DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-ray Revision

DRAFT COMPUTED TOMOGRAPHY X-RAY SYSTEMS, 1.0

Subpart 1. **Applicability.**

A. A registrant who registers a stationary, mobile, or portable CT or medical CBCT x-ray system under this chapter must comply with:

(1) this part

(2) manufacturer specifications; and

(3) Code of Federal Regulations, title 21, section 1020.33, or successor requirements.

B. Diagnostic CT or medical CBCT x-ray systems for living human use must be accredited according to Minnesota Statutes, section 144.1225.

C. For purposes of this part, a CT qualified operator is an individual who is qualified to operate CT or CBCT medical x-ray systems according to subpart 17.

D. PET CT x-ray systems and SPECT CT x-ray systems used in nuclear medicine studies must meet the requirements of this part.

Subp. 2. **Radiation exposure control.**

A. Means must be provided to terminate the x-ray exposure automatically by de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Termination of exposure must occur within an interval that limits the total scan time to no more than 110 percent of its preset value using a backup timer or a device that monitors equipment function. [21CFR1020.33(f)(2)(i)]

B. A visible signal must indicate when the x-ray exposure has been terminated through the means required under item A. [21CFR1020.33(f)(2)(i)]

Commented [JC(1]: Reference to Advanced diagnostic imaging statute

Commented [BB(2]: Similar: AK, IL, NJ, KS, VA, IA, WI, NE, MS, CO

Commented [BB(3]: Similar: AK, IL, NJ, KS, VA, IA, WI, NE, MS, CO

C. A CT qualified operator must be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT or medical CBCT x-ray system control of greater than one-half second duration. [first part of 21CRF1020.33(f)(2)(ii)]

D. Fluoroscopic x-ray systems with CBCT capabilities are exempt from this subpart.

Subp. 3. **Tomographic plane indication and alignment.**

A. For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane. [21CFR1020.33(g)(1)]

B. For any multiple tomogram system, means must be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic planes. [version of 21CFR1020.33(g)(2)]

C. If a mechanism using a light source is used to satisfy the requirements under items A and B, then the light source must allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (46 foot candles). [21CFR1020.33(g)(5)]

D. Fluoroscopic x-ray systems with CBCT capabilities are exempt from this subpart.

Subp. 4. **Safety devices.**

A. The x-ray control and gantry must provide visual indication whenever x-rays are produced and, if applicable, when the shutter is open or closed. [First part of 21CFR1020.33(h)(1)]

Commented [BB(4]: Similar: AK, IL, NJ, KS, VA, IA, WI, NE, MS, CO

Commented [BB(5]: Similar: AK, KS, VA, IA, WI, NE, MS, CO

Commented [BB(6]: Similar: AK, NJ, KS, VA, IA, WI, NE, MS, CO

Commented [BB(7]: Different start: AK, KS, VA, IA, WI, NE, MS
Similar: IL, NJ, CO

Commented [TP(8]: Colorado

Commented [BB(9]: Similar: AK. IL, NJ, KS, VA, IA, WI, NE, MS, CO

B. An emergency off button or switch must be available at the control panel and, if applicable, in the room.

C. Fluoroscopic x-ray systems with CBCT capabilities are exempt from this subpart.

Subp. 5. **Additional requirements applicable to CT or medical CBCT x-ray systems containing a gantry manufactured after September 3, 1985.**

A. The total error in the indicated location of the tomographic plane or reference plane must not exceed 5 millimeters. [21CFR1020.33(g)(3)]

B. If the x-ray production period is less than one-half second, then the indication of x-ray production must be actuated for at least one-half second. Indicators at or near the gantry must be visible and discernible from any point external to the patient opening where insertion of any part of the human body into the useful beam is possible. [second part of 21CFR1020.33(h)(1)]

C. The deviation of indicated scan increment versus actual increment must not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance, or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel. [21CFR1020.33(i)]

D. Premature termination of the x-ray exposure by a CT qualified operator must necessitate resetting of the CT conditions of operation prior to the initiation of another scan. [second part of 21CFR1020.33(f)(2)(ii)]

