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## **Draft CT proposed rules for 4732**

**4732.0110, Subp. 37. Computed tomography or CT.** "Computed tomography" or "CT" is defined as the production of a tomogram by the acquisition and computer processing of x-ray transmission data. This used to be called computed axial tomography or CAT.

**4732.0110, Subp. 37a. Cone Beam Computed Tomography or CBCT.** "Cone Beam Computed Tomography" or "CBCT" is defined as computed tomographic scanner that uses a cone shaped x-ray beam and area detector(s), which includes flat panel detector and image intensifier. Subsequently reconstruction software is applied on the cone beam CT volumetric data to produce a series of planar or 3D rendered volumetric images of the anatomy. The cone beam CT unit can be either mobile or stationary. This also includes 'O' arm imaging systems.

**Subp. 57b. Dual Imaging.** "Dual imaging" is defined as the melding together of two imaging modalities, such as PET/CT or SPECT/CT for the purpose of gathering information from two types of imaging, anatomical and functional to create one image done at the same time.

**4732.0110, Subp. 138B. Qualified Medical Physicist.** For purposes of this rule "qualified Medical Physicist" is defined as an individual qualified to practice independently in the subfields for diagnostic radiological physics who:

- A. Is certified in radiological physics or diagnostic radiological physics by the American Board of Radiology;
- B. Is certified in diagnostic radiological physics by the American Board of Medical Physics;

C. Is certified in diagnostic radiological physics by the Canadian College of Medical Physics; or

D. Holds a masters degree or doctor's degree in medical physics, radiological sciences, or an equivalent field involving graduate study in physics applied to the application of radiation to humans from an accredited college or university and have at least one year of full-time practical training and experience involving work in a radiation diagnostic facility under an individual who meets the qualifications in this item or item A, B, or C.

#### **4732.0520 QUALITY ASSURANCE PROGRAM.**

Subpart 1. **General requirements.** A registrant conducting radiographic or fluoroscopic procedures using radiation-producing equipment must implement a site-specific quality assurance program. The program must include:

A. A description of the quality control procedures for radiation protection;

B. Initial training and documentation for employees as specified in part 4732.0510;

C. The radiographic or fluoroscopic equipment performance tests which are to be completed at intervals not to exceed 24 months, the CT and 'O' arm scanner equipment performance tests are to be completed at intervals not to exceed 12 months and related evaluation documentation, including films, as appropriate, as specified in nationally recognized standards, according to:

(1) Code of Federal Regulations, title 21, section 1020.30, for diagnostic equipment, and Code of Federal Regulations, title 21, section 1020.32 for fluoroscopic equipment, title 21, section 1020.33, for CT equipment, and title 21, section 1020.40 for cabinet x-ray equipment; or

(2) The manufacturer's specifications with a copy on site; or

(3) Part-4732.1100.

D. The documentation of any correction of any deficiencies found during the equipment performance tests and verification of the actions taken;

E. When an operating parameter has been exceeded, the radiation-producing equipment, excluding CT scanners, must not be used or must be limited to those uses permitted by the registrant, radiation safety officer, or qualified medical physicist by established written procedures for no longer than 14 days until corrective actions have been taken and verified to have corrected the out-of-limits parameters;

F. Calibrations and documentation as required in part 4732.0700. This includes the calibration record of any electronic equipment used in quality control tests;

G. Radiation program audits as specified in part 4732.0540; and

H. A retake or reject analysis program as specified in part 4732.0535.

Subp. 2. **Records.** The registrant must maintain the quality assurance program records according to part 4732.0330.

#### **4732.0535 RETAKE OR REJECT ANALYSIS PROGRAM.**

Subpart 1. **Applicability.** The registrant will perform or have performed an analysis of all retaken or rejected radiographs or digital images used in patient diagnosis. This does not include dental facilities that only use intraoral equipment.

