially and annually on radiation safety training according to part 4732.#### [Radiation safety];

F. instructions of operator responsibility to report a medical event notification to the registrant according to part 4732.####;

G. instructions of operator responsibility to report notification of theft or loss of an x-ray system to the registrant according to part 4732.####, if applicable;

H. storing portable x-ray systems when not in use by being secured in a restricted, locked area of the facility;

I. storing mobile x-ray systems when not in use by being:

(1) secured in a restricted, locked area of the facility;

(2) password-protected; or

(3) key-actuated.

J. off-site use of mobile or portable x-ray systems according part 4732.####, if applicable;

K. protective garment integrity according to part 4732.####, subpart 20;

L. declared pregnant workers;

Commented [JC(43]: BB - Similar: IL,

Commented [JC(44]: TP: We have discussed defining this above. When Steph and Bevin review all modalities for consistency we could fix operating procedures in each part.

Commented [JC(45]: MDH will add this definition to definitions part.

4732 - Ancillary personnel means all individuals who, in the course of employment in a year, are likely to receive an occupational dose in excess of 100 millirems (1.0 mSv) must be: (1) kept informed of the use of radiation;
(2) instructed in the health protection problems associated with exposure to radiation, in precautions to procedures to minimize exposure, and in purposes and functions of protective devices employed

Commented [BB(46]: Reference to MEDICAL EVENT.

Commented [BB(47]: Reference to NOTIFICATION OF THEFT OR LOSS.

Commented [JC(48]: Portable x-ray system definition: Mean x-ray system equipment designed to be hand-carried or handheld during operation.

Commented [TP(49]: See Minn Stat. 144.1215

Commented [JC(50]: Mobile x-ray system definition: X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

Commented [JC(51]: Reference to MOBILE OR PORTABLE REGISTRANTS.

Commented [JC(52]: Reference to REGISTRANT RESPONSIBILITIES

M. patient protection including:

(1) screening for pregnancy;

(2) exposure of pregnant patients; and

(3) patient shielding.

N. individuals, ancillary personnel, or occupational workers to:

(1) hold or assist patients; or

(2) remain in the room during radiation exposure

O. perform repeat or reject analysis of radiographic images at least quarterly for each applicable x-ray system; and

P. patient or subject identification.

Subp. 3. **Quality control program.** Each registrant must implement quality control program procedures that are consistent with the registrant's type of x-ray systems that include:

A. documenting the primary and secondary qualified operators responsible for quality control testing and an outline of their responsibilities;

B. a description of the performance standards, with specific tolerance limits established for each quality control test;

C. a description of the method used to test each parameter;

D. a list of each x-ray system parameter to be tested and a schedule of quality control testing for each x-ray system;

E. a procedure for x-ray system artifacts and appropriate actions taken;

F. a procedure for processor densitometer and sensitometer quality control, if applicable; and

Commented [JC(53]: Our proposed Definition: Subp. 63. Quality control. "Quality control" means a series of standardized tests developed to detect changes in x-ray system and imaging receptor system function from its original level of performance. The objective of these tests is to allow prompt, corrective action to maintain x-ray image quality and equipment performance.

Commented [BB(54]: New York QA guide

G. a procedure for image receptor maintenance, if applicable.

Commented [BB(55]: New York QA guide

Subp. 4. **Individual monitoring program.** Each registrant must implement an individual monitoring program that includes procedures for:

A. proper use of individual monitoring devices;

B. evaluating the required use of individual monitoring according to part 4732.####;

Commented [JC(56]: Reference to individual monitoring rule part

C. complying with occupational exposure limits according to part 4732.####;

Commented [BB(57]: Reference to individual monitoring rule part

D. providing an annual notification in writing to each current employee for radiation dose according to part 4732.####;

Commented [BB(58]: Reference to individual monitoring rule part

E. verifying that any employee receiving occupational exposure at multiple registrants does not exceed 5 rem per year;

F. notifying the registrant's administrator when individuals are occupationally over-exposed to radiation according to part 4732.#### [Individual monitoring – Report to individual worker beyond occupational levels];

Commented [BB(59]: OH wording

G. for occupational exposure of declared pregnant workers according to part 4732.####;

Commented [JC(60]: Reference to Dose Monitoring

H. obtaining and maintaining employees' occupational doses;

I. providing a report at the end of employment of a worker's dose of radiation according to part 4732.####; and

Commented [BB(61]: Reference to Individual Monitoring rule part

J. if minors are employed, maintaining occupational limits that must not exceed 500 millirem per year.

Subp. 5. **ALARA program**. Each registrant must implement an ALARA program that includes procedures on personnel protection to include time, distance, and shielding according to this chapter.

A. A registrant must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

B. For purposes of this part, "as low as reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposure to radiation as far below the dose limits as 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.

Commented [TP(62]: SSRCR definition and current 4732. During definition review it was proposed to be included in ALARA rule part.

4732.#### MOBILE OR PORTABLE REGISTRANTS.

