Chapter 4732 Modifications Summary

Purpose, Scope, and Definitions

4732.0100 Purpose and Scope

- No changes at this time.

4732.0110 Definitions

- Amend and update existing definitions. Align definitions, where applicable, with Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulation for Control of Radiation (SSRCR).
- Repeal outdated definitions and those that are not used in rule chapter.
- Add new definitions.
- Add definition of “Operate” or “operating” for qualified operators.
- Add definition of qualified operator
- Add definition of qualified practitioner.
- Add definitions of service provider practice to include qualified expert, qualified medical physicist, physicist assistant, service technician, and vendor.
- Revise certain definitions to reflect industry practice.

Registration Requirements

4732.0200 Registration Requirements for Radiation-Producing Equipment and Other Electronic Devices that Produce Radiation

- Require registration for those that perform mobile/portable imaging outside of the place of registration.
- Add definition of administrative control.
- Clarify change of ownership provision.

4732.0210 Registration Fees

- Changes in fee are according to Minnesota Statutes, 144.121, X-ray Equipment

4732.0220 General Requirements for all Facilities

- Enumerate all general requirements in central location. Most will be discussed in more detail elsewhere in rule chapter.
- Require registrant to post a “notice to employees” provided by the commissioner.
- Create a radiation safety committee if registrant owns and/or operates computed tomography (CT) or fluoroscopic equipment.

4732.0250 Reciprocity for Out-of-State Radiation-Producing Equipment

- Review out-of-state reciprocity.
- 4732.0275 Registration of Service Providers
- Require registration for all service providers that work in the state according to Minnesota Statutes, 144.121, X-ray Equipment.
- Require service providers to provide registrant equipment registration information at the time of sale and/or installation.

4732.0280 Service Provider's Responsibility

- Clarify and possibly expand roles and responsibilities of service providers.
- Add service provider practice responsibilities for qualified expert, qualified medical physicist, physicist assistant, service technician, and vendor.
- Add documentation requirements for survey equipment and calibration.Review applicable tests when there is a change in x-ray tube, x-ray control, image receptor, etc.

General Administration

4732.0300 Exemptions

- Review and clarify the need for MDH to specify the criteria it uses for designating radiation producing equipment as exempt from registration and requirements of this chapter.

4732.0305 Prohibited Uses

- Clarify notification and documentation requirements regarding human research.
- Add and align rules consistent with, Minnesota Statutes, 144.1215, Handheld Dental X-ray Equipment, for hand-held units for human use that are certified and that have been approved for human use by the Food and Drug Administration.
- Add provisions for hand-held non-human use.
- Prohibit the use of radiation equipment on humans that has not been approved for use by the Food and Drug Administration.

- Establish prohibited uses with each modality.

4732.0306 Unauthorized Uses

- Establish unauthorized uses with each modality.

4732.0308 Variance Ionizing Radiation Rules

- No changes at this time.

4732.0310 Data Privacy

- Consider removing this part.

4732.0315 Deliberate Misconduct

- Consider removing this part.

4732.0320 Employee Protection

- Consider removing this part.

4732.0330 Records

- Ensure that each rule part that has a record and/or retention requirement is enumerated in this part so that there is one central location containing all record requirements.

4732.0335 Inspections and Testing

- Align enforcement provisions with Minn. Stat. § 144.989-144.993, Health Enforcement Consolidation Act of 1993, or “HECA”.

4732.0340 Violations and Enforcement Requirements

- Align enforcement provisions with HECA.

Shielding Requirements

4732.0355 General Requirements for Shielding Against Ionizing Radiation

- Review shielding provisions in rule chapter.

4732.0360 shielding plan

- Consider removing requirement that registrants submit shielding plans to MDH.
- Incorporate qualifications for completing expert physics services of Minnesota Statute 144.121 into rule.
- Clarify exemption provision for shielding plan.

4732.0365 Additional Shielding Requirements for Dental Facilities

- Modify and align requirements for panoramic and cone beam computed tomography (CBCT) extraoral equipment.

4732.0370 Additional Shielding Requirements for Industrial Facilities Using

- Clarify the shielding requirements for industrial equipment.

4732.0380 Shielding Requirements for Accelerators

- Update to reflect industrial accelerators only and not for human use.

4732.0385 Caution Signs

- Review for changes.

Dose Levels

Align and modify requirements in parts 4732.0400 to 4732.0440 with Minnesota Rules, Chapter 4731 – Radiation Safety.

4732.0400 Determination of Accumulated Occupational Dose

4732.0410 Occupational Dose Limits for Adults

4732.0415 Dose Equivalent to an Embryo or Fetus

4732.0420 Exposure of Minors

4732.0425 Planned Special Exposures

4732.0430 Dose Limits for Individual Members of the Public

4732.0440 Individual Monitoring.

- Consider requiring dosimetry use for all occupational staff who remain in the room during fluoroscopic and CT procedures.
- Update control device requirements to reflect current standards and best practices.

Radiation Safety Requirements

4732.0500 Registrant's Safety Responsibilities

- Amend the training exemption for licensed practitioners of the healing arts.
- Clarify the requirements for "operation of x-ray equipment on humans".