A. Retake or reject analysis must be done at intervals not to exceed 3 months;

B. CT facilities, including cone beam and 'O' arm CT, will conduct the retake or reject analysis on repeated scan series completed in the quarter. CT facilities that exceed 1000 scan series in a quarter will conduct the retake analysis when a minimum of 1000 scan series have been completed in the quarter. If a scan is repeated and the first scan is archived, the repeated scan

will be counted as a rejected scan for the analysis. For CT, the number of procedural scan slices must be indicated. Any reconstruction scans would not be included in the repeat analysis; and

C. Facilities must include the retake or reject analysis results in the annual audit according to part 4732.0540;

D. The analysis must include at a minimum, the overall retake or reject rate and a summary of the causes for the retakes or rejects;

E. The registrant or radiation safety officer must design the facility specific procedures for the retake and reject analysis. The written procedure must be included in the facility operating procedures; and

F. For facilities using bone density equipment, the retake reject analysis must be done at intervals not to exceed 3 months and will include any scan site that is restarted after 50% of the study is completed. If facilities are using pQCT for bone density evaluation, the facility will follow CT facility repeat or reject analysis requirements in item B.

Subp. 2. **Corrective actions.** Appropriate corrective actions taken based on the results of the analysis must be documented.

Subp. 3. **Records.** The registrant must maintain records according to part 4732.0330.

#### **4732.0540 RADIATION PROGRAM AUDITS.**

Subpart 1. **Applicability.** A registrant must ensure that the entire quality assurance program, its content, and implementation are reviewed annually. The radiation program audit in this part must be reviewed for compliance with this chapter.

##### **Subp. 2. Procedures.**

The registrant must ensure that all radiation program audits are performed according to procedures established by the registrant or radiation safety officer.

Subp. 3. **Corrective actions.** Any noncompliance issues found during the audit must be corrected within 30 days of the audit and documented. The radiation safety officer must review and sign off on any corrective actions.

Subp. 4. **Records.** A record of each audit must be prepared and maintained at the facility until the commissioner's inspection according to the record requirements in part 4732.0330.

#### **4732.0545 UTILIZATION LOG.**

A. Excluding dental facilities using intraoral or panoramic equipment, all other facilities performing radiographic, fluoroscopic, CT including cone beam and 'O' arm, fluoroscopic procedures, or industrial radiography procedures must maintain a utilization log containing:

- (1) Patient identification;
- (2) The type of procedures;
- (3) The dates the procedures were performed;
- (4) The name of the individual performing the x-ray procedure;
- (5) The number of exposures and retakes involved;
- (6) The name of the human holder when the patient or film must be provided with human auxiliary support;
- (7) Utilization logs for fluoroscopic equipment without a dose-area-product monitor must include the patient's exposure received per fluoroscopic procedure in excess of five minutes; ~~and~~
- (8) Utilization logs for fluoroscopic equipment with a dose-area-product monitor must include the patient's exposure received per fluoroscopic procedure in excess of five minutes; and
- (9) Utilization logs for computed tomography equipment must include the number of repeated or rejected scan series. If an electronic

utilization log does not permit the information of repeated or rejected scan series to be entered, they should maintain a separate log.

B. Facilities performing industrial radiography must maintain a utilization log containing:

- (1) A serial number or other unique identification of the equipment;
- (2) The identity of the operator assigned to the equipment;
- (3) The locations and dates where the equipment was used;
- (4) The technique factors specifying the voltage, current, exposure time for each radiographic exposure, and number of exposures.
- (5) For permanent radiographic installations, the dates each radiation machine is energized.

C. Facilities using radiation-producing equipment for gauging must maintain a utilization log containing:

- (1) A serial number or other unique identification of the equipment;
  - (2) The identity of the operator assigned to the equipment;
- and
- (3) The beginning and ending time of use.

D. Industrial cabinet, baggage units, and ion implanters are exempt from the requirements of this part.

E. The registrant must maintain these records according to part 4732.0330.

#### **4732.0565 HEALING ARTS SCREENING.**

Subpart 1. **General requirements.** Any person proposing to conduct a healing arts screening program must not implement the program without prior

approval of the commissioner. An applicant must meet the requirements in this chapter. In addition:

A. The applicant must be registered with the commissioner before application for screening is initiated; and

B. The applicant must submit complete and accurate information in this part on an application form provided by the commissioner or an equivalent form.

