DEPARTMENT OF HEALTH

Draft MN Rules, Chapter 4732 – X-ray Revision, v4

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.#### .

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)

Subp. 3. **Registration.**

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.

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

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.

(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;

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.

(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.

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

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

Commented [TP(12]: MD

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:

Commented [KM(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 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 installation checklist.**

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

A. 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 the registrant installation checklist under subpart 17.

B. For each x-ray system, a registrant is responsible for verifying that a service provider:

(1) reviewed and confirmed the registrant's registration and registration number on the registrant installation checklist;

(2) reviewed and confirmed the registrant's shielding plan, if applicable, on the registrant installation checklist; and

(3) performed the initial equipment performance evaluation and signed the registrant installation checklist, electronically or in writing.

Subp. 17. **Registrant installation checklist requirements.**

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.

B. A registrant installation checklist must be on a form or in a format provided by the commissioner.

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

D. A registrant must not use an x-ray system if the required registered service provider signatures are not on the registrant installation checklist.

E. A registrant must have a copy of the registrant installation checklist available for review by the commissioner upon request.

Subp. 18. **Manufacturer specifications, instruction manuals required.** 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. 19. **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.

Commented [JC(16]: Reference to **Radiation Safety Officer** part

Commented [JC(17]: Reference to RSO qualifications

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.

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. 20. **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 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:

Commented [JC(18]: Reference to RSO qualifications

Commented [BB(19]: Similar: TX, IL

Commented [TP(20]: MDH intends to revisit x-ray system modality and possibly define.

(1) first and last name; and

(2) qualifications.

Subp. 21. **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. 22. **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. 23. **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(22]: Reference to **Quality Management System** part

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

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.

Subp. 24. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(23]: Reference to **RECORDS** part.

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;

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

(8) training and classes completed;

(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 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:

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.

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

(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;

Commented [BB(27]: 75% - AK, CO, ME, NJ, UT, WY, TX
70% - AR, IA, NE, ND, OR,
65%- TN, IL,

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

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

(13) lower leg;

(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.

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

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

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

(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.

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

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

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

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;

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

Subp. 11. **Records.** A limited scope x-ray operator must maintain records under this part according to part 4732.####.

Commented [JC(39]: Reference to **RECORDS** part.

4732.#### TRAINING COURSE APPROVAL FOR LIMITED SCOPE X-RAY OPERATORS.

Subpart 1. **Applicability.**

A. The commissioner must approve all training courses for limited scope x-ray operators under this part.

B. A training course provider must not offer a training course for limited scope x-ray operators until the commissioner issues a notice of approval under subpart 4.

C. For purposes of this part, a training course provider who develops a training course for limited scope x-ray operators must be:

(1) a qualified medical physicist;

(2) a qualified expert; or

(3) a certified radiologic technologist who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) and holds a valid certification.

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

A. the name of the individual developing the training course;

B. the qualifications of the individual developing the training course;

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

D. the mailing address, email address, telephone number, and, if applicable, the website address of the training course provider;

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

F. the training course materials under subpart 3;

G. the date of the application;

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

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

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

A. An applicant must submit the following training course materials for limited scope x-ray operator training course 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 training course participant;

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

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

B. Copies submitted 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 for limited scope x-ray operators must renew its approval for training courses 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 limited scope x-ray operators 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 within 30 days of the receipt of the application.

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.

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

Subp. 7. **Training course certificate.** A training course provider must provide an original certificate to each training course participant who completes and passes the training course for limited scope x-ray operators. The certificate must contain:

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

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

C. the date of the training course;

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

E. the name of the training course provider; and

F. 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 for limited scope x-ray operators 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 days of receipt.

C. A training course provider may revise and resubmit the training course material denied under item B within 30 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 days.

Subp. 9. **Training course examination.** All approved training courses for limited scope x-ray operators must include a written or electronic examination that meets the requirements of this subpart.

A. A training course provider must administer the examination at the end of the training course.

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

C. The examination must consist of at least 30 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 for limited scope x-ray operators 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.#### 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.

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

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

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

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

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

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

Commented [JC(44]: MDH intends to revisit x-ray system modality and possibly define.

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.

(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;

M. patient protection including:

(1) screening for pregnancy;

(2) exposure of pregnant patients; and

(3) patient shielding.

N. members of the public, ancillary personnel, or occupational workers:

(1) to hold or assist patients;

(2) to remain in the room or suite during radiation exposure; and

(3) who remain within the area of mobile or portable x-ray systems 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;

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

Commented [JC(52]: Reference to REGISTRANT RESPONSIBILITIES

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.

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

G. 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;

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(54]: New York QA guide

Commented [BB(55]: New York QA guide

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

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

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

Commented [BB(59]: OH wording

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

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

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.

Subp. 6. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(60]: Reference to Dose Monitoring

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

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

Commented [JC(63]: Reference to **RECORDS** part.

4732.#### MOBILE OR PORTABLE X-RAY SYSTEMS.

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 registrant's 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.

Subp. 4. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(64]: Section same as: TX, DE,

Commented [BB(65]: Reference Shielding rule part

Commented [BB(66]: Reference to Quality Management System

Commented [JC(67]: Instead of "according to this chapter", may include individual references to each modality's rule part for utilization.

Commented [JC(68]: Reference to **RECORDS** part.

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.

Subp. 3. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(69]: Reference to **RECORDS** part.

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.

Subp. 4. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(70]: Reference to **RECORDS** part.

4732.#### VARIANCE.

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

B. A registrant must maintain records under this part according to part 4732.####.

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. **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.

Commented [BB(71]: Similar: LA, NY

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.

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);

Commented [BB(72]: Similar: SC, IA, LA, NY, RI

Commented [JC(73]: SSRCR

Commented [BB(74]: Similar: TX, RI, MI

Commented [JC(75]: Similar: TX, RI, MI

Commented [JC(76]: Reference to Industrial Radiographer qualifications

Commented [JC(77]: Similar: TX, RI, MD

Commented [JC(78]: CO

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.####.

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

Commented [JC(79]: Reference to Service Provider - qualified expert

Commented [JC(80]: Reference to Service Provider - qualified medical physicist

Commented [BB(81]: 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(82]: Reference to Industrial Quality Management System

Commented [BB(83]: Reference to 4732.#### SITE-SPECIFIC AND X-RAY SYSTEM TRAINING.

Commented [BB(84]: Reference CT rule part

(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;

(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.####.

Commented [BB(85]: Reference fluoroscopy rule part

Commented [TP(86]: Reference to RECORDS.

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].

Subp. 10. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [BB(87]: Reference medical event rule part

Commented [BB(88]: Reference theft or loss rule part

Commented [JC(89]: Reference to Records part.

Commented [JC(90]: To include additional exemptions for non-human research, veterinary, security screening….

Commented [JC(91]: Reference to **RECORDS** part.

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

Subpart 1. **Applicability.**

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

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

Commented [JC(92]: Industrial and security screening x-ray systems must follow training in the Industrial and Security Screening rule parts and will have a similar layout/framework.

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 radiographic qualified operators 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 an 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(93]: 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.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(94]: Reference to **RECORDS** part.

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 ##.

Commented [JC(95]: MDH intends to revise this language further.

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;

(4) mammography x-ray systems, excluding tomosynthesis;

(5) mobile radiographic x-ray systems; or

(6) 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 used for five or more days in a 30-day period in the same room or suite.

Commented [JC(96]: Similar: ME, ND, AK, OH, DE, AZ, KS, OR, WI, NC

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. **Registrant shielding requirements prior to construction.**

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.###.

Commented [JC(97]: Sec. D.1201 - Occupational Dose Limits for Adults.
Sec. D.1206 – Planned or Emergent 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.

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 [TP(98]: 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.

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:

Commented [JC(99]: Subitems (14) and (15) may be revised or removed based on NCRP 147 and additional AC feedback.

Commented [JC(100]: Reference to Service Report subpart - Service Providers part.

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.

Commented [JC(101]: SSRCR
Similar: ND, DE, KS, IA, LA, GA

Commented [JC(102]: DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH, Appendix B

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 (2.1 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(103]: 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.####,

Commented [JC(104]: Reference to multiple dose rule parts.

then the registrant must modify the shielding or equipment configuration according to the recommendation of the service provider.

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;

(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 in the same location according to subpart 1, item D;

(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.

Commented [JC(105]: Reference to multiple dose rule parts.

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 [TP106]: 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.

Subp. 9. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(107]: Reference to **RECORDS** part.

4732.#### INDIVIDUAL MONITORING.

Subpart 1. **Applicability.**

A. A registrant is responsible for the individual monitoring requirement in this part.

B. For purposes of this part, occupational dose means the dose received by an individual in the course of employment or educational activities in which the individual worker's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with chapter 4731, from voluntary participation in medical research programs, or as a member of the public.

