Chapter 4732 Modifications Summary

SEPTEMBER 30, 2016

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 CRCPD state suggested regulations.
- Repeal outdated definitions and those that are not used in rule chapter.
- Add new definitions.
- Consider defining “operation of x-ray equipment” for qualified operators.
- Consider adding definition of “mid-level practitioner”.
- Consider revising certain definitions to reflect industry practice.
- Repeal and move radiation therapy-specific definitions to proposed new rule Chapter 4733, Radiation Therapy.

REGISTRATION REQUIREMENTS

4732.0200 REGISTRATION REQUIREMENTS FOR RADIATION-PRODUCING EQUIPMENT AND OTHER ELECTRONIC DEVICES THAT PRODUCE RADIATION.

- Consider best use(s) for “temporary use registration” to accommodate reciprocity and mobile/portable equipment.
- Consider requiring registration for those that perform mobile/portable imaging outside of the place of registration.
- Review concept of *administrative control.*
- Consider adding notification requirements for mobile/portable imaging.
- Clarify *change of ownership* provision.
- Remove staggered fee schedule by county.

4732.0210 REGISTRATION FEES.

- No changes at this time.

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.
- Consider creating a radiation safety committee if registrant owns and/or operates CT or fluoroscopic equipment.

4732.0250 RECIPROCITY FOR OUT-OF-STATE RADIATION-PRODUCING EQUIPMENT.

- Review alternatives for out-of-state reciprocity.
- Consider how a temporary use registration provision might fulfill this purpose.

4732.0275 REGISTRATION OF SERVICE PROVIDERS.

- Consider requiring registration for all service providers that work in the state.
- Require service providers to provide registrant equipment registration information at the time of sale and/or installation.
- Consider adding requirements for in-house service providers.

4732.0280 SERVICE PROVIDER'S RESPONSIBILITY.

- Clarify and possibly expand roles and responsibilities of service providers.
- Consider including persons that *sell, lease, or transfer x-ray equipment* as service providers that must register with MDH.
- Add documentation requirements for survey equipment and calibration.
- Specify when to perform 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 by virtue of being known to be without hazard to health*.

4732.0305 PROHIBITED USES.

- Clarify notification and documentation requirements regarding human research.
- Consider allowing hand-held units for human use that are certified and that have been approved for human use by the Food and Drug Administration.

4732.0306 UNAUTHORIZED USES.

- Consider authorizing use of hand-held x-ray equipment along with requirements.
- Clarify requirements for individuals supervising fluoroscopy.

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.

- Move all shielding provisions to one central location in rule chapter.

4732.0360 SHIELDING PLAN.

- Consider removing requirement that registrants submit shielding plans to MDH.
- Specify qualifications that are required for an individual to perform a shielding plan.
- Clarify exemption provision for shielding plan reviews.
- Clarify what is meant by *permanent basis*.

4732.0365 ADDITIONAL SHIELDING REQUIREMENTS FOR DENTAL FACILITIES.

- Modify and align requirements for equipment other than intraoral.

4732.0370 ADDITIONAL SHIELDING REQUIREMENTS FOR INDUSTRIAL FACILITIES USING

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

4732.0380 SHIELDING REQUIREMENTS FOR ACCELERATORS.

- Update to reflect industrial accelerators only and not for human use.
- Remove radiation therapy-specific provisions to proposed new rule Chapter 4733, Radiation Therapy.

4732.0385 CAUTION SIGNS.

- No changes at this time.

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.
- Consider 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 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 lead equivalency requirements for protection.
- Update *film cassette* with "image receptor" here and throughout the rule.
- Remove radiation-therapy specific provisions to proposed new rule Chapter 4733, Radiation Therapy.

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.

- Include dose to patient provisions with occupational and public requirements.

4732.0535 RETAKE OR REJECT ANALYSIS PROGRAM.

- Require procedures to be in writing or in electronic format.
- Replace *facility* with *registrant* throughout the rule where applicable.
- 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 in part 4732.0305 – Prohibited Uses.

4732.0550 RADIOLOGICAL PRACTICE STANDARDS.

- Consider an initial radiation survey for protective barriers.
- Consider requirements for computed tomography units to have protocols for each examination performed.
- Require annual review of protocols in radiation safety committee.
- Remove radiation-therapy specific provisions to proposed new rule Chapter 4733.

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.
- Align collaborative agreement provision with Board of Dentistry requirements.
- Remove radiation-therapy specific provisions to proposed new rule Chapter 4733, Radiation Therapy.

4732.0565 HEALING ARTS SCREENING.

- Review value of healing arts screening compared to unnecessary radiation exposure to patient.

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 number of exam attempts for limited scope x-ray operator to three times before additional training and education are required.

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.

- Ensure ACRRT limited scope examination is consistent with statutory provisions and specify scope of practice.
- Clarify scope and operating requirements for nuclear medicine technologists to operate CT.