Subpart 1. **Mobile or portable off-site use.** A registrant must maintain the following information with a mobile or portable x-ray system at all times:

A. the shielding plan under part 4732.####, if applicable;

B. the registrant's quality management system under part 4732.####;

C. required qualified operator training according to this chapter;

D. qualified operator qualifications according to this chapter;

E. current equipment performance evaluation for each x-ray system; and

F. utilization record according to this chapter.

Commented [JC(63]: Section same as: TX, DE,

Commented [BB(64]: Reference Shielding rule part

Commented [BB(65]: Reference to Quality Management System

Commented [JC(66]: Instead of "according to this chapter", may include individual references to each modality's rule part for utilization.

Subp. 2. **Off-site location record.** A registrant must document the date and location when a registrant's mobile or portable x-ray system qualified operator uses a registrant's mobile or portable x-ray system at a location that is not listed on the registrant's equipment registration.

Subp. 3. **Out-of-state registrants.** A registrant must have all records according to this chapter available for review by the commissioner when a registrant's mobile or portable x-ray system is operated in the state.

4732.#### NOTICES, INSTRUCTIONS, AND REPORTS.

Subpart 1. **Notice to employees.** A registrant must post a copy of MDH Form 3, "Notice to Employees," or any Form 3 revision provided by the commissioner, no later than 30 days after receiving the revised notice. A registrant may obtain the Notice to Employees from the department of health's website at www.health.state.mn.us.

Subp. 2. **Posting of notice.** A registrant must:

A. display the notice in a prominent location where x-ray systems are located and is visible to all workers; and

B. replace notices that are defaced.

4732.#### INSPECTION AND ENFORCEMENT.

Subpart 1. I**nspections.** The commissioner shall inspect sources of ionizing radiation according to Minnesota Statutes, section 144.121, subdivision 2.

Subp. 2. **Access to information and property.** The commissioner shall inspect a registrant's property and examine a registrant's records according to Minnesota Statutes, sections 144.989 to 144.993.

Subp. 3. **Enforcement.** Violations of the requirements of this chapter constitute grounds for the commissioner to take one or more of the enforcement actions under Minnesota Statutes, sections 144.989 to 144.993, subject to the notice and appeal provisions in applicable law.

4732.#### VARIANCE.

The commissioner shall consider variances for this chapter according to the procedures and criteria under parts 4717.7000 to 4717.7050.

4732.#### RECORDS.

4732.#### RADIATION SAFETY OFFICER.

Subpart 1. **Applicability.** A radiation safety officer is responsible for the radiation safety activities according to this chapter and in the daily operation of a registrant's quality management system.

Subp. 2. **Designation of radiation safety officer**.

A. A radiation safety officer must agree in writing to be responsible for a registrant's radiation safety activities.

B. An individual who serves as both registrant and radiation safety officer and performs all radiation safety activities is exempt from item A.

Commented [BB(67]: Similar: LA, NY

Subp. 3. **Radiation safety delegate.**

A. A radiation safety delegate must agree in writing to be responsible for the delegated activities.

B. A radiation safety delegate must meet the qualifications under subpart 5.

C. A radiation safety officer must not delegate the authority or responsibility to the radiation safety delegate for developing the quality management system.

D. A radiation safety officer must annually review and verify the delegated specific activities of a radiation safety delegate.

Subp. 4. **Radiation safety officer authority.** A registrant must provide the radiation safety officer sufficient authority, organizational freedom, time, and resources to:

A. identify radiation safety hazards;

B. initiate, recommend, or provide corrective actions;

C. stop unsafe operations; and

D. verify implementation of corrective actions.

Subp. 5. **Radiation safety officer; qualifications.**

A. To be qualified as a radiation safety officer, an individual must have knowledge of potential radiation hazards and emergency precautions, complete a radiation safety officer training course, and:

(1) educational courses related to ionizing radiation safety according to subpart 6; or

(2) two years of experience in the use of x-ray systems and familiarity of the registrant's x-ray systems.

Commented [BB(68]: Similar: SC, IA, LA, NY, RI

Commented [JC(69]: SSRCR

Commented [BB(70]: Similar: TX, RI, MI

Commented [JC(71]: Similar: TX, RI, MI

B. A radiation safety officer for industrial radiography x-ray systems is exempt from item A and must follow the requirements under part 4732.####, subpart 10.

Subp. 6. **Healing arts radiation safety officer.** A healing arts radiation safety officer for x-ray systems for use on living humans is limited to an individual with evidence of:

A. licensure by the governing board of a qualified practitioner;

B. registry by the American Registry of Radiologic Technologists (ARRT);

C. an associate degree, or higher, in radiologic technology, health physics, or nuclear technology;

D. licensure as a dental therapist, dental hygienist, or dental assistant under Minnesota Statutes, section 150A.06;

E. certified as a qualified expert according to part 4732.####, subpart 11; or

F. certified as a qualified medical physicist according to part 4732.####, subpart 12.

Subp. 7. **Academic institutions, forensic science, industrial, research, or veterinary facilities radiation safety officer**. An academic institution, forensic science facility, industrial facility, research facility, or a veterinary facility must have a radiation safety officer who:

A. meets the qualifications under subpart 5; or

B. is a faculty or staff member in radiation protection, radiation engineering, or a related ionizing radiation discipline.