Subp. 2. **Content of application.** In the application for screening, the applicant must provide:

A. The name and address of the applicant;

B. Each location of the proposed screening and the name and telephone number of a contact person at each location;

C. The purpose of the proposed screening program planned. This purpose must include the diseases or conditions for which the radiographic, fluoroscopic, or CT examinations are to be used in diagnoses;

D. A detailed description of the radiographic, fluoroscopic, or CT examination proposed in the screening program;

E. A description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information;

F. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the radiographic, fluoroscopic, or CT examinations;

G. An evaluation by a qualified medical physicist of the x-ray systems to be used in the screening program. The evaluation must show that the system satisfies all requirements of these regulations;

H. A measurement of patient doses from the radiographic, fluoroscopic, or CT examination to be performed during the screening;

I. A complete description of the diagnostic radiographic, fluoroscopic, or CT quality assurance program;

J. A copy of the protocol page and equipment technique factors for the screening examination procedures to be used. For CT, this technique factors must indicate techniques for adult patients and include the approximate number of scanned slices for the examination being requested. If dose reduction or automatic exposure control (AEC) systems are used, description of the settings to be used will be reviewed by the operator prior to the patient being exposed and if there is the potential for higher radiation dose when using the AEC versus a manual technique this must be noted in the patient's record;

K. A list of the qualifications of each individual who will be operating the radiographic, fluoroscopic, or CT system for the screening;

L. The qualifications of the individual who will be supervising the operators of the radiographic, fluoroscopic, or CT system. The extent of supervision and the method of work performance evaluation must be specified;

M. A list of the names, business addresses, and qualifications of the individuals who will interpret the radiographs;

N. The procedures for informing the individuals screened and their private practitioners of the results of the screening procedure and any further medical needs indicated;

O. The procedures for the retention or disposition of the radiographs or images and other records pertaining to the screening examinations;

P. The frequency of screening; and

Q. The duration of the entire screening program if less than the one year authorization period.

Subp. 3. **Notification of commissioner's decision.** The applicant must be notified in writing of the commissioner's decision.

Subp. 4. **Changes in screening program.** The applicant is responsible for informing the commissioner of any changes in the screening program described in the application. The applicant must obtain commissioner approval of the changes before the implementation.

Subp. 5. **Appeal procedure.** The applicant may appeal the denial or refusal to approve an application or renewal application by requesting a contested case hearing under the provisions of the Administrative Procedure Act, Minnesota Statutes, Chapter 14. The applicant must submit, within 15 days of the receipt of the department's decision, a written request for a hearing. The request for a hearing must set forth in detail the reasons why the applicant contends that the decision of the department should be reversed or modified.

Subp. 6. **Renewal of screening program application.** Any request for the renewal of a screening program application must be submitted in writing 30 days before its expiration date. Renewal requests must contain the complete information specified in subpart 2.

#### **4732.0860 COMPUTED TOMOGRAPHY REQUIREMENTS.**

##### **Subpart 1. Applicability.**

A. All computed tomography systems must meet the requirements of:

(1) Nationally recognized standards such as Code of Federal Regulations, title 21, section 1020.33; or

(2) The manufacturer's specifications with a copy on site; or

(3) Part 4732.1100.

B. Computed tomography facilities must meet the requirements in this part and other pertinent requirements in this chapter.

**Subp. 2. Facility design requirements.**

A. The control panel must be mounted in a permanently protected area outside the computed tomography room meeting the requirements in part 4732.0355, subpart 4.

B. If the control booth is located within the CT room, the control booth must meet the requirements of part 4732.0355, subpart 4.

C. In either case, the operator is required to remain in that protected area during the entire exposure.

**Subp. 3. Viewing systems.**

A. Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous operator observation of the patient from the control panel during irradiation.

B. When the primary viewing system is by electronic means, an alternate viewing system must be available for use in the event of failure of the primary viewing system.