E. Fluoroscopic x-ray systems with CBCT capabilities are exempt from this subpart.

Commented [JC(10]: Similar to NJ and SSRCR

Commented [BB(11]: Similar: AK, IL, NJ, KS, CO, VA, IA, WI, NE, MS, CO

Commented [BB(12]: Similar: AK, NJ, KS, CO, VA, IA, WI, NE, MS, CO

Commented [BB(13]: Similar: AK, IL, NJ, KS, CO, VA, IA, WI, NE, MS, CO

Commented [BB(14]: Similar: AK, KS, CO, VA, IA, WI, NE, MS, CO

Subp. 6. **Indication of CT conditions of operation.**

A. A CT or medical CBCT system must be designed so that the CT conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence.

B. On a CT or medical CBCT x-ray system having all or some of these CT conditions of operation at fixed values, this requirement may be met by permanent markings.

C. Indication of CT conditions of operation must be visible from any position where scan initiation is possible. [21CFR1020.33(f)]

Technique factors, Part F:

D. For purposes of this part, CT conditions of operation means all selectable parameters governing the operation of a CT or medical CBCT x-ray system including nominal tomographic section thickness, filtration, and the technique factors. The technique factors include:

(1) for CT or medical CBCT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs; or

(2) for CT or medical CBCT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds,

Commented [JC(15): SSRCR, Part F, p. 50

Commented [TP(16): Similar: AK, NJ, KS, CO, VA, IA, WI, NE, MS

Commented [JC(17): Advisory Committee: Discuss allowing qualified operator to start the exam inside the room. CT conditions of operation will not be visible.

Commented [JC(18): "Technique factors" means the following conditions of operation:
(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);
(2) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;
(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.*

Commented [JC(19): MDH intends to define "CT conditions of operation" in Definitions part.

or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent.

E. Fluoroscopic x-ray systems with CBCT capabilities are exempt from this subpart.

Subp. 7. **CT x-ray system patient communication.** A registrant is responsible for the requirements of this subpart for CT x-ray systems.

A. Provisions must be made for two-way audio communication at the control panel between the CT qualified operator and the patient.

Commented [BB(20]: 4732.0860, subpart 4
Similar: AK, IL, NJ, NC, OR, KS, CO, VA, IA, WI, NE, MS, CO

B. Windows, mirrors, closed-circuit television, or an equivalent patient viewing system must:

Commented [BB(21]: 4732.0860, subpart 3, item A
Similar: AK, IL, NJ, KS, CO, VA, IA, WI, NE, MS, CO

(1) permit continuous observation of the patient during irradiation; and

(2) be located so that the CT qualified operator is able to observe the patient from the control panel.

C. When the primary patient viewing system is electronic, an alternate patient viewing system must be available for use in the event of failure of the primary viewing system. The alternate patient viewing system may be electronic.

Commented [BB(22]: 4732.0860, subpart 3 item B
Similar: AK, NJ, KS, VA, IA, WI, NE, MS, CO

D. Patient scanning is allowed only when a viewing system is in working order.

Commented [TP(23]: Colorado

Subp. 8. **Equipment performance evaluation; testing requirements; frequency.** A registrant is responsible for the equipment performance evaluation testing requirements under subpart 9 for CT x-ray systems or under subpart 10 for medical CBCT x-ray systems.

A. A qualified medical physicist or a service technician who is under the general supervision of 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. A registrant may have a grace period of 30 calendar days to comply with the periodic equipment performance evaluation testing interval requirement under this item; and

(3) with a calibrated dosimetry system that must:

a) be traceable to a national standard; and

b) have been calibrated within the preceding two years.

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

C. A QMP must develop equipment performance evaluation standards and tolerances according to subpart 9 for a CT x-ray system and subpart 10 for a medical CBCT x-ray system. These standards and tolerances must meet nationally recognized standards and tolerances for the CT or medical CBCT x-ray system.