4732.0505 Radiation Safety Officer Responsibilities

- Clarify the requirements of a quality assurance program and its implementation.
- Require all policies, procedures, and programs, and instructions be written and/or in an electronic format.

4732.0510 Procedures and Safety Instruction for Facilities

- Clarify and require that site-specific requirements for temporary and float staff who work for different registrants.
- Consider annual refresher training for all individuals.
- Require all policies, procedures, programs, and instructions to be written and/or in an electronic format.
- Add radiation safety training requirements for any staff who must remain in the room during exposures.
- Review protective garment lead equivalency requirements for consistency with SSCRC and national standards.
- Review and develop requirements for the use of Enhanced Radiation Protection Devices (ERPDs)
- Update film cassette with "image receptor" here and throughout the rule.

4732.0520 Quality Assurance Program

- Ensure quality assurance provisions are consistent throughout rule chapter.
- Review use of x-ray equipment that has failed a calibration test.

4732.0530 ALARA Program

- Review for changes.4732.0535 Retake or Reject Analysis Program

- Require procedures to be in writing or in electronic format.
- Clarify document incidences for retake.

4732.0540 Radiation Program Audits

- Require procedures to be in writing and/or in electronic format.

4732.0545 Utilization Log

- Align utilization requirements with any changes to extraoral, CBCT and hand-held dental imaging.

4732.0550 Radiological Practice Standards

- Consider an initial radiation survey for supplemental protective barriers.
- Consider requirements for CT units to have protocols for each examination performed.
- Require annual review of protocols in radiation safety committee.

4732.0555 X-Ray Film Processing Requirements

- Revise processing requirements for registrants who process fewer than ten patient films per week.

4732.0560 Ordering of Diagnostic Radiographic or Therapeutic Procedures

- Clarifying equivalent procedures and documentation.
- Align collaborative agreement provision with Board of Dentistry requirements.

4732.0565 Healing Arts Screening

- Review value of healing arts screening.

4732.0570 Operator Requirements

- Consider adding continuing education requirements for operators.

4732.0575 Examination Requirements

- Consider adding prerequisite didactic and clinical training requirements for limited scope x-ray operators.
- Consider limiting the number of exam attempts for limited scope x-ray operator to three times before additional training and education are required.

- Clarify examinations approved by the commissioner according to Minnesota Statute 144.121.

4732.0580 Registrant Requirements for Operators in Facilities Using X-Ray Equipment

- Require all ARRT credentialed operators to maintain compliance with their certification.

4732.0585 Equivalent Examinations

- Clarify equivalent examinations according to the qualification requirements of Minnesota Statute 144.121.

4732.0590 Individuals Operating X-Ray Equipment During Training

- Specify notification requirements to the commissioner of externship sites and dates.
- Add requirements for registrants with respect to externships at their location
- Clarify commissioner approved training programs for operation of x-ray equipment on humans while participating in the approved training program.

Reports and Notifications

4732.0600 Reports of Theft or Loss of Radiation-Producing Equipment

- Update reporting requirements to reflect use of additional technology.

4732.0610 Reports of Medical Events or Incidents Involving Radiation-Producing Equipment

- Align with CRCPD H-38 Committee recommendations.

4732.0620 Warning and Control Devices for High and Very High Radiation Areas

- Align requirements with Minn. Rules, chapter 4731 – Radiation Safety.

4732.0630 Bypassing a Safety Device

- Clarify the type of x-ray equipment.

Calibrations and Measurement Instruments

4732.0700 Calibrations

- Identify specific equipment requirements, based on nationally recognized guidelines that must be performed after replacing components that cause a change in radiation output.

4732.0710 Radiation Survey or Measurement Instruments

- Add requirements when survey meters are used for measurement including certificate of calibration, who performed, date performed, and measurements identified.

Equipment Requirements

4732.0800 General Equipment Requirements for all Diagnostic Radiation-Producing Systems

- Update nationally recognized standards with "nationally recognized performance standards."
- Require that service providers give registrant manufacturer's specifications and/or nationally recognized standards.
- Registrant must make these manufacturers' specifications and/or national recognized standards and available for review.

4732.0820 General Purpose Diagnostic Radiation-Producing Equipment Manufactured Before 1973

- X-ray systems regardless of age must be in compliance with MDH X-ray performance standards and the applicable Code of Federal Regulations, Title 21, section 1020.30 through 1020.40 or successor requirements.

4732.0825 Fluoroscopic X-Ray Systems Except Radiation Therapy Simulators

- Amend the training exemption for licensed practitioners of the healing arts.
- Specify other miscellaneous items appropriate to site-specific use pertaining to fluoroscopic training requirements.
- Add requirements for a radiation safety committee for registrants that perform fluoroscopy including fluoroscopically-guided interventional procedures.

4732.830 Fluoroscopic Dose-Area-Product Monitor

- Review and update requirements consistent with Displays of values of AKR and cumulative air kerma according to Code of Federal Regulations, Title 21, section 1020.32 or successor requirements.