**Subp. 4. Audio communication.** Provision must be made for two-way audio communication between the patient and operator at the control panel.

**Subp. 5. Radiation surveys.** All computed tomography systems installed must have a radiation survey made to identify radiation levels at the control panel and spaces adjoining the room. In addition, the radiation surveys must be completed after any change in the facility or equipment which might cause a

significant increase in radiation output. The radiation survey must be maintained by the registrant according to part 4732.0330.

**Subp. 6. Equipment performance measurements.**

A. The registrant must ensure that the equipment performance measurement procedures in this part are performed at intervals not to exceed 12 months according to:

(1) Nationally recognized standards, such as Code of Federal Regulations, title 21, section 1020.33;

(2) The manufacturer's specifications; or

(3) Part 4732.1100; and

(4) If applicable, those aspects of processing according to part 4732.1100.

B. The equipment performance measurement of the radiation output of the CT x-ray system must be performed by a registered service provider, qualified medical physicist, or an individual under the supervision of a qualified medical physicist;

C. The equipment performance measurements of a CT system must be performed at intervals not to exceed 12 months or after change or replacement of components that could cause an increase in radiation hazard or that could result in the minimum performance criteria in part 4732.1100 not being met.

D. The measurements of the radiation output of a CT system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding 24 months.

E. CT dosimetry phantoms must be used in determining the radiation output of a CT system. The phantoms must comply with Code of Federal Regulations, title 21, Section 1020.33.

F. The computed tomography dose index (CTDI) must be completed using the CT dosimetry phantom or equivalent phantom. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be used.

G. The dose measurements must be made for standard head and body scan modes of operation used at the facility. If a facility applies to do healing arts screening, dose measurements or calculations from dose measurements for screening protocols must be made and kept according to 4732.0565 for verification of the information on the screening application.

H. The image quality measurements must be made using a typical clinical technique in the standard head and body scan modes of operation.

Subp. **7. Equipment performance measurements performed by the CT operator.** In addition to the equipment performance measurements in subpart 6, an operator must:

A. Complete the daily or monthly equipment performance procedures in part 4732.1100, including all processing procedures in parts 4732.1100 and 4732.0555, if applicable.

B. For mobile CT, cone beam CT, or 'O' arm equipment must complete daily and monthly equipment performance procedures in part 4732.1100 or meet the manufacturer's specifications before patient use. This includes all processing procedures in parts 4732.1100 and 4732.0555, if applicable; and

C. Acquisition of images obtained with the CT quality control phantoms using the same processing mode and CT conditions of operation that are used to perform the equipment performance measurements required by part 4732.1100.

Subp. 8. **Program review.** The registrant, radiation safety officer, CT manager or equivalent, or qualified medical physicist must review, sign, or use an electronic signature and date the operator's equipment performance measurements at least quarterly and during the annual audit;

Subp. 9. **Operating and emergency procedures.**

A. **Operating procedures.** The registrant must supply information about the operating procedures, emergency procedures, radiation surveys, and equipment performance measurements of the system and make available at the control panel for the employees and for the commissioner at the time of an inspection. The registrant must ensure that the operating procedures contain, at a minimum:

- (1) Scan protocols to be followed for the scans appropriate for the type of facility;
- (2) Technique factors to be reviewed prior to the exposure of the patient;
- (3) Procedures for assessing images to be kept or rejected; and
- (4) The scan procedures for adult and pediatric patients must be available at the operator's console, which specifies the scan parameters for each routine examination, the CT conditions of operation, the number of scans per examination, and an appropriate technique chart. For techniques, if AEC is used, manual techniques must be listed in procedures in case of AEC failure.
- (5) Instructions on the use of the CT dosimetry or image quality phantoms including the allowable variations for the indicated parameters.

B. **Emergency procedures.** The registrant must supply information about emergency procedures and make available at the control panel for the employees and for the commissioner at the time of an

inspection. The registrant must ensure that the emergency procedures contain, at a minimum:

- (1) Procedures for notifying the registrant, radiation safety officer in case of equipment malfunction;
- (2) Procedures for the operator to follow in the event of complete failure of the equipment; and
- (3) Procedures for reporting and documenting any irregularities to the registrant or radiation safety officer.