Commented [JC(108]: SSRCR, Part A

Subp 2. **Individual monitoring device.** Each registrant must monitor exposures from sources of radiation at levels sufficient to comply with the occupational dose limits of parts 4732.####.

Commented [TP(109]: SSRCR D.1502

Commented [TP(110]: References draft rule, occupational dose limits: rule parts that includes adult, minor, declared pregnancy, public dose

A. Each registrant must monitor occupational exposure to radiation from x-ray systems under its control and must supply and require the use of individual monitoring devices by:

Commented [JC(111]: Occupational dose limits are cumulative between radioactive material use and x-ray use.

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 4732.####, subpart 2;

(2) minors likely to receive, in one year from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);

(4) each individual entering a high or very high-radiation area; and

(5) individuals operating x-ray systems for medical fluoroscopically guided interventional procedures.

B. Each individual monitoring device must be assigned to and worn by only one individual.

Subp. 3. **Evaluation for the need of individual monitoring device**. A registrant must perform an evaluation to identify if an individual worker will exceed the dose limits in subpart 2, item A (1).

A. A registrant must use one or more of the following methods for the evaluation:

(1) the results of individual monitoring for each individual worker for a period of six months;

(2) the results of area monitoring at the individual worker position for a period of six months;

Commented [TP(112]: References draft rule, occupational dose limits: Occupational dose limits for adults: Subp. 2. Item A

Commented [JC(113]: Similar: SSRCR, AZ, IA, DE, NE

Commented [V(114R113]: NCRP Report 168 Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures does not specifically require individual monitoring; however it does state that "appropriately modified personal monitoring policies are needed for this group of workers.

(3) the registrant's previous individual monitoring records;

(4) the occupational dose assessment completed by a qualified expert;

(5) the radiation protection survey or area survey for each x-ray system; or

(6) an alternative method for evaluation approved by the commissioner.

B. Evaluations for individual monitoring must be completed using conditions representative of the x-ray system, volume of use, and proximity for each occupational worker.

Subp. 4. **Individual monitoring device location.** Each registrant must verify that individuals who are required to monitor occupational doses under subpart 2 wear individual monitoring devices according to this subpart.

A. An individual monitoring device used for monitoring the dose to the whole body must be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device must be at the collar or chest pocket.

B. An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman according to part 4732.#### must be located at the waist under any protective apron being worn by the woman.

C. An individual monitoring device used for monitoring the lens dose equivalent, to comply with part 4732.#### must be located at the collar or chest pocket, outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

Commented [TP(115]: SSRCR D.1503

Commented [TP(116]: References draft rule, occupational dose limits: Declared Pregnancy Dose Limits

Commented [TP(117]: References draft rule, occupational dose limits: Occupational dose limits for adults: Subp. 2. Item B(1)

D. An individual monitoring device used for monitoring the dose to the extremities, to comply with part 4732.#### must be worn on the extremity likely to receive the highest exposure. Each individual monitoring device must be oriented to measure the highest dose to the extremity being monitored.

E. When only one individual monitoring device is used to determine the effective dose equivalent for external radiation according to part 4732.#### it must be located at the collar or chest pocket outside the protective apron. When a second individual monitoring device is used for the same purpose, it must be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

Subp. 5. **Individual monitoring devices.**

A. All individual monitoring devices must be processed and evaluated by a dosimetry processor:

(1) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology; and

(2) approved in the accreditation process for the type of radiation or radiations included in the National Voluntary Laboratory Accreditation Program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

B. The following individual monitoring devices are exempt from being processed and evaluated under item A:

(1) direct and indirect reading pocket ionization chambers;

Commented [TP(118]: References draft rule, occupational dose limits: Occupational dose limits for adults: Subp. 2. Item B(2)

Commented [TP(119]: SSRCR D.1502 v.(3)

Commented [TP(120]: References draft rule, Dose Equivalent item B

Commented [TP(121]: SSRCR D.1501 (c)

(2) those dosimeters used to measure the dose to any extremity; and

(3) digital radiation-monitoring devices.

Subp. 6. **Individual monitoring reports; current workers.**

A. A registrant must make individual monitoring dose information available to workers.

B. An individual worker must supply dose information to the registrant about other current occupational does received due to employment at multiple facilities. An individual worker who is employed by multiple registrants must supply dose information quarterly to each registrant.

C. A registrant must provide an annual report to each individual monitored under subpart 2 of the dose received in that monitoring year if:

(1) the individual's occupational dose records exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue; or

(2) the individual requests their annual report.

D. A registrant may provide the individual's request and the annual report in an electronic or a written format.

Subp. 7. **Individual monitoring; former workers.**

Commented [TP(122]: 4731.1030 EXPOSURE NOTIFICATIONS AND REPORTS Subp. 3

A. A registrant must provide a written report of an individual's exposure to radiation upon request of the individual formerly engaged in radiation activities controlled by the registrant.

B. A registrant must provide the written report required under item A within 30 days of the request or within 30 days after the registrant has determined the dose of the individual, whichever is later.

Subp. 8. **Report at end of employment.**

Commented [TP(123]: 4731.1030 EXPOSURE NOTIFICATIONS AND REPORTS Subp. 4

A. A registrant must provide a report of an individual worker's dose of radiation to:

(1) a worker who is terminating employment; or

(2) a worker who, while employed by another person, is terminating a work assignment involving radiation dose in the registrant's facility.

B. The report of an individual's dose of radiation under item A must:

(1) be provided to the individual worker within 30 days after the exposure has been determined by the registrant;

(2) cover the calendar quarter in which the individual worker's activities involved exposure to radiation; and

(3) include the dates and locations of work under the registrant.

C. A registrant is not required to provide a report of an individual's dose of radiation to an individual worker who does not meet the individual monitoring requirements under subpart 2.

Subp. 9. **Report to individual worker exposed beyond occupational dose limits**.

A. A registrant must notify an individual worker who was exposed beyond the annual occupational dose limits according to part 4732.####, subparts 2, 5, and 6.

Commented [JC(124]: Reference to Dose Limits

B. The report to the individual worker exposed beyond the annual occupational dose limits must include:

(1) the individual worker's occupational dose;

(2) the name of the exposed individual worker who received a dose that exceeds the limits for occupational exposure;

(3) the reporting period in which the individual worker reached the annual occupational dose limits; and

(4) the alternative work conditions that removes the individual worker from additional exposure to radiation.

C. A registrant may provide the report under this subpart in electronic or written form.

Subp. 10. **Individual monitoring records.**

A. A registrant must maintain records showing the radiation doses of all individuals for whom individual monitoring is required according to this part. The records must be clear and legible.

B. A registrant must retain the record required under this part until the registrant terminates its registration with the commissioner.

4732.#### CAUTION SIGNS; POSTING.

Subpart. 1. **Applicability.**

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

(1) research;

(2) academic

(3) forensic science; and

(4) security screening.

B. Industrial x-ray systems must post signs according to parts 4732.#### to 4732.####.

Commented [JC(125]: Reference to Industrial rule parts

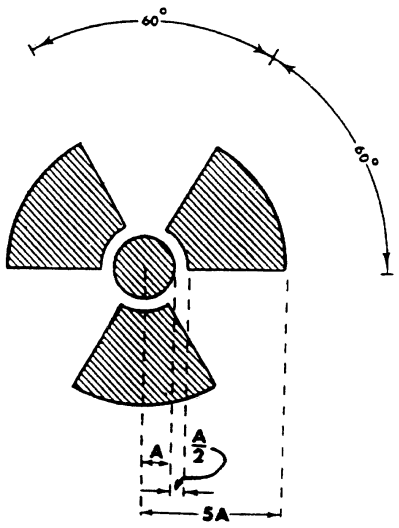
Subp. 2. **Standard radiation symbol and posting**.

A. Each radiation sign 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 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. **Warning and control devices; high radiation areas.**

Commented [TP(126]: 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.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(127]: Reference to **RECORDS** part.

4732.#### DOSE LIMITS.

Subpart 1. **Applicability.**

A. A registrant must comply with the dose limits in this part.

B. For purposes of this part, occupational dose means the dose received by an individual in the course of employment or educational activities in which the individual worker's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with chapter 4731, from voluntary participation in medical research programs, or as a member of the public.

Commented [JC(128]: SSRCR, Part A

Subp. 2. **Occupational dose limits for adults.** A registrant must control the occupational dose to individual adults to:

A. an annual limit, which is the more limiting of:

(1) the total effective dose equivalent being equal to 5 rem (0.05 Sv); or

Commented [TP(129]: SSRCR D.1201
Il, WA, CO
Definition:
"Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(2) the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye equal to 50 rem (0.5 Sv).