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.

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.
- Specify the required method for calculating the patient exposure dose.
- Align with proposed/draft Minnesota Rules, Chapter 4733 medical event provisions.

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.
- Consider moving remaining provisions to 4732.1100.

- Move radiation therapy-specific provisions to proposed new rule Chapter 4733, Radiation Therapy.

4732.0710 RADIATION SURVEY OR MEASUREMENT INSTRUMENTS.

- Add requirements when survey meters are used for measurement including 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 manufacturer's specifications and/or national recognized standards and available for review.
- Require PBL systems to comply with federal standards, *21 CFR 1020.31*.

4732.0820 GENERAL PURPOSE DIAGNOSTIC RADIATION-PRODUCING EQUIPMENT MANUFACTURED BEFORE 1973.

- Revise and move this part to 4732.0800 - General Equipment Requirements For All Diagnostic Radiation-Producing Systems.

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.

4732.0830 FLUOROSCOPIC DOSE-AREA-PRODUCT MONITOR.

- Replace *installed* with "manufactured".

4732.0835 REQUIREMENTS FOR COMPUTED RADIOGRAPHY, DIGITAL RADIOGRAPHY, OR PHOTOSTIMULABLE STORAGE PHOSPHOR RADIATION-PRODUCING EQUIPMENT.

- Revise and update to reflect digital imaging systems.

4732.0850 BONE DENSITOMETRY SYSTEMS.

- Review nationally recognized documentation to assess patient benefit versus unnecessary exposure to radiation exposure pertaining to precision assessment.
- 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 patient 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 cone beam computed tomography (CBCT) technology.

4732.0870 REQUIREMENTS FOR STEREOTACTIC MAMMOGRAPHIC EQUIPMENT.

- Update to reflect who is authorized to perform mammography procedures.

4732.0875 VETERINARY MEDICAL RADIOGRAPHIC SYSTEMS.

- Review lead equivalency requirements for protection.
- Remove radiation therapy-specific provisions to proposed new rule Chapter 4733, Radiation Therapy.

4732.0880 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.

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

4732.0890 EXTRAORAL DENTAL SYSTEMS.

- No changes at this time.

4732.0895 DENTAL COMPUTED TOMOGRAPHY SYSTEMS.

- Review nationally recognized guidelines and update rule part to include current and emerging cone beam computed tomography (CBCT) technology.

RADIATION THERAPEUTIC REQUIREMENTS

4732.0900 GENERAL REQUIREMENTS FOR FACILITIES USING ACCELERATORS.

- Establish requirements for industrial accelerators that are consistent with proposed new Minnesota Rules, Chapter 4733, Radiation Therapy.

4732.0925 GENERAL REQUIREMENTS FOR THERAPEUTIC EQUIPMENT.

- Repeal and move to proposed new rule Chapter 4733, Radiation Therapy.

4732.0930 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 KV.

- Repeal and move to proposed new rule Chapter 4733, Radiation Therapy.

4732.0940 THERAPEUTIC RADIATION MACHINES - PHOTON THERAPY SYSTEMS (500 KV AND ABOVE) AND ELECTRON THERAPY SYSTEMS (500 KEV AND ABOVE).

- Repeal and move to proposed new rule Chapter 4733, Radiation Therapy.

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.

- Consider provisions requiring only a diagnostic medical physicist to perform equipment performance evaluations on computed tomography and fluoroscopy.
- Clarify provisions for mobile and/or portable x-ray equipment
- 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 temperature check provision so that it is consistent with x-ray film requirements in 4732.0555.
- Remove mammography provisions.
- Align calibration provisions with SSRCR to include PBL requirements.

- Amend headnote in subparts 6 and 7 by removing *except radiation therapy simulators, manufactured before May 19, 1995*.
- Require all other tests indicated for diagnostic radiographic tubes (subpart 5) for facilities with fluoroscopes and c-arm fluoroscopes.
- Amend minimum test interval frequency.
- Research nationally recognized guidelines for use of tomography and cinefluorography systems and revise provisions accordingly.
- Verify that the current tests, and frequency of these tests, are applicable for facilities with CT scanners.
- Verify the minimum test intervals for CT 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 cone beam computed tomography (CBCT) and bone densitometry.
- Consider provisions to address emerging technology.

4732.1120 THERAPEUTIC EQUIPMENT PERFORMANCE TESTS AND LIMITS FOR MEASUREMENT EQUIPMENT.

- Repeal and move to proposed new rule Chapter 4733, Radiation Therapy.

4732.1130 EQUIPMENT PERFORMANCE TESTS FOR EXTERNAL BEAM TELETHERAPY AND SIMULATION SYSTEMS.

- Repeal and move to proposed new rule Chapter 4733, Radiation Therapy.