D. If a registrant's CT or medical CBCT x-ray system fails to meet any of the equipment performance evaluation testing under subpart 9 and 10, then a registrant must:

(1) not use the CT or medical CBCT x-ray system; or

(2) follow written instructions developed by the QMP to limit the use of a CT or medical CBCT x-ray system on patients for no longer than 14 days when an equipment performance evaluation exceeds tolerance; and

Commented [JC(24]: Similar: KS

Commented [JC(25]: Similar: PA

(3) have a service provider calibrate the CT or medical CBCT x-ray system so that the operating parameter complies with item C.

E. If a QMP determines that the change or replacement of components under item A, subitem (3) does not cause a change in the radiation output (dose indices) or image quality, then an equipment performance evaluation is not required. The QMP must retain the following documentation for review by the commissioner:

(1) the type of component repaired or replaced; and

(2) the reason for not performing an equipment performance evaluation based on nationally recognized guidelines.

F. If a QMP determines that the change or replacement of components causes a change in the radiation output (dose indices) or image quality, then an equipment performance evaluation under item A is required.

G. A registrant must maintain the standards and tolerances under item C for review by the commissioner.

Subp. 9. **Equipment performance evaluation; CT x-ray system.** An equipment performance evaluation for a CT x-ray system must include:

A. geometric factors and alignment, including:

(1) alignment light accuracy; and

(2) table increment accuracy.

B. image localization from scanned projection radiograph;

C. radiation beam width;

D. image quality including:

(1) high-contrast spatial resolution;

(2) low-contrast resolution;

(3) image uniformity;

(4) noise; and

(5) artifact evaluation.

E. CT number accuracy;

F. dosimetry;

G. image quality for acquisition workstation display devices; and

H. a safety evaluation of the patient communication system under subpart 7.

Subp. 10. **Equipment performance evaluation; medical CBCT x-ray system.** An equipment performance evaluation for a medical CBCT x-ray system must include:

A. half value layer measurements;

B. kVp measurements;

C. beam collimation;

D. image quality including:

(1) high-contrast spatial resolution;

(2) low-contrast resolution;

(3) image uniformity;

(4) noise; and

(5) artifact evaluation.

E. CT number accuracy;

F. dosimetry; and

G. a safety evaluation of the patient communication system under subpart 7, if applicable.

Subp. 11. **Quality assurance.** A registrant's quality assurance program must comply with the requirements under 21 CFR 1020.33, paragraph (d) and this subpart.

A. A phantom capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or a reference material.

B. Instructions on the use of a phantom, including a schedule of testing for the CT or medical CBCT x-ray system, allowable variations for the indicated parameters, and a method to store as records, quality assurance data.

C. Representative images obtained with the phantom using the same processing mode and CT conditions of operation under 21 CFR 1020.33, paragraph (c)(3) for a properly functioning system of the same model.

D. Representative images under item C must be maintained for 60 days and must be either:

(1) photographic copies of the images obtained from the image display device; or

(2) images stored in digital form on a storage medium compatible with the CT or medical CBCT x-ray system and must be provided with the means to display these images on the image display device.

Commented [JC(26]: Advisory Committee: Does the following language work instead?
"[…] and a method to store quality assurance data as records."

Subp. 12. **Routine quality control; development and requirements.**

A. A QMP must develop a routine quality control program for a CT or medical CBCT x-ray system.

B. A quality control program for a CT or medical CBCT x-ray system must include:

(1) acceptable standards and tolerances for points evaluated;

(2) a schedule for quality control testing for each x-ray system; and

(3) the use of a CT water equivalent phantom.

C. A quality control program for a CT or medical CBCT x-ray system must at a minimum evaluate noise, CT number, and artifacts on a daily basis when patients are being imaged. The quality control program must be completed:

(1) by a CT qualified operator; and

(2) prior to first patient use; or

(3) every 24 hours if the CT or medical CBCT x-ray system operates continuously.

D. If a registrant's CT or medical CBCT x-ray system fails to meet any of the routine quality control testing under this subpart then a registrant must:

(1) not use the CT or medical CBCT x-ray system; or

(2) follow written instructions developed by the QMP to limit the use of a CT or medical CBCT x-ray system on patients for no longer than 14 days when routine quality control testing exceeds acceptable standards and tolerances; and

(3) have a service provider calibrate the CT or medical CBCT x-ray system so that the operating parameter meets the requirements under item B, subitem (1).