B. the annual limit to the lens of the eye, to the skin of the whole body, and to the extremities, which is:

(1) a lens dose equivalent of 15 rem (0.15 Sv); and

(2) a shallow-dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

C. Planned special exposures are exempt from the requirement of this subpart.

Subp. 3. **Dose in excess of annual limits**. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that an individual may receive during the current year.

Subp. 4. **Dose equivalent.** The assigned deep dose equivalent and shallow dose equivalent must be for the portion of the body receiving the highest exposure.

A. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from a survey or other radiation measurements, for complying with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of the individual monitoring are unavailable; or

B. When a protective apron is worn while working with medical fluoroscopic x-ray systems and monitoring is conducted as specified in part 4732.#### the effective dose equivalent for external radiation must be determined as follows:

Commented [JC(130]: Occupational dose limits are cumulative between radioactive material use and x-ray use.

Commented [TP(131]: SSRCR D.1201
IL, WA, CO

Commented [TP(132]: IL, WA, CO
In current Chapter 4732 and SSRCR

Commented [TP(133]: Definition:
"Planned Special Exposures" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Commented [TP(134]: SSRCR D.1201, item C(i)

Commented [TP(135]: References draft rule, individual monitoring: Individual monitoring device, Subp. 2. Item A (5)

(1) when only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent must be the effective dose equivalent for external radiation;

(2) when only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent of the limits under subpart 2, the reported deep dose equivalent value multiplied by 0.3 must be the effective dose equivalent for external radiation;

(3) when individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation must be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04; or

(4) by determining the effective dose equivalent based on National Council on Radiation Protection and Measurements Report No. 122, "Use of Personal Monitors to Estimate Effective Dose Equivalent and Effective Dose to Workers for External Exposure to Low-Let Radiation" or other nationally recognized guidelines.

(5) A registrant must include any documented occupational dose received by a worker while employed at another registrant when calculating an individual worker's total annual occupational dose.

Commented [TP(136]: SSRCR D.1201, item f II, WA, CO

Subp. 5. **Occupational dose limits for minors.** The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in subpart 2.

Commented [TP(137]: SSRCR D.1207
Il, WA, CO

Subp. 6. **Dose equivalent to an embryo/fetus.** A registrant is required to comply with this part for a woman who declares her pregnancy in writing.

Commented [TP(138]: SSRCR D.1208
Il, WA, CO

A. A registrant must limit the dose equivalent to an embryo/fetus during the entire pregnancy due to occupational exposure of a declared pregnant woman so that it does not exceed 0.5 rem (5 mSv).

Commented [TP(139]: **Definition:**
"Declared Pregnant Woman" means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

B. A registrant must avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the dose equivalent in item A.

C. A registrant is considered to be in compliance with item A if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy if the dose equivalent to the embryo/fetus exceeds 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose by the time the woman declares the pregnancy to the registrant.

Subp. 7. **Planned special exposures.** A registrant may authorize an adult worker to receive doses in addition to, and accounted for separately, from the doses received under the limits under subpart 2, if items A to G of this subpart are met.

Commented [TP(140]: SSRCR D.1206
Il, WA, CO

A. The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

B. The registrant and employer, if the employer is not the registrant, authorize the planned special exposure, in writing, before the exposure occurs.

C. Before a planned special exposure, the registrant verifies that each individual involved is:

(1) informed of the purpose of the planned operation;

(2) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

D. Before permitting an individual to participate in a planned special exposure, the registrant determines prior doses as required by 4732.#### during the lifetime of the individual for each individual involved.

Commented [TP(141]: References draft rule, individual monitoring:
Individual monitoring records, subp. 9

E. Subject to subpart 3, the registrant must not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(1) the numerical values of any of the dose limits under subpart 2 in any year; and

(2) five times the annual dose limits under subpart 2 during the individual's lifetime.

F. The registrant maintains records of the conduct of a planned special exposure according to part 4732.#### and submits a written report according to part 4732.####.

Commented [TP(142]: References draft rule, individual monitoring:
Individual monitoring records, subp. 9

Commented [TP(143]: References draft rule, Notification of occupational exposures exceeded.

G. The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposure must not be considered in controlling future occupational dose of the individual under subpart 2, but must be included in evaluations required under items D and E.

Subp. 8. **Dose limits for individual members of the public.**

Commented [TP(144]: SSRCR D.1301
II, WA, CO

A. Each registrant must conduct operations so that:

(1) the total effective dose equivalent to individual members of the public from the registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released according to Minnesota Rules, chapter 4731.4427, voluntary participation in medical research programs, or security screening the individual has received; and

Commented [TP(145]: Consistent with Minnesota Rules, Chapter 4732.0430

Commented [TP(146]: Public dose limits are cumulative between radioactive material use and x-ray use.

(2) the dose in any unrestricted area does not exceed 0.002 rem (0.02 mSv) in any one hour.

Commented [TP(147]: Consistent with Minnesota Rules, Chapter 4732.0430

B. If the registrant permits members of the public to have access to restricted areas, the dose limits for members of the public continue to apply to those individuals.

C. A registrant must comply with the annual dose limit in this subpart by measuring or calculating the total effective dose equivalent to the individual member of the

Commented [TP(148]: SSRCR D.1302
II, WA, CO

public likely to receive the highest dose from the registered operation does not exceed the annual dose limit.

Incident Reports and Notifications

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;

B. a patient receiving an unintended dose other than 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;

Commented [TP(149]: SSRCR, Part F medical event definition
Medical event" means one or more of the following criteria have occurred:
a. Unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rad);
b. Unintended dose other than skin dose in a single procedure greater than:
i. 5 times the facility's established protocol, and > 0.5 Gy (50 rad) to any organ, or
ii. 5 times the facility's established protocol, and > 0.05 Sv (5 rem) effective dose;
c. Wrong patient or wrong site for entire procedure when the resultant dose is:
i. Dose > 0.5 Gy (50 rad) to any organ or,
ii Effective dose ≥ 0.05 Sv (5 rem).

CRCPD H-38 for reporting diagnostic medical events.

Commented [TP(150]: SSRCR, Part F, unintended definition
New definition:

"Unintended" means a patient radiation dose resulting from a human error or x-ray system malfunction during the procedure.

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 that is greater than 5 rem (0.05 Sv) dose equivalent.

Commented [TP(151]: NRC

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 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.

Subp. 7. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(152]: Reference to **RECORDS** part.

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 or emergent special exposures are exempt from this part if they are:

(1) within the limits for planned or emergent 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 or emergent special exposures; contents.**

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

B. A report of planned or emergent special exposures must include:

(1) why a planned or emergent special exposure was conducted;

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

(3) the date the planned or emergent special exposure occurred;

(4) the name of the management official who authorized the planned or emergent 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 or emergent special exposure.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(153]: Reference to **RECORDS** part.

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

Subpart 1. **Applicability.**

Commented [TP(154]: Sec. D.2201 from SSRCR

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

B. For purposes of this part, loss means an x-ray system that is unrecoverable.

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 or 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 was 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(155]: MDH record draft rule part.

Subp. 4. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(156]: Reference to **RECORDS** part.

X-ray System Operation and Use Requirements

4732.#### [DENTAL.]

4732.#### RADIOGRAPHIC X-RAY SYSTEMS.

Subpart 1. **Applicability**.

A. A registrant who registers a stationary, mobile, or portable radiographic x-ray system for use on living humans must comply with:

1) this part; and

2) Code of Federal Regulations, Title 21, section 1020.30, 1020.31, or successor requirements.

B. All radiographic x-ray systems must be certified according to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020), or successor requirements.

C. All radiographic x-ray systems must meet manufacturer's specifications.

D. Podiatry x-ray systems must meet the requirements of this part.

E. For purposes of this part, a radiographic qualified operator is an individual who is qualified to operate radiographic x-ray systems according to subpart 26.

Subp. 2. **Leakage radiation from the diagnostic source assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means must be provided

Commented [BB(157]: F.4 (l)

Commented [BB(158]: F.4 (b) Similar: OR, WA, AK, ME, IA, TN, NE, GA, SC, IN, MS, WV, FL, CO,

to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. [21CFR1020.30(k)]

Subp. 3. **Radiation from components other than the diagnostic source assembly.** The radiation emitted by a component other than the diagnostic source assembly must not exceed an air kerma of 18 microgray (vice 2 milliroentgens exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. [21CFR1020.30(l))]

Commented [BB(159]: F.4 (c) Similar: WA, AK, ME, OR, IA, TN, NE, SC, IN, MS, WV, FL, CO,

Subp. 4. **Mechanical support of tube head.** The tube housing assembly supports must be adjusted so that the tube housing assembly remains stable during an exposure unless tube housing movement is a designed function of the radiographic x-ray system.

