DEPARTMENT OF HEALTH

Draft MN Rules, Chapter 4732 – X-ray Revision, v2

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

(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.

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.

Commented [JC(2]: FL definition

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

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

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

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

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

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

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

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

(12) the imaging receptor type, if applicable;

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

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

(15) the date of the application;

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

(17) 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.

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

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 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.

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.

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.

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) the manufacturer and serial number of the x-ray system tube insert;

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

(7) the imaging receptor type, if applicable;

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

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

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

(10) the date of the application;

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

(12) 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:

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

(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:

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

A. the legal name of the facility;

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 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.####.

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.####.

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

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

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 associate radiation safety officer.

E. A registrant must attest in writing that the associate 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.

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

Subp. 19. **Individuals qualified to operate x-ray systems on humans.** A registrant must only allow individuals to operate an x-ray system if they meet the requirements under:

A. part 4732.#### for a CT qualified operator;

B. part 4732.#### for a fluoroscopic qualified operator;

C. part 4732.#### for a radiographic qualified operator;

D. part 4732.#### for a dental qualified operator;

Commented [JC(18]: Reference to RSO qualifications

Commented [JC(19]: Reference to RSO qualifications

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

E. part 4732.#### for a breast biopsy qualified operator;

F. part 4732.#### for a bone densitometry qualified operator; and

G. part 4732.#### for a security screening qualified operator.

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

Commented [BB(21]: 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 an audit according to part 4732.#### or part 4732.#### for industrial x-ray systems.

Commented [JC(22]: Reference to **Quality Management System** part

B. A registrant must perform an 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.

Commented [JC(23]: CO

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.

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 educational and 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) educational course attended;

(8) training and classes completed;

Commented [JC(24]: Dakota County Technical College; Inver Hills Community College https://minnesotatraining.com/programs/healthcare/limited-scope-x-ray-certification/

(9) modules;

(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 educational 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(25]: Similar: WI, TN, DE, TX

Commented [BB(26]: Multiple states limit the specific views and prohibit specific x-ray exams from being completed by limited scope x-ray operators.

Commented [BB(27]: 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(28]: Similar: NE, IL, KY,

Commented [BB(29]: 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(30]: Similar: NE, IL

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

Commented [BB(32]: 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(33]: **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(34]: 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 educational course.** An applicant for a limited scope x-ray operator registration must complete and pass an educational course under subpart 7 that is approved by the commissioner according to part 4732.#### and meets the requirements of this part.

Subp. 7. **Educational course content.** An educational 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;

Commented [TP(35]: 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(36]: 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,

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

(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(37]: 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(38]: 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 procedures, with the radiation safety officer that meet the requirements of this part.

Commented [BB(39]: Ohio 3701:1-66-04

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

Commented [JC(40]: 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 procedures for:

Commented [JC(41]: **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 all 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. operating procedures for each type of x-ray system;

Commented [BB(42]: Similar: IL,

D. emergency procedures for malfunctioning x-ray systems;

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

F. medical event notification and reporting according to part 4732.####;

G. notification of theft or loss of an x-ray system according to part 4732.####, if applicable;

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

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

J. protective garment integrity according to part 4732.####, subpart 20 [Registrant Responsibilities];

K. patient protection including:

1) screening for pregnancy;

2) exposure of pregnant patients; and

3) patient shielding.

L. individuals or occupational workers to:

1) hold or assist patients; or

2) remain in the room during radiation exposure;

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

N. patient or subject identification.

Commented [BB(43]: Reference to Medical Event

Commented [BB(44]: Reference to Notification of theft or loss

Commented [TP(45]: See Minn Stat. 144.1215

Commented [BB(46]: Reference to MOBILE OR PORTABLE REGISTRANTS.

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

A. a list of the 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 processor densitometer and sensitometer quality control, if applicable; and

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

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.####;

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

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

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

Commented [JC(47]: 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(48]: New York QA guide

Commented [BB(49]: New York QA guide

Commented [JC(50]: Reference to individual monitoring rule part

Commented [BB(51]: Reference to individual monitoring rule part

Commented [BB(52]: Reference to individual monitoring rule part

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];

G. addressing a declaration of pregnancy;

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

I. obtaining and maintaining employees' occupational doses;

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

K. 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 [BB(53]: OH wording

Commented [JC(54]: Reference to Dose Monitoring

Commented [BB(55]: Reference to Individual Monitoring rule part

Commented [TP(56]: 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.

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.