Subp. 8. **Radiation safety officer responsibilities.** A radiation safety officer is responsible for the activities under this subpart.

A. Establish and oversee the registrant's quality management system according to part 4732.#### or part 4732.####.

Commented [JC(72]: Reference to Industrial Radiographer qualifications

Commented [JC(73]: Similar: TX, RI, MD

Commented [JC(74]: CO

Commented [JC(75]: Reference to Service Provider - qualified expert

Commented [JC(76]: Reference to Service Provider - qualified medical physicist

Commented [BB(77]: Similar: TX, SSRCR

TX [§289.226 (e)(3)(B)(ii)]:
(ii) Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. This individual may also serve as the RSO over the healing arts section of the facility.

Commented [JC(78]: Reference to Industrial Quality Management System

B. Review and maintain the following written or electronic documentation for a registrant's qualified operator for each x-ray system modality:

(1) the completed 24 continuing educational credits according to part 4732.####;

(2) the computed tomography site-specific training under part 4732.####, subpart 18; if applicable; and

(3) a certificate of completion of fluoroscopy training under part 4732.####, subpart 28, item A, if applicable.

C. Verify that operators of x-ray systems are trained and comply with the applicable requirements of this chapter.

D. Verify that occupational staff who are provided individual monitoring:

(1) properly use individual monitoring devices according to part 4732.####;

(2) use calibrated individual monitoring devices; if applicable

(3) receive timely annual individual exposure notifications according to part 4732.####; and

(4) maintain records of individual monitoring results according to part 4732.####.

E. Verify that the registrant has performed, and maintain documentation the following for each x-ray system, if applicable, according to this chapter for:

(1) shielding plans;

(2) radiation protection surveys;

(3) area surveys;

(4) equipment performance evaluations;

Commented [BB(79]: Reference to 4732.#### SITE-SPECIFIC AND X-RAY SYSTEM TRAINING.

Commented [BB(80]: Reference CT rule part

Commented [BB(81]: Reference fluoroscopy rule part

Commented [TP(82]: Reference to RECORDS.

(5) equipment preventative maintenance;

(6) calibrations;

(7) corrective measures for x-ray system failures; and

(8) corrective measures when levels of radiation exceed dose limits under parts 4732.####.

F. Verify that the registrant has performed calibration of sensitometer and densitometer for film processing, if applicable.

G. Review quality control tests for each x-ray system.

H. Investigate and report to the commissioner:

(1) known or suspected cases of radiation exposure to an individual or radiation level detected in excess of dose limits under parts 4732.####;

(2) medical events under part 4732.####; and

(3) the theft or loss of an x-ray system after determining the cause and taking steps to prevent its recurrence according to part 4732.####.

I. Implement corrective actions of x-ray systems, including shut-down of operations in emergency situations or unsafe conditions.

J. Maintain records required under part 4732.####.

Subp. 9. **Exemptions.**

A. An industrial registrant is exempt from subpart 8, items B, F, G, and H(2).

B. [TBD]; and

C. [TBD].

Commented [BB(83]: Reference medical event rule part

Commented [BB(84]: Reference theft or loss rule part

Commented [JC(85]: Reference to Records part.

Commented [JC(86]: To include additional exemptions for non-human research, veterinary, security screening….

4732.#### SITE-SPECIFIC AND X-RAY SYSTEM TRAINING.

Subpart 1. **Applicability.** A registrant is responsible for the training requirements of this part for individuals operating x-ray systems.

Subp. 2**. Training; initial and before first use.** An individual operating x-ray systems must be initially trained before first use in:

A. the registrant's x-ray systems;

B. the quality assurance program;

C. the quality control program;

D. the use of individual monitoring, if applicable;

E. prohibited uses of x-ray systems; and

F. information on the effects of radiation exposure to the human body and the embryo-fetus.

Subp. 3. **Additional training.** A registrant must provide additional training for individuals operating x-ray systems at the time of any modification in radiation output:

A. to the x-ray system; or

B. as a result of new software, modality, or technology.

Subp. 4. **Continuing education unit requirement.**

A. The following individuals must obtain the continuing education unit requirements of this subpart:

(1) a limited x-ray operator;

(2) an individual working as a x-ray operator who has original documentation from the commissioner or the examination provider of passing the

examination that was required before January 1, 2008, under Minnesota Statutes, section 144.121, subdivision 5a(b)(1);

(3) an individual working as a radiologic technologist who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) and holds a valid certification; and

(4) an individual working as a cardiovascular technologist according to Minnesota Statutes, section 144.121, subdivision 5a(b)(5).

B. The individuals under item A must meet the following continuing education unit requirements:

(1) obtain a minimum of 24 hours of continuing education units every 24 months in the areas of radiology, radiography or radiation safety from nationally recognized professional associations including:

a) American College of Radiology;

b) American Society of Radiologic Technologists;

c) American Healthcare Radiology Administrators;

d) Association of Vascular and Interventional Radiographers; and

e) Canadian Association of Medical Radiation Technologists

(2) retain proof of attendance and documentation of all continuing education units for five years and have it available for inspection upon request by the commissioner.