Commented [BB(160]: F.4 (j) Similar: OR, IA, TN, NE, GA, SC, IN, MS, WV, IL, TX, AK, WA, ME, FL, CO

Subp. 5. **Locks.** All position locking, holding, and centering devices on radiographic x-ray system components and systems must function as intended.

Commented [BB(161]: F.4 (k)
Similar: NE, MS, WV, AK, ME, CO

Subp. 6. **Source-to-skin distance.** A radiographic x-ray system must not be used in procedures where the source-to-skin distance is less than 30 centimeters (11.8 inches).

Commented [JC(162]: SSRCR; 4732.0550; 21 CFR 1020.31 (i) (2)

Subp. 7. **Radiation exposure control.** A registrant is responsible for the radiation exposure control requirements of a radiographic x-ray system.

A. An x-ray control must:

(1) be incorporated into each radiographic x-ray system so that an exposure can be terminated by a radiographic qualified operator at any time;

(2) be of the continuous pressure type; and

(3) bear the warning statement under 21 CFR 1020.30(j) which is legible and accessible to view: "WARNING This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed", or successor requirements.

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

Commented [BB(163]: F.4 (g) Similar: WA, AK, ME, OR, IA, TN, NE, GA, SC, IN, MS, WV, TX, FL, CO,
Added to this subpart, on own in SSRCR; 21 CFR 1020.31 (i) (2)

Subp. 8. **Beam-on indicators.** A registrant must have:

Commented [JC(164]: From 4732.0800, subp. 2, Items C & F.
No changes – consistent with SSRCR, Part F, p. 50.; 21 CFR 1020.31 (j)

A. a visual indication that is observable at or from a radiographic qualified operator's protected position whenever x-rays are produced; and

Commented [BB(165]: Similar: CA, SC, MT, IL, TX, MI, NJ, ME, FL, CO; 21 CFR 1020.31 (j)

B. a signal that is audible to a radiographic qualified operator that the exposure has terminated.

Subp. 9. **Technique factors.** A registrant is responsible for the technique factor requirements for a radiographic x-ray system.

Commented [JC(166]: Specifying provisions for technique factors that were not part of 4732.0800, subp. 2. **(GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)**
From *SSRCR, Part F, p. 50*

A. The technique factors on manual and automatic exposure control x-ray systems must be:

Commented [BB(167]: (21CFR1020.31(a)(1))
Similar: OR, IA, NE, CA, GA, SC, IN, MS, MT, WV, OH, IL, TX, AK, WA, MI, ME, FL, CO,

(1) indicated; and

(2) visible to a radiographic qualified operator before the exposure begins.

B. The requirements of item A may be met by permanent markings on x-ray systems that have fixed technique factors.

Commented [BB(168]: (21CFR1020.31(a)(1))
Similar: OR, IA, NE, GA, IN, MS, WV, IL, TX, AK, WA, MI, NJ, ME, FL, CO

C. A radiographic x-ray system not equipped with an operational anatomic programming option must have an electronic or written radiographic technique chart available at the control panel. The technique chart must identify:

(1) patient's body part and anatomical size for adult and pediatric;

(2) the technique factors including kVp, mA, and time;

(3) the type of image receptor used;

(4) the source-to-image receptor distance used; and

(5) the type of grid, if any.

Subp. 10. **Equipment performance evaluation; testing requirements; frequency.** A registrant using a radiographic x-ray system is responsible for the equipment performance evaluation testing requirements under subparts 11 to 22.

A. A service provider must complete equipment performance evaluations:

(1) at installation prior to first patient use;

(2) at intervals not to exceed 24 months (730 calendar days) from the date of the previous equipment performance evaluation; and

(3) with a radiation measurement instruments that is calibrated according to part 4732.####.

B. A registrant may have a grace period of 30 calendar days to comply with the periodic equipment performance evaluation testing interval requirement under item A, subitem (2).

C. A registrant must have equipment performance evaluation testing performed over all clinical ranges used by the registrant.

Commented [JC(169]: SSRCR, F.3

Commented [JC(170]: Subp. 7 comprised of 4732.1100, subparts 1, 2, and 11 - **INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.**

Commented [JC(171]: Reference to radiation measurement instruments in Service Providers part.

D. If a registrant's radiographic x-ray system fails to meet any of the equipment performance evaluation testing under subparts 11 to 22, then a registrant must:

(1) not use the radiographic x-ray system; and

(2) have a service provider calibrates the radiographic x-ray system so that the operating parameter complies with this part.

E. A service provider must perform an equipment performance evaluation after replacing or repairing any component of a registrant's radiographic x-ray system that potentially causes a change in the radiation output. The service provider must provide the service report under part 4732.####, subpart 5, to the registrant.

Subp. 11. **Equipment performance evaluation; filtration (half-value layer) test.**

Commented [V(172]: Items A - D are in 21 CFR 1020.30 (m) Beam Quality

A. The half-value layer of the useful beam for a given kVp must not be less than the values shown in item B.

B. Values for half-value layer of useful beam for x-ray tube:

Design operating range (kVp)	Measured kVp	Half-value layer (millimeter of aluminum) Other x-ray Systems*
Below 50	30	0.3
	40	0.4
	50	0.5

51-70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1 [2.5]
	80	2.3 [2.9]
	90	2.5 [3.2]
	100	2.7 [3.6]
	110	3.0 [3.9]
	120	3.2 [4.3]
	130	3.5 [4.7]
	140	3.8 [5.0]
	150	4.1 [5.4]

*X-ray systems manufactured before June 10, 2006, are not in brackets. X-ray systems manufactured on or after this date are in brackets.

C. To determine a half-value layer at a kVp (x-ray tube potential) listed under item B, a service provider must:

(1) make a linear interpolation or extrapolation; and

(2)include this determination in the service report under part 4732.####.

D. For capacitor energy storage equipment, compliance must be determined with the maximum selectable quantity of charge per exposure.

Commented [JC(173]: Similar: IA, IN

Commented [JC(174]: Reference to Service Provider part.

Commented [BB(175]: F.4 e (iii) similar: OR, IA, TN, NE, GA, SC, IN, MS, WV, IL, TX, AK, WA, FL, CO,

Subp. 12. **Equipment performance evaluation; timer test.**

A. The accuracy of the timer must meet the manufacturer's specifications.

B. The manufacturer specifications required under item A must be available for:

(1) use by a service provider; and

(2) review by the commissioner at the time of inspection.

C. If the manufacturer specifications under item B are not available, then the timer accuracy must be ±10 percent of the indicated time with testing performed at 0.5 second.

D. Means must be provided to terminate the exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

E. It must not be possible to make an exposure when the timer is set to a "zero" or "off" position, if either position is provided.

Subp. 13. **Equipment performance evaluation; source to image distance (SID) accuracy test.** SID must be indicated in centimeters or inches and the measured SID must correspond to the indicated value within 2 percent.

Subp. 14. **Equipment performance evaluation; x-ray and light field alignment test.** The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field must not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam. [21CFR1020.31(d)(2)(i)]

Commented [BB(176]: Similar: NE,

Commented [BB(177]: Similar: NE, NJ,

Commented [BB(178]: (21CFR1020.31(a)(2))
F.6 b (i) Similar: OR, TN, NE, CA, GA, MT, OH, IL, WA, NJ, ME,

Commented [BB(179]: (21CFR1020.31(a)(2)(i))
F.6 b (i) (2) Similar: OR, TN, NE, GA, OH, IL, WA, NJ, ME,

Subp. 15. **Equipment performance evaluation; x-ray and image receptor alignment test.** Means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID. [21CFR1020.31(e)(1)]

Subp. 16. **Equipment performance evaluation; collimator dial accuracy test.** Indication of field size dimensions and SIDs must be specified in centimeters or inches and must be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor. [21CFR1020.31(e)(3)]

Subp. 17. **Equipment performance evaluation; collimator illuminance test.** When a light localizer is used to define the x-ray field, it must provide an average illuminance of not less than 160 lux (15 foot candles) at 100 cm or at the maximum SID, whichever is less. The average illuminance must be based on measurements made in the approximate center of each quadrant of the light field. [21CFR1020.31(d)(2)(ii)]

Commented [BB(180]: F.6 (e)(ii)(2)
Similar: NJ

Subp. 18. **Equipment performance evaluation; linearity test.**

A. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings must not differ by more than 0.10 times their sum. This is: $|X1 - X2| \leq 0.10(X1 + X2)$; where X1 and X2 are the average mGy/mAs values obtained at each of two consecutive mAs selector

Commented [BB(181]: F.6 (d)(i and ii)

settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection. [21CFR1020.31(c)(1)]

B. For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum. This is: X1 - X2 [le]0.10 (X1 + X2); where X1 and X2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

Subp. 19. **Equipment performance evaluation; kVp accuracy test.**

A. A registrant's radiographic x-ray system must meet manufacturer's specifications for the kilovolt peak.

B. The manufacturer specifications required under item A must be available for:

(1) use by a service provider; and

(2) review by the commissioner at the time of inspection.