**Subp. 10. Corrective actions.**

A. Correction of the problem must take place and be verified by performing the equipment performance measurements according to Code of Federal Regulations, title 21, section 1020.33, the manufacturer's specifications or part 4732.1100.

B. Corrective action must take place, prior to use on patients, if the equipment performance measurement of the CT system indicate that a system operating parameter has exceeded a tolerance established:

- (1) In part 4732,1100;
- (2) In the manufacturer' specifications;
- (3) By a manufacturer's representative who is a MN registered service provider; or
- (4) A qualified medical physicist.

**Subp. 11. CT Operator site-specific training.** The registrant must ensure that:

A. The CT system is operated by an individual who meets the qualifications in 4732.0861- 4732.0890:

B. Has been specifically trained on the equipment by the manufacturer, radiation safety officer, qualified CT operator or equivalent;

C. Has had training in appropriate CT positioning and anatomy for procedures performed at the facility according to 4732.0861 to 4732.0863; and

D. All training is documented and kept according to 4732.0330.

Subp. 12. **CT fluoroscopic procedures.**

A. If the equipment has the capabilities of performing fluoroscopic procedures, the x-ray control may be operated in the CT room and essential personnel may remain in the room during the fluoroscopic procedures provided they:

(1) Are wearing personal protective garments; and

(2) Have individual personal monitoring devices.

B. Except for licensed practitioners of the healing arts or qualified medical physicist conducting equipment performance evaluations, any individual operating a CT scanner with fluoroscopic capabilities must have been trained in the aspects of fluoroscopic equipment used and items (1) to (8) listed below:

(1) Fluoroscopic generation and control;

(2) X-ray dosimetry;

(3) Image formation;

(4) Image processing and management;

(5) Radiation safety and biological effects of radiation

- (6) Patient dose-management fundamentals;
- (7) Professional standards and regulatory requirements; and
- (8) Other miscellaneous items appropriate to site-specific use.

**Subp. 13. COMPUTED TOMOGRAPHY PROGRAM.**

A. The facility's computed tomography program must be under the general supervision of individuals who have CT training and experience. This could be the registrant, a licensed practitioner of the healing arts, radiation safety officer, or a computed tomography operator who has passed a nationally recognized examination and maintains their registration or certification with organizations such as the American Registry of Radiologic Technologists.

B. The registrant must ensure the CT patient doses conform to a nationally recognized standards or do not exceed any dose requirements found in this chapter.

Subp. 14. **Records.** The registrant will ensure that the required documentation is maintained according to part 4732.0330.

**4732.0861. MINIMUM QUALIFICATIONS FOR COMPUTED TOMOGRAPHY OPERATORS.** Except as indicated in 4732.0570 to 4732.0575, any individual functioning as a computed tomography operator in Minnesota must meet the following minimum eligibility requirements:

- A. Graduation from high school or its equivalent; and
- B. Attainment of 18 years of age; and

C. Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients, other employees or members of the public; and

D. Meet the x-ray operator qualifications in 4732.0570; or

E. Be registered by a nationally recognized organization such as the ARRT in either Radiography or Computed Tomography and continue to maintain registration or certification.

**4732.0862.TRAINING AND EXPERIENCE FOR DIAGNOSTIC COMPUTED TOMOGRAPHY OPERATOR.**

Subp.1. Individuals functioning as a computed tomography operator who are not registered or certified by a nationally recognized organization after the effective date of this rule must have:

A. At least 8 hours of training on cross-sectional anatomy and positioning; and

B. At least 8 hours of computed tomography equipment training by the manufacturer, the radiation safety officer, qualified registered service provider, qualified CT operator or qualified medical physicist. This must include appropriate computer software training; and

C. At least 3 months under the direct supervision of an individual qualified in computed tomography; and

D. At least 3 months under the general supervision of an individual qualified in computed tomography.

Subp. 2. Records. All training must be documented according to 4732.0330.