C. A valid certification from the American Registry of Radiologic Technologists (ARRT) can replace the documentation of the continuing education units under item B(1).

Commented [JC(87]: https://www.arrt.org/docs/default-source/governing-documents/continuing-education-requirements.pdf?sfvrsn+c39e02fc_32

D. A valid certification from Cardiovascular Credentialing International as a registered cardiovascular invasive specialist or registered cardiac electrophysiology specialist for cardiovascular technologists can replace documentation of the continuing education units under item B(1).

E. A qualified practitioner, a medical resident or fellow, and a radiologic technologist student in training are exempt from the requirements of this subpart.

4732.#### TRAINING COURSE APPROVAL.

Subpart 1. **Applicability.**

A. This part applies to all training courses that require approval from the commissioner.

B. A training course provider must not offer a training course until the commissioner issues a notice of approval under subpart 4.

Subp. 2. **Application; initial.** The initial application for training course approval must be on a form or in a format prescribed by the commissioner and includes:

A. the name of the person providing the training course;

B. the mailing address, email address, telephone number, and, if applicable, the website address;

C. the name, email address, and telephone number of the responsible individual for the training course;

D. the training course materials under subpart 3;

E. the date of the application;

F. the signature or electronic authorization by the responsible individual certifying that the information is accurate and complete; and

G. any additional information the commissioner deems necessary for evaluation of the application for registration.

Subp. 3. **Training course materials.**

A. An applicant must submit the following training course materials to the commissioner:

(1) the course syllabus;

(2) copies of presentations used in training;

(3) other media used for training, if applicable;

(4) all materials provided to the course participant;

(5) a sample certificate that meets the requirements of subpart 7;

(6) all questions that might be used in the course examination with the correct answers identified; and

(7) a description of the proportion of course examination questions for each major topic in the course.

B. Copies provided under this subpart part must be legible and may be provided in an electronic format.

C. Training may be provided in a classroom setting or remotely using electronic technology.

Subp. 4. **Notice of approval; issuance.**

A. The commissioner shall issue a notice of approval to a training course provider for an application that meets the requirements of subpart 2.

B. A notice of approval is valid for two years from the date of issuance.

Subp. 5. **Training course renewal.** A training course provider must renew its training course approval every two years by submitting a completed application according to subparts 2 and 3 within 60 days of the expiration date of the current training course approval.

Subp. 6. **Denial of training course application.**

A. The commissioner shall deny an application for a training course approval if an applicant fails to comply with the requirements of this part.

B. The commissioner must notify an applicant, in writing, of the denial of the application and provide the reason for the denial.

C. An applicant must submit the corrected deficiencies enumerated in the commissioner's denial notification within 30 days of the receipt of a denial notice.

Subp. 7. **Training course certificate.** When a training course is approved under this part, a training course provider must provide an original certificate to each training course participant who completes and passes the training course. The certificate must contain:

A. the first and last name of the training course participant;

B. a unique numeric identifier for the training course participant;

C. the course name that the training course participant completed;

D. the date of the training course;

E. the number of content hours of the training course;

F. the name, address, and telephone number of the training course provider;

G. the location of the training course; and

H. the statement "Approved by the State of Minnesota under Minnesota Rules, parts 4732.####."

Subp. 8. **Revised training course material; approval required.** A training course provider must receive written approval from the commissioner before presenting revised training course material in an approved training course.

A. A training course provider must notify the commissioner of any change in training course material by submitting the revised material to the commissioner for approval.

B. The commissioner must provide written notice of approval or denial to a training course provider of revised training course material submitted under item A within 30 calendar days of receipt.

C. A training course provider may revise and resubmit the training course material denied under item B within 30 calendar days of the date of the commissioner's written denial notice.

D. The commissioner shall provide written notice of approval or denial to training course materials that are resubmitted under item C within 30 calendar days.

Subp. 9. **Training course examination.** All approved training courses must include a written or electronic examination that meets the requirements of this subpart.

A. Each training course must include a written or electronic examination that is administered by the training course provider at the end of the training course.

B. A training course participant must achieve a score of 70 percent or greater to pass examinations.

C. The examination must consist of at least 30 multiple choice questions.

D. A training course provider must submit a revised examination to the commissioner for review upon renewal of the training course.

Subp. 10. **Required records; retention period.**

A. A training course provider must maintain the records in this subpart for five years for each training course at the address specified on the application.

B. A training course provider must maintain:

(1) training course materials under subpart 3;

(2) the results of each training course participant's examinations; and

(3) a copy of each training course participant's certificate.

4732.#### SHIELDING AND SHIELDING PLANS.

Subp. 1. **Applicability.**

A. A registrant must meet the applicable requirements of this part before operating an x-ray system.

B. A shielding plan, a shielding plan evaluation, and a radiation protection survey, under this part must be performed by a qualified expert, or a service technician

under the general supervision of a qualified expert under part 4732.####, subpart ##.