C. If the manufacturer's specifications under item B are not available, then the indicated kilovolt peak of a registrant's radiographic x-ray system must be accurate to within ±10 percent of the indicated setting(s).

Subp. 20. **Equipment performance evaluation; exposure output reproducibility test.** When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems must be less than or equal to five percent.

Subp. 21. **Equipment performance evaluation, automatic exposure controls (AEC).**

A. When an automatic exposure control is provided indication must be made on the control panel when this mode of operation is selected. [21CFR1020.31(a)(3)(i)]

B. When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation must be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment must be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater. [21CFR1020.31(a)(3)(ii)]

C. Either the product of peak x-ray tube potential, current, and exposure time must be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time must be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time must be limited to not more than 2,000 mAs per exposure. [21CFR1020.31(a)(3)(iii)]

D. A visible signal must indicate when an exposure has been terminated at the limits described in item C and manual resetting must be required before further automatically timed exposures can be made. (21CFR1020.31(a)(3)(iv)]

Subp. 22. **Equipment performance evaluation; positive beam limitation (PBL).** The requirements of this subsection apply to radiographic systems that contain PBL. [21CFR1020.31(g)]

Commented [BB(182]: F.6 (b)(ii) (includes A, B, C, D)

Commented [BB(183]: Similar: OR, TN, GA, OH, IL, WA, NJ, ME, FL, CO

Commented [BB(184]: Similar: OR, TN, WA, ME, FL, CO,

Commented [BB(185]: Similar: OR, TN, ME, FL, CO,

Commented [BB(186]: Similar: OR, TN, ME, FL, CO

Commented [BB(187]: F.6 (h)
New CO rule has this

A. When a PBL system is provided, it must prevent x-ray production when: [21CFR1020.31(g)(1)]

(1) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or [21CFR1020.31(g)(1)(i)]

(2) The sum of the length and width differences stated in item A (1) without regard to sign exceeds 4 percent of the SID. [21CFR1020.31(g)(1)(ii)]

(3) The beam-limiting device is at an SID for which PBL is not designed for sizing. [21CFR1020.31(g)(1)(iii)]

B. When provided, the PBL system must function as described in item A whenever all the following conditions are met: [21CFR1020.31(g)(2)]

(1) the image receptor is inserted into a permanently mounted cassette holder; [21CFR1020.31(g)(2)(i)]

(2) the image receptor length and width are less than 50 cm; [21CFR1020.31(g)(2)(ii)]

(3) the x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive; [21CFR1020.31(g)(2)(iii)]

(4) the x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and [21CFR1020.31(g)(2)(iv)]

(5) neither tomographic nor stereoscopic radiography is being performed. [21CFR1020.31(g)(2)(v)]

C. Compliance with the requirements of item A must be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of item B are met. Compliance must be determined no sooner than 5 seconds after insertion of the image receptor. [21CFR1020.31(g)(3)]

D. The PBL system must be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less than 5 cm. Return to PBL function as described in part A must occur automatically upon any change of image receptor size or SID. [21CFR1020.31(g)(4)]

E. A capability may be provided for overriding PBL in case of PBL system failure and for servicing the x-ray system. This override may be for all SIDs and image receptor sizes. A key must be required for any override capability that is accessible to the operator. It must not be possible to remove the key while PBL is overridden. Each key switch or key must be clearly and durably labeled as follows: For X-Ray Field Limitation System Failure. The override capability is considered accessible to the radiographic qualified operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the radiographic qualified operator would consider it part of the operational controls. [21CFR1020.31(g)(5)]

F. A registrant has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.

Subp. 23. **Analog imaging; screen-film evaluations.** A registrant must perform the screen-film evaluations under this subpart initially, and at intervals not to exceed 24 months.

A. For screen-film contact, no significant areas of poor contact as measured by no less than:

(1) 8 wires per inch mesh for regular film; or

(2) 7 holes per inch for regular film.

B. For screen film cassette speed match, densities must be within ± 0.10 optical density for all cassettes of the same speed used for imaging.

Commented [JC(188]: 4732.1100

Subp. 24. **Darkroom fog tests.** A registrant must perform the darkroom fog tests under this subpart initially and at intervals not to exceed 6 months.

A. A registrant must maintain a darkroom that is free of light and must use proper safelighting and safeguards so that any film type in use, when exposed to radiation, does not increase in density during processing.

B. A darkroom must be tested for film fog using the most sensitive film.

C. Tests for the film fog must be completed:

(1) when fog is suspected;

(2) after a filter or a bulb is replaced; and

(3) after any change in darkroom conditions.

D. The amount of fog for radiographic film must not exceed an optical density from 1.0 to 2.0 when processed an increase in optical density greater than 0.1 when exposed in the darkroom for two minutes with all safelights on.

E. If used, daylight film handling boxes must preclude fogging of the film.

Subp. 25. **Shielding requirements.** A registrant must meet the shielding requirements under part 4732.####.

Subp. 26. **Radiographic qualified operator qualifications.** A qualified operator of a radiographic x-ray system for use on living humans is limited to:

A. a qualified practitioner who is performing within the qualified practitioner's scope of practice;

B. an individual who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) under Minnesota Statutes, section 144.121, subdivision 5a(b)(2), and holds a valid certification;

C. a medical resident or fellow in training;

D. a radiologic technologist student in training under Minnesota Statutes, section 144.121, subdivision 5a, (b)(4), and only under the general supervision of a qualified practitioner or a certified radiologic technologist;

E. a limited scope x-ray operator who meets the requirements under Minnesota Statutes, section 144.121, subdivisions 5 and 5a and part 4732.####; or

F. an individual working as an 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).

Subp. 27. Prohibited uses.

Commented [JC(189]: CO

Commented [JC(190]: Reference to limited scope x-ray operators.

Commented [JC(191]: Replaces 4732.0305, subp. 1, item A (Prohibited Uses).
Based on SSRCR part F p. 18
MDH intends to move this to General Requirements for all registrants and add a comparable qualified service provider requirement.

A. A registrant must prohibit the exposure of an individual to the useful beam from radiographic x-ray systems except when authorized by a qualified practitioner for healing arts purposes.

B. A registrant must prohibit the exposure of an individual to the useful beam from radiographic x-ray systems for:

(1) training;

(2) demonstration; and

(3) other non-healing arts purposes.

Subp. 28. **Ordering of diagnostic radiographic examinations.**

A. A registrant must have an order for a diagnostic radiographic examination.

B. An order for a diagnostic radiographic examination must be:

(1) authorized by a qualified practitioner; and

(2) available to the qualified operator at the time of the examination, unless the order is a verbal order.

C. A qualified practitioner must authenticate a verbal order no later than 48 hours after a diagnostic radiographic examination.

D. An order for a diagnostic radiographic examination must include:

(1) the identification of the patient;

(2) the identification of the individual ordering the examination;

(3) the clinical indications for the examination;

(4) the anatomical part to be examined; and

(5) the examination to be performed.

Subp. 29. **Utilization record.** A registrant performing a diagnostic radiographic examination must maintain a utilization record, in electronic or written form, including:

A. a patient identifier;

B. the type of examination;

C. the date the examination was performed;

D. identification of the radiographic x-ray system and the room in which it was used;

E. the first and last name of the radiographic qualified operator who is operating the medical x-ray system;

F. the name of all individuals in the room when the patient or image receptor must be provided with support; and

G. the number of repeat exposures and retakes involved.

Subp. 30. **Repeat analysis.** A registrant must perform, or have performed, a repeat analysis of the retake or reject images used in patient diagnosis.

A. The analysis must include the overall repeat rate and the causes for the repeats.

B. Repeat analysis must be done at least quarterly.

C. Corrective actions taken based on the results of the analysis must be documented.

D. A repeat analysis is not required when a single radiographic qualified operator serves as both the owner and radiographic qualified operator.

Subp. 31. **Mobile diagnostic x-ray system; off-site use.** A registrant must document off-site use according to part 4732.####.

Commented [JC(192]: Mobile or portable registrants, subpart 2.

Subp. 32. **Protection from radiation.** A registrant is responsible for the radiation protection requirements for a radiographic qualified operator, ancillary personnel, and members of the public during a radiographic examination.