4732.0835 Requirements for Computed Radiography, Digital Radiography, or Photostimulable Storage Phosphor Radiation-Producing Equipment

- Imaging receptors and requirements will be identified within each imaging modality.

4732.0850 Bone Densitometry Systems

- Review nationally recognized standards and best practices for bone densitometry systems.
- Clarify specific tests needed to perform calibrations or equipment performance evaluations.

4732.0860 Computed Tomography Requirements

- Make conforming changes with duplicative requirements.
- Clarify that daily QC performed by operators is prior to first use.

4732.0865 Computerized Tomography Designed for Visualization of the Head and Soft Tissue of the Neck

- Review nationally recognized guidelines and update to include current and emerging CBCT technology.
- Clarify CBCT x-ray system requirements for use in a medical and a dental capacity.

4732.0870 Requirements for Stereotactic Mammographic Equipment

- Update to reflect who is authorized to perform mammography procedures.
- Add requirements for diagnostic and screening mammography facilities and systems that are consistent with the Mammography Quality Standards Act.

4732.0875 Veterinary Medical Radiographic Systems

- Review and update requirements consistent with human-use radiographic systems for the protection of occupational staff and the public.

Add requirements for the operation of, quality control requirements for, and equipment performance evaluations for fluoroscopic, CT and

CBCT systems used in veterinary practice 4732.0880 Intraoral Dental Radiographic Systems

- Modify to differentiate between human and non-human use.

4732.0890 Extraoral Dental Systems

- Review for changes.

4732.0895 Dental Computed Tomography Systems

- Review nationally recognized guidelines and update rule part to include current and emerging CBCT technology.

Radiation Therapeutic Requirements

4732.0900 General Requirements for Facilities using Accelerators

- Review for changes.

4732.0925 General Requirements for Therapeutic Equipment

- Review for changes.

4732.0930 Therapeutic Radiation Machines of less than 500 kv

- Review for changes.

4732.0940 Therapeutic Radiation Machines - Photon Therapy Systems (500 kv and above) and Electron Therapy Systems (500 kev and above)

- Review for changes.

4732.1000 Requirements for X-Ray Fluorescent Analyzers and Bomb Detection Units

- Clarify XRF equipment use and safety procedures.
- Update the requirements for industrial facilities to include a radiation safety/quality assurance program in all industrial rule provisions.
- Move bomb detection provisions to a new part and require additional safety measures.

4732.1040 Industrial Facility Requirements for using Radiation-Producing Equipment in Manufacturing Processes, Gauges, and Cabinets

- Review new industrial equipment and uses.
- Revise to accommodate these newer uses.

4732.1050 Requirements for Permanent Industrial Radiographic Installations

- Review similar industrial radiography rules in Minnesota Rules, Chapter 4731, Radioactive Materials, to ensure accuracy and consistency with 4732.1050 through 4732.1070.

4732.1055 Industrial Radiographic Operating and Emergency Procedures

4732.1058 Industrial Radiography in a Temporary Job Site

4732.1060 Instruction and Training for Industrial Radiography

4732.1063 Warning Devices for Industrial Radiography Facilities

4732.1065 Posting Requirements for Industrial Radiography

4732.1067 Surveillance for Industrial Radiography

4732.1070 Radiographer Certification

4732.1100 Installation Calibration Tests and Equipment Performance Tests for a Quality Assurance Program

- Move the specific equipment performance evaluation tests within each imaging modality.
- Update requirements consistent with Code of Federal Regulations, Title 21, section 1020.30 through 1020.33 or successor requirements.
- Consider provisions requiring only a qualified medical physicist or physicist assistant to perform equipment performance evaluations on CT, medical CBCT, and fluoroscopy.
- Specify that calibration/equipment performance evaluations must be performed by a registered service provider.

- Review nationally recognized guidelines to identify equipment requirements that must be performed after replacing components that cause a change in radiation output. See also 4732.0700.
- Update for digital (CR and DR) imaging for QC and frequency by reviewing SSRCR or other nationally recognized standard(s).
- Update and include provisions for dental imaging.
- Update processor quality control requirements and incorporate requirements into each applicable imaging modality.
- Require all other tests indicated for diagnostic radiographic tubes (subpart 5) for facilities with CT, CBCT, fluoroscopes and c-arm fluoroscopes.
- Amend minimum test interval frequency.
- Research nationally recognized guidelines for use of CT, fluoroscopy, and dynamic digital radiography systems and revise provisions accordingly.
- Verify that the current tests, and frequency of these tests, are applicable for facilities with CT and CBCT scanners.
- Verify the minimum test intervals for CT and CBCT quality control performed daily and prior to first use on patients.
- Add manufacturer's recommended tests and frequency for digital imaging for all technology.
- Add performance standards, according to nationally recognized guidelines and/or SSRCR, for CBCT and bone densitometry.
- Consider provisions to address emerging technology.

4732.1120 Therapeutic Equipment Performance Tests and Limits for Measurement Equipment

4732.1130 Equipment Performance Tests for External Beam Teletherapy and Simulation Systems

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