C. A room or suite within a facility where x-ray imaging is conducted is exempt from this part if the registrant has:

(1) only a dental intraoral x-ray system;

(2) a mini-c-arm x-ray system;

(3) a bone densitometry x-ray system; or

(4) any mobile or portable x-ray system that is operated for fewer than 5 days in a 30-day period in the same room or suite.

D. For purposes of this part, mobile and portable x-ray systems are considered stationary x-ray systems and must meet the requirements of this part if:

(1) used continuously for five or more days in a 30-day period in the same room, or suite; or

(2) used fewer than five days in a 30-day period in the same room or suite, then a registrant must protect the operator during exposures with:

a) a lead apron;

b) a leaded protective barrier at least 6.5 feet (2 meters) high; or

c) a means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly during the exposure.

E. A shielding plan or radiation protection survey prepared before the effective date of this part is not required to meet the requirements of this part.

Subp. 2. **Shielding plan evaluation prior to construction.**

Commented [JC(88]: Similar: ME, ND, AK, OH, DE, AZ, KS, OR, WI, NC

Commented [JC(89]: Similar: CO, ND, OH, DE, KS, OR, IA, WI,

A. Prior to construction, the floor plan and equipment configuration of a registrant's facility must be designed to:

(1) meet the requirements of this part; and

(2) prevent an individual from receiving a dose in excess of the limits under parts 4732.###.

B. A registrant must submit the architectural drawing and equipment configuration of each x-ray system to a service provider to determine the shielding requirements according to this subpart and subparts 3, 4, and 5.

C. A shielding plan must be completed prior to:

(1) construction of a new facility;

(2) any renovation or modification of an existing facility that has the potential to reduce the effectiveness of existing shielding from x-ray radiation; or

(3) construction of a new room or suite in an existing facility.

D. A service provider must provide to the registrant a completed shielding plan that:

(1) meets the requirements of subpart 3; and

(2) includes an annotated scale drawing under subpart 4.

E. A registrant must construct the shielding and configure the x-ray system according to the shielding plan developed by a service provider.

Subp. 3. **Shielding plan requirements.** For each room or suite in which a stationary x-ray system is located, a registrant is responsible for the shielding plan requirements under this subpart.

Commented [JC(90]: Sec. D.1201 - Occupational Dose Limits for Adults.
Sec. D.1206 - Planned Special Exposures.
Sec. D.1207 - Occupational Dose Limits for Minors.
Sec. D.1208 - Dose Equivalent to an Embryo/Fetus.
Sec. D.1301 - Dose Limits for Individual Members of the Public.
Sec. D.1302 - Compliance with Dose Limits for Individual Members of the Public.

Commented [TP(91]: INFORMATION REQUIRED FOR EVALUATION OF RADIATION SHIELDING, Appendix C

A. A shielding plan must be based on National Council on Radiation Protection and Measurements Report No. 147, "Structural Shielding Design for Medical Imaging Facilities" or other nationally recognized guidelines.

B. A shielding plan must include:

(1) an evaluation of the overall layout of the architectural drawing of the room or suite including the location and configuration of the x-ray systems in each room or suite, based on the information under this subpart and subpart 5;

(2) an evaluation of workload based on the volume of work and x-ray system usage anticipated in the information provided under subitem 16;

(3) location and types of permanent and temporary barriers and shielding;

(4) normal location of the x-ray system's radiation port;

(5) radiation port's travel and traverse limits;

(6) general directions of the useful beam;

(7) location of interior and exterior walls, any windows, doors, floor, ceilings or other openings;

(8) location of the operator's booth;

(9) location of any controls and the control panel;

(10) location of exposure switch;

(11) the structural composition and thickness or lead equivalence of all walls, doors, partitions, floor, and ceiling of the room or suite;

(12) the dimensions of the room or suite and inter-floor distances if the space above or below is occupied;

(13) the type of occupancy of all adjacent areas including the space above and below the room or suite. If there is an exterior wall, show distance to the closest area where it is likely that individuals may be present;

(14) the make and model of the x-ray system, the maximum technique factors, and the energy waveform;

(15) the type of examinations to be performed with the x-ray system;

(16) information on the anticipated workload of the x-ray system in mA-minutes per week; and

(17) a service report according to part 4732.####, subpart #, that contains all basic assumptions used in the development of the shielding plan.

Commented [JC(92]: Reference to Service Report subpart - Service Providers part.

C. A current scale drawing under subpart 4, including specifications for construction and layout, must meet the requirements of this subpart and subpart 5.

Subp. 4. **Scale drawing requirements.** A scale drawing must include:

A. identification and use of each room or suite adjacent to the x-ray room and an estimation of the extent of occupancy in each area; and

B. results of the calculations provided by a service provider, indicating the type and thickness of materials in each protective barrier:

(1) after installation according to subpart 2;

(2) whenever shielding is modified according to the results of subpart 6; and

(3) calculations must be performed prior to construction.

C. When shielding plan calculations are not available, other methods according to subpart 3, item A, must be used to verify the presence of any necessary shielding.