A. All individuals who must remain in the room or suite where stationary radiographic x-ray systems are in operation must be protected with personal protective equipment of at least 0.25 mm of lead equivalent thickness by:

(1) wearing a full apron;

(2) wearing a vest and half apron; or

(3) remaining behind a full body mobile shield.

B. All radiographic qualified operators or ancillary personnel where mobile or portable x-ray systems are in operation must be protected with personal protective equipment of at least 0.25 mm of lead equivalent thickness by:

(1) wearing a full apron; or

(2) wearing a vest and half apron.

C. Individuals must not be in the path of the useful beam during an exposure.

D. The useful beam must be limited to the patient's area of clinical interest.

E. A registrant must shield a patient according to part 4732.####.

Subp. 33. **Digital imaging.** A registrant is responsible for performing image quality control for digital imaging receptors according to this subpart.

A. A registrant must establish and maintain an image quality control program for digital imaging receptors according to manufacturer specifications and part 4732.####.

Commented [BB(193]: F.6 (k) (iii)

Commented [JC(194]: Advisory Committee: Is there potential for a full body mobile shield to obstruct patient viewing for the qualified operator?

Commented [JC(195]: Reference to Quality Management System (registrant's policy on patient shielding).

Commented [JC(196]: Reference to Quality Management Systems, quality control program subpart.

B. A registrant must follow nationally recognized guidelines and part 4732.#### to establish an image quality control program if specifications from the digital imaging receptor manufacturer under item A are not available.

C. The image quality control program under items A or B must be available:

(1) to a qualified operator; and

(2) for review by the commissioner.

D. If a registrant's digital imaging system fails to meet any of the image quality control testing under this subpart, then a registrant must:

(1) not use the digital imaging system; and

(2) have a service provider repair the digital imaging system so that the operating parameter meets the requirements of the registrant's image quality control program.

E. A registrant using a digital imaging receptor must establish and implement a policy that is documented in written or electronic form for determining an acceptable range for the exposure values for radiographic examinations performed when exposure indicators are available.

F. The indicated exposure values for each image must be compared to the established acceptable range under item E.

G. A registrant must:

(1) investigate deviations from the established acceptable range under item E;

(2) perform corrective actions, if needed; and

(3) document the results of any corrective actions.

Commented [JC(197]: Reference to Quality Management Systems, quality control program subpart.

H. Initially, and at least quarterly, a registrant must complete a phantom image evaluation using a phantom approved by the digital imaging system manufacturer. The phantom image evaluation must include:

(1) artifacts;

(2) spatial resolution;

(3) contrast/noise;

(4) workstation monitors; and

(5) exposure indicator constancy.

I. A registrant using computed radiography image receptors must erase all computed radiography cassettes at least weekly.

Subp. 34. **Film processing; manual or automatic.** A registrant must establish and implement quality control program, electronically or written, for manual or automatic processing of analog images that meets the requirements of this subpart.

A. A registrant must perform and document film processing quality control by:

(1) using sensitometry and densitometry equipment each day prior to any diagnostic films being processed where an evaluation of:

a) film speed and contrast density difference is +/- 0.15 optical density; and

b) base plus fog is no less than 0.25 optical density with a density difference that is not greater than 0.05 optical density; and

(2) performing corrective actions and conducting verification tests if any parameters under subitem (1) are outside of performance criteria.

B. The sensitometry test in item A, subitem (1), must be performed and evaluated using the most sensitive film.

C. A registrant must not use expired x-ray film for diagnostic images.

Subp. 35. **Film processing; manual.**

A. For manual processing of analog images, a registrant must:

(1) maintain the temperature of solutions in the tanks within the range of 60 degrees Fahrenheit to 80 degrees Fahrenheit (15.6 degrees Celsius to 26.7 degrees Celsius) with the time-temperature relationships recommended by the film manufacturer;

(2) maintain a copy of the film manufacturer's specifications for a radiographic qualified operator; and

(3) have the manufacturer's specifications available at the time of inspection by the commissioner.

B. In the absence of manufacturer specifications, a registrant must use the following time-temperature chart:

Time-Temperature Chart

Thermometer Reading	Thermometer Reading	Minimum Developing Time	
Celsius	Degrees Fahrenheit	Degrees	(Minutes)
26.7	80		2
26.1	79		2
25.6	78		2-1/2

Thermometer Reading Celsius	Thermometer Reading Degrees	Reading Fahrenheit	Minimum Developing Time Degrees	(Minutes)
25.0		77		2-1/2
24.4		76		3
23.9		75		3
23.3		74		3-1/2
22.8		73		3-1/2
22.2		72		4
21.7		71		4
21.1		70		4-1/2
20.6		69		4-1/2
20.0		68		5
19.4		67		5-1/2
18.9		66		5-1/2
18.3		65		6
17.8		64		6-1/2
17.2		63		7
16.7		62		8
16.1		61		8-1/2
15.6		60		9-1/2

C. A registrant must verify and document the time and temperature when processing analog images under items A or B by:

(1) using a thermometer to verify the actual temperature of the developer; and

(2) using a timer for accurate development time.

Subp. 36. **Film processing; automatic.**

A. For automatic processing of analog images, a registrant must:

(1) operate and maintain automatic processors following manufacturer specifications;

(2) maintain a copy of the film manufacturer's specifications for a radiographic qualified operator;

(3) have the manufacturer's specifications available at the time of inspection by the commissioner; and

(4) develop films according to the time-temperature relationships recommended by the film manufacturer.

B. In the absence of manufacturer specifications, a registrant must use the following time-temperature chart:

Developer Temperature		Minimum Immersion Time*
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28

Developer Temperature		Minimum Immersion Time*
30	86	29
29.5	85	30

**Immersion time only, no crossover time included.*

C. A registrant must verify the time and temperature when processing analog images under items A or B by:

(1) using a thermometer to verify that the developer temperatures fall within manufacturer's specifications;

(2) documenting the developer temperature before first patient use;

(3) weekly when the processor has a digital read-out or ready light; or

(4) daily when the processor does not have a digital read-out or ready light.

Subp. 37**. Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(198]: Reference to **RECORDS** part. There will be one Records provision applicable to all registrants.

4732.#### BONE DENSITOMETRY X-RAY SYSTEMS.

Subpart 1. **Applicability**.

Commented [JC(199]: Advisory Committee: MDH is seeking feedback on CT scanners performing DEXA scans. Is there anything that MDH needs to consider in addition to the current and/or proposed CT rules?

Commented [BB(200]: Similar: ND, VA; SSRCR

A. A registrant who registers a bone densitometry x-ray system for use on living humans must comply with:

(1) this part; and

(2) the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act or successor requirements.

B. All bone densitometry x-ray systems must meet manufacturer's specifications.

C. For purposes of this part, a bone densitometry qualified operator is an individual who is qualified to operate a bone densitometry x-ray system according to subpart ##.

D. A bone densitometry operator who operates a finger bone densitometry x-ray system that meets the definition under Minnesota Statutes, section 144.121, subdivision 8(a), and the registrant's facility where a bone densitometry operator operates such a finger bone densitometry x-ray system, are exempt from the requirements of Minnesota Statutes, section 144.121, subdivisions 5 and 6.

Subp. 2. **Radiation exposure control.** A registrant is responsible for the radiation exposure control requirements of a bone densitometry x-ray system. An x-ray control must:

A. be incorporated into each bone densitometry x-ray system so that an exposure can be terminated by a bone densitometry qualified operator at any time; and

B. bear the warning statement under 21 CFR 1020.30(j) which is legible and accessible to view: "WARNING This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed", or successor requirements.

Subp. 3. **Technique factors.** The technique factors on a bone densitometry x-ray system must be visible to a bone densitometry qualified operator before the exposure begins.

Subp. 4. **Equipment preventative maintenance.** A registrant using on a bone densitometry x-ray system is responsible for preventative maintenance under this part.

A. A service provider must complete preventative maintenance on a bone densitometry x-ray system according to the manufacturer specifications:

Commented [JC(201]: Reference to qualifications subpart

Commented [TP(202]: Advisory Committee: SSRCR does not have this language. A few states have this, including MN.

A bone densitometry x-ray system with stepless collimators must be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2.0% of the SID.

(1) at installation prior to first patient use; and

(2) initially and at intervals not to exceed 12 months (365 calendar days) from the date of the previous preventative maintenance.

B. A registrant may have a grace period of 30 calendar days to comply with the preventative maintenance requirement under item A, subitem (2).

C. If a registrant's bone densitometry x-ray system fails to meet any of the manufacturer's specifications under this subpart, a registrant must:

(1) not use the bone densitometry x-ray system; and

(2) have a service provider calibrate the bone densitometry x-ray system so that the operating parameter meets the requirements under item A.

D. A registrant must maintain the manufacturer specifications under item A and have the manufacturer specifications available for review by the commissioner.