E. A radiation safety officer or delegated CT qualified operator of CT or medical CBCT x-ray systems must review, sign, and date the routine quality control results at least quarterly.

Subp. 13. **Shielding plan.** A registrant with a stationary, mobile, or a portable CT or medical CBCT x-ray system must comply with the shielding plan requirements under part 4732.####.

Subp. 14. **Shielding requirements.** A registrant operating a stationary, mobile, or a portable CT or medical CBCT x-ray system must maintain the dose levels so that they do not exceed the limits under part 4732.####.

Subp. 15. **Radiation protection surveys; CT or medical CBCT x-ray systems.** A registrant must have a radiation protection survey for a CT or medical CBCT x-ray system made to identify radiation levels at the control panel and spaces adjoining the room according to this subpart.

A. A CT or medical CBCT x-ray system must have a radiation protection survey performed by:

(1) a qualified expert; or

(2) a service technician who is under the general supervision of a qualified expert.

B. For stationary x-ray systems, a radiation protection survey must be performed:

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

(2) after a change in the facility or equipment that might cause an increase in radiation hazard.

Commented [TP(27]: *SSRCR Volume I - April 2015*
Stationary Radiographic Systems.

Stationary radiographic systems shall be required to have the x-ray control, including the exposure switch, permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

Mobile and Portable Systems.
Mobile and portable x-ray systems which are:

Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.6k.iii.(1) (stationary above);

Used for less than one week at the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

JC: Reference to public and occupational dose limits.

Commented [JC(28]: Advisory Committee: Should we identify specific facility changes (ie – change in occupancy factor or work load)?

C. For mobile or portable CT or medical CBCT x-ray system that are considered stationary x-ray systems, a radiation protection survey must be performed after any initial installation or relocation.

D. A registrant must obtain a written report of the radiation protection survey and a copy of the report must be made available to the commissioner upon request.

Subp. 16. **CT fluoroscopic x-ray system examination**.

A. If a CT x-ray system has the capabilities of performing fluoroscopic examination, then the x-ray control may be operated in the CT room.

B. Essential personnel may remain in the CT room during a fluoroscopic examination if the personnel are:

(1) trained on radiation safety of CT;

(2) wearing personal protective equipment; and

(3) wearing individual personal monitoring devices.

Subp. 17. **CT qualified operator qualifications.**

A. A qualified operator of a CT or medical CBCT x-ray system for use on living humans is limited to:

(1) a qualified practitioner who is performing within the qualified practitioner's scope of practice.

(2) an individual who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) and holds a valid certification;

(3) a medical resident or fellow in training;

(4) a radiologic technologist student in training; and

Commented [TP(29]: Colorado proposed rules; part F

Commented [JC(30]: CO

(5) an x-ray operator who has the original certificate or the original letter of passing the examination that was required before January 1, 2008 under Minnesota Statutes, section 144.121, subdivision 5a(b)(1).

B. PET CT or SPECT CT x-ray systems that are used as a fusion imaging device or as a dual imaging source must be operated according to part 4731.4620, subpart 1.

Commented [TP(31]: Reference to radioactive material chapter

C. CT simulators that are used only for the purpose of treatment planning must be operated according to chapter 4733.

Commented [JC(32]: Reference to radiation therapy/accelerator chapter

Subp. 18. **CT qualified operator; training requirements.** A CT qualified operator of a CT or medical CBCT x-ray system must comply with the training requirements of this subpart.

A. A CT qualified operator must document at least 20 hours of training and experience under item C.

B. A CT qualified operator must be trained on each manufacturer's operational features of the CT or medical CBCT x-ray system by:

(1) a manufacturer's applications specialist;

(2) a qualified medical physicist; or

(3) a registrant's CT qualified operator that has received the training for by an individual under subitems (1) or (2).

C. A CT qualified operator must receive training in CT or medical CBCT x-ray system operation including:

(1) evaluation of examination order and medical record;

(2) patient assessment and education concerning the examination;

(3) preparation and administration of contrast media when indicated;

(4) patient positioning;

(5) protocol selection;

(6) parameter selection;

(7) initiating a scan;

(8) image display and archiving;

(9) radiation safety;

(10) radiation protection;

(11) emergency stops;

(12) image quality;

(13) demonstration of anatomical region; and

(14) exam completeness.