Subp. 5. **Design requirements for an operator's booth.**

A. An operator's booth must meet the following space requirements:

(1) an operator must have at least 7.5 square feet (0.7 square meters) of unobstructed floor space in the booth;

(2) an operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.6 meters);

(3) an operator's booth allotted space must exclude any encumbrance by the x-ray control panel such as overhang, cables, or other similar encroachments; and

(4) an operator's booth must be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor cannot reach the operator's position in the booth.

B. An operator's booth must meet the following structural requirements:

(1) the booth walls must be permanently fixed barriers of at least 7 feet (2 meters) high;

(2) a door or movable panel that is used as an integral part of the operator's booth structure must have an interlock that prevents an exposure when the door or panel is not closed in its shielding position;

(3) shielding must be provided to meet the requirements of part 4732.#### .

Commented [JC(93]: SSRCR
Similar: ND, DE, KS, IA, LA, GA

Commented [JC(94]: DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH, Appendix B

Commented [JC(95]: Reference to Dose limits

C. The radiation exposure control for the x-ray system must:

(1) be permanently mounted in the operator's booth; and

(2) be at least 40 inches (1.0 meter) from any point subject to direct scatter, leakage, or useful beam radiation.

D. An operator's booth must meet the following viewing system requirements.

(1) Each operator's booth must have at least one viewing device that permits an operator to view:

a) the patient during any exposure;

b) any occupant of the room; and

c) any entry into the room.

(2) If any door which allows access to the room cannot be seen from the operator's booth, then:

a) outside that door there must be an "x-ray on" warning sign that must be illuminated anytime the rotor of the x-ray tube is activated; or

b) an interlock must be present so that exposures are prevented unless the door is closed.

E. When the viewing system of an operator's booth is a window, the following requirements apply:

(1) the window must have a viewing area of at least 0.09 m2 (1 square foot); and

(2) the window must have at least the same lead equivalence as that required in the operator's booth's wall in which it is mounted.

G. When the viewing system of an operator's booth is by mirrors, the mirrors must be located to meet the requirements of item D.

H. When the viewing system of an operator's booth is by electronic means:

(1) the camera must be located as to meet the requirements of item D; and

(2) there must be an alternate viewing system as a backup for the primary system.

Subp. 6. **Post-construction evaluation.**

A. A registrant is responsible for having a service provider:

(1) evaluate the shielding plan prior to construction according to subpart 2 and document the post-construction evaluation in a service report; or

(2) perform a radiation protection survey to determine radiation levels present under specified test conditions:

a) at the operator's position; and

b) at identifiable points outside the room.

B. If the evaluation under item A, subitem (1) or (2), indicates that an individual has the potential to receive a dose in excess of the limits under parts 4732.####, then the registrant must modify the shielding or equipment configuration according to the recommendation of the service provider.

Commented [JC(96]: Reference to multiple dose rule parts.

Subp. 7. **Any changes after operations.**

A. A registrant is responsible for having a service provider conduct a radiation protection survey if:

(1) an equipment performance evaluation or a radiation protection survey during operation shows that dose in excess of the limits under parts 4732.#### is possible;

Commented [JC(97]: Reference to multiple dose rule parts.

(2) a modification to an existing facility or room that has the potential to reduce the effectiveness of the existing shielding;

(3) a new x-ray system with a potential of a higher radiation output is installed in an existing room or suite;

(4) the orientation of the useful beam is changed;

(5) the primary shielding is altered due to the modification or renovation of the facility;

(6) mobile or non-handheld portable x-ray equipment is used continuously in the same location according to subpart 2, item F;

(7) x-ray system workload (for example, mA-minute-per-week workload) has increased or is projected to increase above that which was the basis for the original shielding plan; or

(8) the registrant is unable to produce for inspection a shielding plan completed according to subpart 2 or subpart 7.

B. A radiation protection survey must determine radiation levels present under specified test conditions:

(1) at the operator's position; and

(2) at identifiable points outside the room or suite.

C. If the evaluation under item A indicates that an individual has the potential to receive a dose in excess of the limits under part 4732.####, then the registrant must modify the shielding or equipment configuration according to the recommendation of the service provider.

Commented [TP98]: Reference to multiple dose rule parts.

Subp. 8. **Shielding plan retention.**

A. A registrant must retain a copy of the shielding plan and scale drawing, or a radiation protection survey, for each room or suite in which a stationary x-ray system is located until the commissioner terminates each pertinent registration requiring the record.

B. A registrant must maintain a shielding plan for each x-ray system including:

(1) architectural drawings and equipment configurations;

(2) shielding plans and scale drawings; and

(3) post-construction evaluation.

C. A registrant must maintain the radiation protection survey if the registrant does not have the information under item B.

D. If a registrant is unable to produce a shielding plan upon request by the commissioner, then a registrant may perform a radiation protection survey to determine radiation levels present according to subpart 7, item B.

4732.#### [INDIVIDUAL MONITORING.]

4732.#### CAUTION SIGNS, POSTING, AND LABELING.

Subpart. 1. **Applicability.**

A. The following registrants must label or post according to this part:

(1) research;

(2) academic

(3) forensic science; and

(4) security screening.