Subp. 5. **Routine quality control; development and requirements.**

A. A registrant must establish a routine quality control program for a bone densitometry x-ray system according to:

(1) manufacturer specifications;

(2) recommendations of nationally recognized guidelines of professional societies such as the International Society for Clinical Densitometry or the American College of Radiology; and

(3) part 4732.####.

Commented [JC(203]: Reference to Quality Management Systems, quality control program subpart.

B. A quality control program for a bone densitometry x-ray system must be performed daily, at a minimum, when patients are being imaged. The quality control program must be performed:

(1) by a bone densitometry qualified operator; and

(2) prior to first patient use.

C. A registrant must maintain the routine quality control program under item A for:

(1) a bone densitometry qualified operator; and

(2) review by the commissioner.

Subp. 6. **Shielding plan exemption.** A registrant's bone densitometry x-ray system is exempt from the shielding plan requirements under part 4732.####.

Commented [JC(204]: Reference to Shielding part.

Subp. 7. **Bone densitometry qualified operator qualifications.** A qualified operator of a bone densitometry x-ray system for use on living humans is limited to:

A. a qualified practitioner who is performing within the qualified practitioner's scope of practice;

B. an individual who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) under Minnesota Statutes, section 144.121, subdivision 5a(b)(2), and holds a valid certification;

C. a medical resident or fellow in training;

D. a radiologic technologist student in training under Minnesota Statutes, section 144.121, subdivision 5a, (b)(4), and only under the general supervision of a qualified practitioner or a certified radiologic technologist; and

E. an individual working as an 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).

Subp. 8. **Prohibited uses.**

Commented [JC(205]: **Advisory Committee:** MDH is looking for feedback and discussion on precision assessment.

A. A registrant must prohibit the exposure of an individual to the useful beam from a bone densitometry x-ray system except when authorized by a qualified practitioner for healing arts purposes.

B. A registrant must prohibit the exposure of an individual to the useful beam from a bone densitometry x-ray system for:

(1) precision assessment;

(2) training;

(3) demonstration; and

(4) other non-healing arts purposes.

Commented [TP(206]: Prohibited: KS, Exam conducted only under a prescription of qualified practitioner: IA, VA, AR, ND, OK

Subp. 9. **Ordering of diagnostic bone densitometry examinations.**

A. A registrant must have a written or electronic order for a bone densitometry examination.

B. A written or electronic order for a bone densitometry examination must be:

(1) authorized by a qualified practitioner; and

(2) available to the bone densitometry qualified operator at the time of the examination.

C. An order for a bone densitometry examination must include:

(1) the identification of the patient;

(2) the identification of the individual ordering the examination;

(3) the clinical indications for the examination;

(4) the anatomical part to be examined; and

(5) the examination to be performed.

Subp. 10. **Utilization record.** A registrant performing a bone densitometry examination must maintain a utilization record, in electronic or written form, including:

A. a patient identifier;

B. the type of examination;

C. the date the examination was performed;

D. identification of the radiographic x-ray system and the room in which it was used;

E. the first and last name of the bone densitometry qualified operator who is operating the bone densitometry x-ray system;

F. the name of all individuals in the room when the patient or image receptor must be provided with support; and

G. the number of repeat exposures and retakes involved.

Subp. 11. **Repeat analysis.** A registrant must perform, or have performed, a repeat analysis of the retake or reject images used in patient diagnosis.

A. A repeat analysis must include the overall repeat rate and the causes for the repeats.

B. A repeat analysis must be done at least quarterly.

C. Corrective actions taken based on the results of the repeat analysis must be documented.

D. A repeat analysis is not required when a single bone densitometry qualified operator serves as both the owner and bone densitometry qualified operator.

Subp. 12. **Protection from radiation.** A registrant is responsible for the radiation protection requirements for a bone densitometry qualified operator, ancillary personnel, and members of the public during a bone densitometry examination.

A. A qualified expert, or a service technician under the general supervision of a qualified expert, must perform a radiation protection survey to determine the safe distance from the patient and radiation source for individuals in the room.

B. In the absence of a radiation protection survey under item A, individuals in the room must:

(1) be positioned at least 6 feet (2.0 meters) from the patient and radiation source; or

(2) be protected with personal protective equipment of at least 0.25 mm of lead equivalent thickness by:

a) wearing a full apron;

b) wearing a vest and half apron; or

c) remaining behind a full body mobile shield.

C. A qualified expert must place clear, identified markings that outline the safe distance for individuals in the room.

Subpart 13. **Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(207]: Reference to **RECORDS** part. There will be one Records provision applicable to all registrants.

4732.#### BREAST BIOPSY X-RAY SYSTEMS.

Subpart 1. **Applicability**.

A. A registrant who registers a breast biopsy x-ray system for use on living humans under must comply with:

(1) this part; and

(2) Code of Federal Regulations, Title 21, section 1020.30, 1020.31, or successor requirements.

B. All breast biopsy x-ray systems must be certified according to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020), or successor requirements.

C. All breast biopsy x-ray systems must meet manufacturer's specifications.

D. For purposes of this part, breast biopsy interventional imaging not regulated under Mammography Quality Standards Act [citation] is subject to this part.

E. For purposes of this part, a breast biopsy qualified operator is an individual who is qualified to operate breast biopsy x-ray systems according to subpart 20.

Subp. 2. **Locks.** All position locks, detents, angulation indicators, mechanical support devices for the x-ray tube, the compression plate, and the image receptor holder assembly on a breast biopsy x-ray system must function as intended.

Subp. 3. **Radiation exposure control.** A registrant is responsible for the radiation exposure control requirements of a breast biopsy x-ray system.

A. An x-ray control must:

(1) be incorporated into each breast biopsy x-ray system so that an exposure can be terminated by a breast biopsy qualified operator at any time; and

(2) bear the warning statement under 21 CFR 1020.30(j) which is legible and accessible to view: "WARNING This x-ray unit may be dangerous to patient

Commented [BB(208]: Taken from General
Similar: MI

Commented [JC(209]: Based on Texas administrative code.
3. Adding "by a qualified operator". Consistent with both SSRCR and Michigan administrative code.
4. Adding subitem 2 – consistent with both SSRCR and Michigan and Texas administrative code.

and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed", or successor requirements.

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

Subp. 4. **Technique factors.** A registrant is responsible for the technique factor requirements for a breast biopsy x-ray system.

C. The technique factors on manual and automatic exposure control x-ray systems must be:

(3) indicated; and

(4) visible to a breast biopsy qualified operator before the exposure begins.

D. The requirements of item A may be met by permanent markings on breast biopsy x-ray systems that have fixed technique factors.

E. A breast biopsy x-ray system not equipped with an operational anatomic programming option must have an electronic or written breast biopsy technique chart available at the control panel. The technique chart must identify:

(6) breast thickness;

(7) the technique factors including kVp, mA, and time;

(8) the type of image receptor used;

(9) the source-to-image receptor distance used; and

(10) the type of grid, if any.

Commented [BB(210]: Advisory Committee: Are battery-powered generators applicable to breast biopsy imaging that MDH regulates.

SSRCR F.4 (g)
Similar: WA, AK, ME, OR, IA, TN, NE, GA, SC, IN, MS, WV, TX, FL, CO,
Added to this subpart, on own in SSRCR; 21 CFR 1020.31 (i) (2)

Commented [JC(211]: Specifying provisions for technique factors that were not part of 4732.0800, subp. 2. (**GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)**
From *SSRCR, Part F, p. 50*

Commented [JC(212]: SSRCR, F.3

Commented [TP(213]: Advisory Committee: Are subitems (3), (4), and (5) needed for breast biopsy x-ray systems?

Subp. 5. **Equipment performance evaluation; testing requirements; frequency.** A registrant using a breast biopsy x-ray system is responsible for the equipment performance evaluation testing requirements under subparts 6 to 17.

A. A qualified medical physicist must complete equipment performance evaluations:

(1) at installation prior to first patient use;

(2) at intervals not to exceed 12 months (365 calendar days) from the date of the previous equipment performance evaluation; and

(3) with radiation measurement instruments that are calibrated according to part 4732.####.

Commented [JC(214]: Reference to radiation measurement instruments in Service Providers part.

B. A registrant may have a grace period of 30 calendar days to comply with the periodic equipment performance evaluation testing interval requirement under item A.

C. A registrant must have equipment performance evaluation testing performed over all clinical ranges used by the registrant.

D. If a registrant's breast biopsy x-ray system fails to meet any of the equipment performance evaluation testing under subparts 6 to 17, then a registrant must:

(1) not use the breast biopsy x-ray system; and

(2) have a service provider calibrates the breast biopsy x-ray system so that the operating parameter complies with this part.