Subp. 19. **Conditions of operation; control panel operating procedures.**

A. A registrant must maintain the following information at the control panel for a CT qualified operator of a CT or medical CBCT x-ray system:

Commented [JC(33]: Similar: KS, WI, NE, CO

(1) instructions on performing routine quality control, including the use of a CT phantom;

(2) a schedule of routine quality control appropriate for a CT x-ray system or a medical CBCT x-ray system that is developed by a qualified medical physicist;

(3) acceptable standards and tolerances developed by a qualified medical physicist for the indicated parameters;

(4) the documented results of routine quality control completed on the CT or medical CBCT x-ray system;

(5) CT scanning protocols established by the radiation safety committee, including instructions on reporting deviations;

Commented [BB(34]: Similar: CO

(6) written instructions, developed by the qualified medical physicist, to limit the use of a CT or medical CBCT x-ray system on patients when an equipment performance evaluation or routine quality control of the x-ray system identifies a system operating parameter that exceeds a tolerance established by the qualified medical physicist; and

(7) the technical and safety information supplied by the CT manufacturer required under 21 CFR 1020.33(c).

B. The information relating to the conditions of operation, dose information and imaging performance under this subpart must be available to the commissioner upon request.

C. Fluoroscopic x-ray systems with CBCT capabilities are exempt from this subpart.

Subp. 20. **Radiation safety committee; CT x-ray system.** A registrant that registers a CT x-ray system under this chapter must establish a radiation safety committee that meets the requirements of this subpart.

A. Required members of a radiation safety committee minimally include:

(1) a CT radiologist overseeing the CT x-ray systems;

(2) a qualified medical physicist;

(3) a radiation safety officer; and

(4) a CT qualified operator who operates CT x-ray systems.

B. A registrant's qualified medical physicist and a radiation safety officer may be the same individual for purposes of this subpart if they are so designated at the facility.

C. The required members under item A must meet at least annually.

Commented [BB(35]: Similar: CO

Commented [JC(36]: *See* 21 CFR 1020.33(c) - *Information to be provided for users.*

D. A registrant's existing radiation safety committee may be used to meet the requirements of this subpart if the committee's membership complies with item A.

E. Each registrant must have a record of all radiation safety committee meetings. The record must include:

(1) the date;

(2) the names of individuals in attendance;

(3) the meeting minutes; and

(4) any actions taken.

F. A radiation safety committee may meet in person or remotely using electronic technology.

G. CBCT x-ray systems, PET CT x-ray systems, or SPECT x-ray systems are exempt from the radiation safety committee requirements under this part.

Subp. 21. **Radiation safety committee; responsibilities.** A registrant's radiation safety committee must meet the requirements of this subpart.

A. Establish CT scanning protocols that include CT conditions of operation, adult and pediatric parameters, acquisition and reconstruction parameters, image quality, and radiation dose.

B. A radiation safety committee must review existing protocols, at intervals not to exceed 12 months, along with:

(1) the capabilities of the individual CT scanner to ensure maximum performance is achieved; and

Commented [JC(37]: SSRCR

(2) the implementation of new and innovative technologies that improve image quality or lower patient dose compared to the older protocol.

C. Establish and implement policies that are written or documented in an electronic recordkeeping system that include:

(1) a method to monitor the CT radiation output;

(2) a standardized CT scanning protocol naming policy;

(3) a DRL, notification value, and dose alert value for CT procedures reviewed under item A.

(4) actions to be taken when the dose alert value is exceeded that include:

a) patient follow-up; and

b) notification to the commissioner when the dose levels meet the requirements of a medical event under part 4732.####; and

(5) determining which individuals have access and the authority to change the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.

D. Notification and alert values under item C, subitem 3 may be applied by using trigger values that are established using nationally recognized guidelines or by a QMP.

E. If CT fluoroscopy is performed, then a radiation safety committee must establish and implement operating procedures and training that minimize patient and occupational radiation exposure.