B. Industrial x-ray systems must be labeled with a visible and discernible sign or signs according to parts 4732.#### to 4732.####.

Commented [JC(99]: Reference to Industrial rule parts

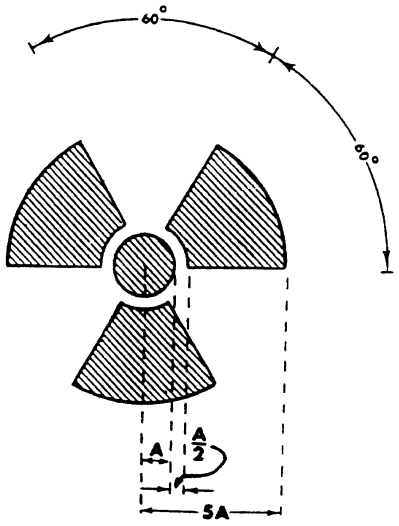
Subp. 2. **Standard radiation symbol and labeling**.

A. Each radiation sign or label must bear:

(1) the standard radiation symbol in this subpart; and

(2) the printed warning, in capital block letters in subpart 3.

B. The standard symbol for designating any radiation hazard is a circle with three propeller-like blades arranged around it as illustrated:



(1) the cross-hatched area must be magenta, purple, or black; and

(2) the background must be yellow.

Subp. 3. **Posting and labeling requirements.**

A. A registrant must post each radiation area with a conspicuous signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

B. A registrant must post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

Subp. 4. **Labeling x-ray systems.** Each registrant must verify that each x-ray system is labeled with a visible and discernible warning sign that cautions individuals that radiation is produced when it is energized.

Subp. 5. **Warning and control devices; high radiation areas.**

Commented [TP(100]: SSRCR D. 1601

A. A registrant must verify that each entrance or access point to a high-radiation area has one or more features:

(1) a control device, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 100 millirems (1.0 mSv) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

(2) a control device that energizes a visible or audible alarm signal so that an individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

B. A registrant may use a continuous, direct surveillance system or an electronic surveillance system that prevents unauthorized entry instead of the controls required under item A.

C. A registrant must establish the controls under item A in a way that does not prevent individuals from leaving a high radiation area.

4732.#### [OCCUPATIONAL DOSE LIMITS.]

4732.#### [DECLARED PREGNANCY DOSE LIMITS.]

4732.#### [PUBLIC DOSE LIMITS.]

4732.#### [MINOR DOSE LIMITS (individuals under the age of 18).]

4732.#### MEDICAL EVENT; NOTIFICATION AND REPORT.

Subpart 1. **Applicability.**

A. A registrant must comply with the requirements of this part.

B. For purposes of this part, an affected patient means an individual who is the subject of a medical event.

Subp. 2. **Notification within 24 hours.** A registrant must notify the commissioner within 24 hours after the discovery of a medical event. The notification may be provided electronically.

Subp. 3. **Medical event; patient intervention.** A registrant must prepare a medical event report under subpart 5 for a computed tomography or fluoroscopy x-ray system medical event that results from:

A. a patient receiving an unintended skin dose in a single procedure greater than 200 rads (2 Gy) to the same area;

B. a patient receiving an unintended skin dose in a single procedure greater than:

(1) 50 rads (0.5 Gy) to any organ and exceeded the facility's established protocol by 5 times; or

(2) 5 rem (0.05 Sv) effective dose and exceeded the facility's established protocol by 5 times;

C. a wrong patient or wrong site for the entire imaging procedure when the dose:

(1) is greater than 50 rads (0.5 Gy) to any organ; or

(2) is greater than or equal to 5 rem (0.05 Sv) total effective dose; or

D. an unintended dose to an embryo/fetus.

Subp. 4. **Notice to affected patient and referring qualified practitioner by a registrant.**

A. No later than 24 hours after discovering a medical event, a registrant must provide notification electronically to:

(1) the referring qualified practitioner; and

(2) the affected patient.

B. A registrant must consult with the referring qualified practitioner before notifying the affected patient. If the referring qualified practitioner cannot be

Commented [TP(101]: SSRCR, Part F and CRCPD H-38 for reporting diagnostic medical events.

reached within 24 hours, then the registrant must notify the affected patient as soon as possible thereafter.

C. A registrant must document attempts to notify the referring qualified practitioner under item B for the commissioner to review upon inspection.

D. A registrant is not required to notify an affected patient under item A if the referring qualified practitioner informs the affected patient.

E. When notifying an affected patient of a medical event, an affected patient must be informed that a medical event report is available upon request from the registrant.

F. A registrant must provide a medical event report within 30 days of a request to an affected patient.

Subp. 5. **Medical event report; contents.** A registrant must submit a medical event report to the commissioner no later than 30 days after the discovery of a medical event. A medical event report may be submitted in written or electronic form.