E. A qualified medical physicist must perform an equipment performance evaluation after replacing or repairing any component of a registrant's breast biopsy x-ray system that potentially causes a change in the radiation output. The

qualified medical physicist must provide the service report under 4732.####, subpart 5 to the registrant.

Subp. 6. **Equipment performance evaluation; filtration (half-value layer) test.** The half-value layer must be greater than or equal to the value kvp/100 in units of millimeter of aluminum.

Subp. 7. **Equipment performance evaluation; collimator assessment test.** A registrant is responsible for image receptor testing for breast biopsy x-ray systems. For a digital image receptor, an x-ray field must not extend beyond the image receptor by more than 5 mm on any side.

Subp. 8. **Equipment performance evaluation; focal spot performance and system limiting spatial resolution test.** A registrant is responsible for focal spot performance and system limiting spatial resolution tests for breast biopsy x-ray systems. For a digital image receptor, the focal spot must not degrade from the initial measurement at installation. The initial measurement must be maintained by the registrant for each x-ray system.

Commented [TP(215]: Wording from IA

Commented [TP(216]: **Advisory Committee**: Is there a recommended focal spot and spatial resolution requirements from a manufacturer or national recognized guidelines?

Subp. 9. **Equipment performance evaluation; kVp accuracy.** The indicated kilovolt peak of a registrant's breast biopsy x-ray system must be accurate to within ±5 percent of the indicated settings.

Subp. 10. **Equipment performance evaluation; kVp reproducibility test.** A registrant's breast biopsy x-ray system kilovolt peak must be reproducible having a coefficient of variation equal to or less than 0.02.

Commented [TP(217]: NY

Subp. 11. **Equipment performance evaluation; automatic exposure control system or manual exposure performance assessment test.** A registrant is responsible for image receptor testing for breast biopsy x-ray systems. For a digital image receptor, the signal value at the

center of the digital field of view must remain within 20 percent of the signal obtained for the 4 cm phantom when thicknesses of a homogeneous material is varied over a range of 4 to 8 cm using the clinical techniques for each thickness. If the signal values do not meet this criteria, the qualified medical physicist must develop a technique chart that meets the criteria of this subpart and include in subpart 4.

Subp. 12. **Equipment performance evaluation; receptor speed uniformity test.** A registrant is responsible for image receptor testing for breast biopsy x-ray systems.

A. For a digital image receptor, the signal-to-noise ratios measured in each corner of the image must be within 15 percent of the signal-to-noise ratios measured at the center of the field of view.

B. For a digital image receptor that is not equipped with region of interest signal measurements, the breast biopsy x-ray system must meet the image receptor uniformity requirements specified by the manufacturer.

C. A registrant must maintain the manufacturer specifications under item B and have them available for review by the commissioner.

Subp. 13. **Equipment performance evaluation; breast entrance exposure and average glandular dose test.** A registrant's breast biopsy x-ray system average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast for breast entrance exposure and average glandular dose.

Subp. 14. **Equipment performance evaluation; exposure output reproducibility test.** The registrant's breast biopsy x-ray system must meet the coefficient of variation for both air kerma and current-time product (mAs) must not exceed 0.05 for exposure output reproducibility.

Subp. 15. **Equipment performance evaluation; image quality evaluation test.** A registrant is responsible for image quality evaluation testing for breast biopsy x-ray systems. For a digital image receptor, the phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

Subp. 16. **Equipment performance evaluation; artifact evaluation test.** A registrant's breast biopsy system must be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the full area of the exposed image receptor on the breast support assembly when testing for artifacts. Any significant black or white artifacts seen in the image detector field must be corrected.

Subp. 17. **Equipment performance evaluation; localization accuracy test.** A registrant's breast biopsy system must be tested using a phantom made of gelatin or similar material for the localization accuracy test where:

A. the biopsy needle must capture the intended object in the phantom;

B. the accuracy must be within 1 mm of target; and

C. the test must include a portion of the test lesion in the sample chamber.

Subp. 18. **Routine quality control; development and requirements.**

A. A radiation safety officer must establish and maintain a routine quality control program for a breast biopsy x-ray system according to manufacturer specifications, part 4732.####, and:

(1) a localization accuracy test to be performed daily where each of the indicated needle tip coordinates must be within 1 mm of the actual preset needle tip location;

Commented [BB(218]: Taken from IA

Commented [JC(219]: Advisory Committee: Do we need to qualify the phantom (ie – ACR accredited, or mammography standard)?

Commented [JC(220]: Advisory Committee: Are items A and C saying the same thing? If so, which is preferred or more accurate?

Commented [JC(221]: Advisory Committee: Who should be developing quality control program? RSO, QMP?

(2) a phantom image evaluation test to be performed at least weekly where the phantom image must achieve at least the minimum score for a digital image receptor, the phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer;

(3) a hard copy output quality test to be performed at least monthly, if hard copies are produced from digital data; and

Commented [JC(222]: Only maintain for 60 days.

(4) a compression test to be performed at intervals not to exceed six months where the maximum compression force for the power drive mode must be between 25 and 45 pounds.

B. A quality control program for a breast biopsy x-ray system must be performed on a daily basis when patients are being imaged. The quality control program must be completed:

(1) by a breast biopsy qualified operator; and

(2) prior to first patient use.

C. A registrant must maintain the routine quality control program under item A for a breast biopsy qualified operator and for review by the commissioner.

Subp. 19. **Shielding requirements.** A registrant must meet the shielding requirements under part 4732.####.

Subp. 20. **Breast biopsy qualified operator qualifications.** A qualified operator of a breast biopsy x-ray system for use on living humans is limited to:

A. a qualified practitioner who is performing within the qualified practitioner's scope of practice;

B. an individual who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) under Minnesota Statutes, section 144.121, subdivision 5a(b)(2), and holds a valid certification;

C. a medical resident or fellow in training; or

D. a radiologic technologist student in training under Minnesota Statutes, section 144.121, subdivision 5a, (b)(4), and only under the general supervision of a qualified practitioner or a certified radiologic technologist.

Subp. 21. **Prohibited uses.**

C. A registrant must prohibit the exposure of an individual to the useful beam from breast biopsy x-ray systems except when authorized by a qualified practitioner for healing arts purposes.

D. A registrant must prohibit the exposure of an individual to the useful beam from breast biopsy x-ray systems for:

(4) training;

(5) demonstration; and

(6) other non-healing arts purposes.

Subp. 22. **Ordering of breast biopsy examinations.**

A. A registrant must have an order for a breast biopsy examination.

B. An order for a breast biopsy examination must be:

(1) authorized by a qualified practitioner; and

(2) available to the breast biopsy qualified operator at the time of the examination.

Subp. 23. **Utilization record.** A registrant performing a breast biopsy examination must maintain a utilization record, in electronic or written form, including:

H. a patient identifier;

I. the type of examination;

J. the date the examination was performed;

K. the first and last name of the breast biopsy qualified operator who is operating the breast biopsy x-ray system; and

L. the name of all individuals in the room when the patient or image receptor must be provided with support.

Subp. 24. **Protection from radiation.**

A. A registrant is responsible for the radiation protection requirements for a breast biopsy qualified operator, ancillary personnel, and members of the public during a breast biopsy examination.

B. In a room where breast biopsy x-ray systems are in operation, all individuals must be protected with personal protective equipment of at least 0.25 mm by:

(4) wearing a full apron;

(5) wearing a vest and half apron; or

(6) remaining behind a full body mobile shield.

Subp. 25. **Digital imaging.**

E. A registrant must establish an image quality control program according to specifications from the digital imaging receptor manufacturer and perform image quality control according to the program.

F. If specifications from the digital imaging receptor manufacturer under item A are not available, then a registrant must follow nationally recognized guidelines to establish an image quality control program.

G. The image quality control program under items A or B must be available:

(1) to a qualified operator; and

(2) for review by the commissioner.

D. If a registrant's digital imaging system fails to meet any of the image quality control testing under this subpart, then a registrant must:

(1) not use the digital imaging system; and

(2) have a service provider repair the digital imaging system so that the operating parameter meets the requirements of the registrant's image quality control program.

H. A registrant using a digital imaging receptor must establish and implement a policy that is written or documented in an electronic recordkeeping system for determining an acceptable range for the exposure values for breast biopsy examinations performed when exposure indicators are available.

I. The indicated exposure values for each image must be compared to the established acceptable range under item D.

J. A registrant must:

(4) investigate deviations from the established acceptable range under item D;

(5) perform corrective actions, if needed; and

(6) document the results of any corrective actions.

Subp. 26**. Records.** A registrant must maintain records under this part according to part 4732.####.

Commented [JC(223]: Reference to **RECORDS** part. There will be one Records provision applicable to all registrants.