**4732.0863 EXCEPTIONS.** The following individuals are exempt from the requirements in 4732.0861:

- A. A licensed practitioner of the healing arts who specializes in computed tomography;
- B. Individuals who function under the direct supervision of a licensed practitioner of the healing arts specializing in computed tomography or qualified computed tomography operator;
- C. Students enrolled in and participating in an accredited program for computed tomography and as part of their clinical rotation are under the direct supervision by qualified CT operator;
- D. Students enrolled in and participating in a school of medicine or school of osteopathy, who have computed tomography as part of their course of study; or
- E. An individual who has graduated from an accredited program for computed tomography and who will be scheduled to take and pass the ARRT computed tomography examination within six months from graduation. The individual will be under direct supervision until the passing of that examination.

**4732.0863. REQUIREMENTS FOR OPERATORS OF DUAL IMAGING DEVICES.**

Subpart 1. **Operator requirements.** Nuclear medicine technologists may operate a PET /CT or SPEC/ CT as an integral part of a nuclear medicine procedure if:

- A. They have completed training for computed tomography procedures as part of their nuclear medicine course and examination; or
- B. Complete on-site training in the CT scan procedure requirements for PET/CT or SPECT/CT for the facility by the radiation safety officer, manufacturer of the equipment, or qualified CT technologist; and

C. They wear an individual monitoring badge according to 4732.0440.

Subp. 2. **Diagnostic CT.** A nuclear medicine technologist may not do diagnostic CT unless they meet the qualifications for x-ray operators in 4732.0570 to 4732.0585.

**4732.0865 CONE BEAM COMPUTERIZED TOMOGRAPHY  
DESIGNED FOR VISUALIZATION OF THE HEAD AND SOFT  
TISSUE OF THE NECK.**

Subpart 1. **Applicability.** Computed tomography systems designed for visualization of head and soft tissues of the neck must meet requirements of this chapter and:

- A. Nationally recognized standards such as Code of Federal Regulations, title 21, section 1020.33;
- B. The manufacturer's specifications with a copy on site; or
- C. Part 4732.1100.

Subp. 2. **Operator Training.**

- A. For operators of the CT equipment used for head and soft tissue of the neck visualization must meet the requirements in 4732.0861 and 4732.0862.
- B. Additional staff training must be conducted if there is a change in the equipment or software that would affect the radiation output; and
- C. All training must be documented according to 4732.0330.

Subp. 3. **Operator training for industrial or research & development cone beam CT systems.**

A. The registrant must ensure that any operator using cone beam CT for industrial or research and development must complete the training as in 4732.1040 subpart 4. and

B, The registrant must ensure the cone beam CT equipment meets manufacturer's recommendations for quality control tests and equipment performance testing.

**Subp. 3. Facility design requirements.**

A. The control panel must be mounted in a permanently protected area outside the computed tomography room and meet the requirements of part 4732.0355, subpart 2.

B. If the control area is within the CT room, the requirements for a control booth in part 4732.0355, subpart 2 must be followed.

C. The operator is required to remain in the protected area during the entire exposure.

D. Viewing systems must be windows, mirrors, closed-circuit television, or an equivalent able to provide continuous operator observation of the patient from the control panel during irradiation.

E. Provision must be made for two-way audio communication between the patient and operator at the control panel.

Subp. 4. **Radiation surveys.** All computed tomography systems installed must have a radiation survey to identify radiation levels at the control panel and the spaces adjoining the CT room. In addition, the surveys must be completed after any change in the facility or equipment that might cause a significant increase in radiation hazard. The survey must be maintained by the registrant according to part 4732.0330.

**Subp. 5. Equipment performance measurements.**

A. The registrant must ensure that the equipment performance measurement procedures are performed at intervals not to exceed 12 months according to:

(1) Nationally recognized standards, such as Code of Federal Regulations, title 21, section 1020.33;

(2) The manufacturer's specifications with a copy on site; or

(3) Part 4732.1100; and

(4) Processing requirements in part 4732.1100, if applicable.