A. A medical event report must contain:

(1) the name of the registrant;

(2) the name of the referring qualified practitioner;

(3) the date of the medical event;

(4) the date of the discovery;

(5) a medical event analysis by a qualified medical physicist;

(6) a description of why and how the medical event occurred including:

a) the type of x-ray system involved;

b) the x-ray system manufacturer and model;

c) the serial number of x-ray system;

d) the imaging procedure performed;

e) the individual who discovered the event;

f) how it was discovered;

g) did the affected patient require any follow-up care or treatment due to the medical event; and

h) was the radiation safety officer involved with the registrant's medical event response and reporting;

(7) the total estimated dose received during the medical event;

(8) the first and last names of all individuals involved in the medical event, including professional titles;

(9) actions taken to prevent recurrence;

(10) actions taken for the radiation safety committee to review, if applicable;

(11) documentation that the registrant notified, or attempted to notify the affected patient; and

(12) a written explanation if the registrant did not notify as required under subitem (11).

B. A medical event report that is submitted to the commissioner must not contain the affected patient's name.

C. A registrant must maintain the medical event report as part of the affected patient's permanent medical record.

Subp. 6. **Providing medical event report to referring qualified practitioner.** A registrant must:

A. provide a copy of the medical event report to the referring qualified practitioner, if other than the registrant; and

B. annotate the copy of the medical event report that is provided to the referring qualified practitioner by adding the name or other information that identifies the affected patient.

4732.#### NOTIFICATION OF OCCUPATIONAL LEVELS EXCEEDED.

Subpart 1. **Applicability.** A registrant must comply with the requirements of this part.

Subp. 2. **Notification within 24 hours.** A registrant must notify the commissioner of any individual worker who was exposed beyond the worker's occupational dose under part 4732.#### within 24 hours of discovery by the registrant. The notification may be provided electronically.

Subp. 3. **Occupational levels exceeded report; contents.** A registrant must submit an occupational levels exceeded report to the commissioner of any individual worker who was exposed beyond the worker's occupational dose limit under part 4732.#### no later than 30 days after providing notification under subpart 2. An occupational levels exceeded report may be submitted in written or electronic form.

A. A registrant must prepare an occupational levels exceeded report that contains the following information:

(1) the name of the registrant;

(2) the name of the exposed individual worker;

(3) the date of the discovery;

(4) the individual worker's dose;

(5) a description of the individual worker's radiation responsibilities that led to the exposure;

(6) occupational dose data and results;

(7) the date of the dose report; and

(8) actions taken to prevent recurrence.

B. Occupational doses that result from planned special exposures are exempt from this part if they are:

(1) within the limits for planned special exposures; and

(2) reported according to subpart 4.

C. A registrant must provide a copy of the occupational levels exceeded report to the individual worker no later than 30 days after providing notification under subpart 2.

D. A registrant must maintain a record of the occupational dose limits exceeded report as part of the individual monitoring records.

Subp. 4. **Reports of planned special exposures; contents.**

Commented [TP(102]: **Advisory Committee**: Do we need special exposures for the x-ray rules?

A. A registrant must submit a report of planned special exposures to the commissioner no later than 30 days following any planned special exposure.

B. A report of planned special exposures must include:

(1) why a planned special exposure was conducted;

(2) the unique situation requiring the use of a planned special exposure;

(3) the date the planned special exposure occurred;

(4) the name of the management official who authorized the planned special exposure;

(5) a copy of the signed authorization;

(6) what actions were necessary;

(7) why the actions were necessary;

(8) what precautions were taken to verify that occupational doses were maintained according to ALARA;

(9) the name of the individual worker;

(10) collective doses the individual worker was expected to receive; and

(11) the occupational doses actually received in the planned special exposure.

4732.#### REPORT OF THEFT OR LOSS OF X-RAY SYSTEM.

Subpart 1. **Applicability.** A registrant must comply with the requirements of this part.

Commented [TP(103]: Sec. D.2201 from SSRCR

Subp. 2. **Immediate notification required.** A registrant must notify the commissioner of the theft or loss of any registered x-ray system immediately after the theft or loss becomes known to the registrant. The notification may be submitted electronically.

Subp. 3. **Theft or loss report; report contents.** A registrant must submit a theft or loss report to the commissioner no later than 30 days after notifying the commissioner under subpart 2. A theft or loss report may be submitted in written or electronic form.

A. A registrant must prepare a theft of loss report that contains the following information:

(1) the name of the registrant;

(2) the date of the discovery;

(3) a description of the theft or loss of the x-ray system that includes:

a) type of x-ray system involved,

b) specific manufacturer and model,

c) serial number of x-ray system;

d) maximum energy of radiation emitted;

e) how the theft or loss of the x-ray system was discovered; and

f) if the radiation safety officer notified of the theft or loss of the x-ray system;

(4) a description of the circumstances under which the theft or loss occurred;

(5) actions that the registrant have taken, or intends to take, to recover the x-ray system; and

(6) the registrant procedures or measures that have been implemented to prevent the recurrence of the theft or loss of an x-ray system.

B. If a registrant learns of any additional information after submitting the theft or loss report under this subpart, then the registrant must submit to the commissioner that additional information within 30 days of the additional information becoming known to the registrant.

C. A registrant must maintain a record of the theft or loss report according to part 4732.####.

Commented [TP(104]: MDH record draft rule part.