F. A radiation safety committee must review, at intervals not to exceed 12 months, the standards and tolerances including:

Commented [JC(38]: SSRCR

Commented [TP(39]: MDH intends to define "DRL" in Definitions part.

DRL means "Diagnostic reference level" (DRL) is an investigational level used to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

Commented [JC(40]: Reference to medical event subpart (TBD)

Commented [TP(41]: SSRCR, part F, section 11 Notification and alert values may be applied by using trigger values in conformance with NEMA XR-29 or facility-established values and procedures as defined by the QMP.

(1) equipment performance evaluation under subpart 8; and

(2) routine quality control program under subpart 12.

G. A radiation safety committee must establish and implement the CT training that a registrant is using to comply with the CT x-ray system training under subpart 18.

H. Review a registrant's site-specific policies in this subpart at an interval not to exceed 12 months.

I. When a registrant revises the standards and tolerances under this part, the registrant must maintain the previous documentation after the revision for the commissioner's review upon inspection.

Subp. 22. **Radiation safety committee; document review.**

A. A registrant's radiation safety committee must review and maintain the following documentation for a CT qualified operator:

(1) a list identifying all CT qualified operators by first and last name;

(2) computed tomography site-specific training under subpart 18.

B. A registrant's radiation safety committee must review and maintain the following written or electronic documentation:

(1) CT x-ray system quality control, equipment testing, service reports, and corrective actions;

(2) exceeded DRLs and follow-up; and

(3) medical event notifications.

Subp. 23. **Prohibited uses.**

A. A registrant must prohibit the exposure of an individual to the useful beam from CT or medical CBCT 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 CT or medical CBCT x-ray systems for:

(1) training;

(2) demonstration; and

(3) other non-healing arts purposes.

Subp. 24. **Ordering of CT or medical CBCT examinations.**

A. A registrant must have an order for a diagnostic CT or medical CBCT examination.

B. An order for a CT examination must be:

(1) authorized by a qualified practitioner; and

(2) available to the CT 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 computed tomography examination.

D. An order for a computed tomography 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. 25. **Utilization record.** A registrant performing CT or medical CBCT examinations 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 CT or medical CBCT x-ray system used;

E. the dose values the CT or medical CBCT x-ray system provides; and

F. the first and last name of the CT qualified operator who is operating the medical CT or medical CBCT x-ray system.

Subp. 26. **Repeat and reject analysis.** A registrant is responsible for an analysis of the retake or reject images used in patient diagnosis.

A. Retake or reject analysis must be done at least quarterly.

B. The CT or medical CBCT repeat rate is defined and documented as:

(1) CT repeat rate equals the total number of repeated series divided by the total number of series; or

(2) CT repeat rate equals the total number of repeated examination divided by the total number of examinations.

C. Localization images are excluded from the retake or reject analysis.

Subp. 27. **Off-site use of a mobile or portable CT or medical CBCT x-ray system.** A registrant must document the date and location when a registrant's CT qualified operator uses

a registrant's mobile or portable CT or medical CBCT x-ray system at a location that is not listed on the registrant's equipment registration.

Subp. 28. **Medical event.** A registrant must notify the commissioner after the discovery of a medical event under part 4732.####.

Commented [JC(42]: Reference to medical event rule part (TBD).

Subp. 29. **Protection from radiation.** A registrant is responsible for the radiation protection requirements in this subpart.

A. In a room where CT x-ray systems are being used, an individual must be protected with personal protective equipment lead equivalent shielding of at least 0.50 mm by:

(1) wearing a full apron and thyroid; or

(2) remaining behind a full body mobile shield.

B. When mobile or portable equipment is in use, a qualified expert must determine if personal protective equipment is needed for a CT qualified operator and any other individuals who are at least 9 feet (2.7 meters) from the tube housing assembly during the exposure.

C. A qualified expert must place clear, identified markings that outline a safe distance of 9 feet (2.7 meters) for a CT qualified operator and any other individuals.

Subp. 30. **Records.**

Commented [TP(43]: There will be one Records provision applicable to all registrants.