Commented [JC(57]: Section same as: TX, DE,

Commented [BB(58]: Reference Shielding rule part

Commented [BB(59]: Reference to Quality Management System

Commented [JC(60]: Instead of "according to this chapter", may include individual references to each modality's rule part for utilization.

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.

Subp. 3. **Associate radiation safety officer.**

A. An associate radiation safety officer must agree in writing to be responsible for the delegated activities.

B. An associate radiation safety officer must meet the qualifications under subpart 5.

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

D. A radiation safety officer must annually review, verify, and sign and date the delegated specific activities of an associate radiation safety officer.

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

Commented [BB(61]: Similar: LA, NY

Commented [BB(62]: Similar: SC, IA, LA, NY, RI

D. verify implementation of corrective actions.

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

A. A radiation safety officer must have knowledge of potential radiation hazards and emergency precautions and:

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

(2) a radiation safety officer training course; or

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

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 in radiologic technology, health physics, or nuclear technology;

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

E. licensure as a dental hygienist under Minnesota Statutes, section 150A.06;

F. licensure as a dental assistant under Minnesota Statutes, section 150A.06;

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

Commented [JC(63]: SSRCR

Commented [BB(64]: Similar: TX, RI, MI

Commented [BB(65]: Similar: TX, RI, MI

Commented [JC(66]: Advisory Committee: Should there be a specific hour limit or topics listed to this training course?

Commented [JC(67]: Reference to Industrial Radiographer qualifications

Commented [JC(68]: Similar: TX, RI, MD

Commented [JC(69]: CO

Commented [JC(70]: Reference to Service Provider - qualified expert

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

Commented [JC(71]: Reference to Service Provider - qualified medical physicist

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:

Commented [BB(72]: Similar: TX, SSRCR

A. meets the qualification under subpart 5; and

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

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

Commented [JC(73]:

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

Commented [JC(74]: 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:

Commented [TP(75]: **Advisory Committee**: Discussion on defining this term.

(1) a list identifying all qualified operators including:

a) first and last name; and

b) qualifications.

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

Commented [BB(76]: Reference to 4732.#### SITE-SPECIFIC AND X-RAY SYSTEM TRAINING.

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

Commented [BB(77]: Reference CT rule part

(4) a certificate of completion of the eight-hour fluoroscopy training under part 4732.####, subpart 28, item A; if applicable.

Commented [BB(78]: Reference fluoroscopy rule part

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.####.

Commented [TP(79]: Records

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

(1) shielding plans,

(2) radiation protection surveys,

(3) area surveys;

(4) equipment performance evaluations;

(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. Assume control of the x-ray system and implement corrective actions, including shut-down of operations in emergency situations or unsafe conditions.

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

Subp. 9. **Exemptions.**

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

B. [TBD]; and

C. [TBD].

Commented [JC(80]: The internal reference could be to multiple rule parts.

Commented [BB(81]: Reference medical event rule part

Commented [BB(82]: Reference theft or loss rule part

Commented [JC(83]: Reference to Records part.

Commented [JC(84]: 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 requirement.** An individual operating x-ray systems must be initially instructed before first use and annually retrained in:

A. the registrant's x-ray system;

B. facility-specific and system-specific operating procedures;

C. emergency procedures for malfunctioning x-ray systems;

D. quality assurance program;

Commented [TP(85]: 4732
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

E. quality control;

F. personal protective equipment;

G. use of individual monitoring, if applicable; and

H. prohibited uses of x-ray systems.

Subp. 3. **Operating procedures.** As part of the training requirement under subpart 2, a registrant must provide written or electronic operating procedures for the facility and x-ray systems to individuals including:

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

B. projections where holding devices cannot be used;

C. any restrictions of the operating technique required for the safe operation of the particular x-ray systems;

D. instructions of operator responsibility to report to the registrant any condition that leads to or causes a violation of this chapter, including a medical event, theft or loss of equipment, or any unnecessary exposure to radiation; and

E. instructions for responding in the event of any malfunction that involves potential exposure to radiation.

Subp. 4. **Additional training.** A registrant must provide additional training for individuals operating x-ray systems at the time of any modification:

A. to the x-ray system;

B. to the registrant's quality assurance program;

C. to the registrant's quality control; or

Commented [TP(86]: 4732
The registrant must maintain safety procedures including patient holding, if applicable, and any restrictions of the operating technique required for the safe operation of the particular system. The procedures must be made available to x-ray operators.

D. in radiation output from new software, modality, or technology.

Subp. 5. **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;

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

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 24 hour continuing education units.

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