B. The equipment performance measurement of the radiation output of the CT x-ray system must be performed by a registered service provider or qualified medical physicist.

C. The equipment performance measurements of a CT system must be performed at intervals not to exceed ~~24~~ 12 months or after change or replacement of components that could cause an increase in radiation hazard or that could result in the minimum performance criteria in part 4732.1100 not being met.

D. The measurements of the radiation output of a CT system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding 24 months.

E. CT dosimetry phantoms must be used in determining the radiation output of a CT system. The phantoms must comply with Code of Federal Regulations, title 21, section 1020.33 or equivalent phantom.

F. The dose measurements must be made for standard head scan mode of operation used at the facility.

G. The image quality measurements must be made using a typical clinical technique in the standard head scan mode of operation.

Subp. 6. **Equipment performance measurements performed by the CT operator.** In addition to the equipment performance measurements described in subpart 4, an operator must:

A. Complete daily and monthly equipment performance procedures according to part 4732.1100 or those equipment performance procedures designed by the manufacturer and include all processing procedures in part 4732.0510; and

B. Complete acquisition of images obtained with a CT phantom recommended by the manufacturer using the same processing mode and CT conditions of operation that are used to perform the equipment performance measurements required by part 4732.1100.

Subp. 8. **7. Program review.** The registrant, ~~or~~ radiation safety officer, or CT manager must review, sign, or use electronic signature and date the operator's equipment performance measurements at intervals not to exceed 12 months. This review would be included in the annual audit.

Subp. 8. **Operating procedures.** The registrant must ensure that:

A. The CT system is operated by an individual who:

(1) Is a licensed practitioner of the healing arts, or individuals who meet the requirements in Minnesota Statutes, section 144.121, subdivision 5;

(2) Has been specifically trained by the equipment manufacturer or equivalent; and

(3) Has training on appropriate positioning, anatomy and other topics the registrant and radiation safety officer deem necessary for safe use of the equipment in the facility; and

B. Information of the system is available at the control panel regarding the operation. The information must include the following:

(1) A current protocol sheet and technique chart available at the control panel, which specifies for each routine examination; the CT conditions of operation and the number of scan slices per examination, CTDI vol radiation dose for the study; and

(2) Instructions on the use of the CT image quality phantoms including the allowable variations for the indicated parameters. Operator must be familiar with appropriate CTDI vol radiation dose values and ensure that a CT scan series does not use inappropriate high dose.

Subp. 9. Corrective actions.

A. Correction of the problem must take place and be verified by performing the equipment performance measurements according to:

(1) Code of Federal Regulations, title 21, section 1020.33;

(2) The manufacturer's specifications; or

(3) Part 4732.1100.

B. The equipment must not be used on patients until corrective actions have been taken, verified, and documented, if the equipment performance measurement or spot check of the CT system indicates that a system operating parameter has exceeded a tolerance established:

(1) In part 4732.1100;

(2) By the manufacturer specifications; or

(3) By manufacture's representative who is a MN registered service provider; or

(3) A qualified medical physicist.

Subp. 10. **CT fluoroscopic procedures.** If the equipment has the capabilities of performing fluoroscopic procedures, the x-ray control may be operated in the CT room and essential personnel may remain in the room during the fluoroscopic procedures provided they:

- A. Have been trained on radiation safety issues of CT;
- B. Are wearing personal protective garments; and
- C. Have individual personal monitoring devices.

Subp. 12. **Records.** The registrant will ensure that the required documentation is maintained according to part 4732.0330.

#### **4732.0870. MEDICAL USE OF CONE BEAM COMPUTED TOMOGRAPHY SYSTEMS.**

Subp. 1. **Requirements for Cone beam CT for medical use.** In addition to other applicable parts of this chapter, the registrant must ensure:

A. That for stationary units, a radiation shielding plan or evaluation has been completed prior to patient use;

B. For mobile units, that a radiation survey of the areas of use has been completed prior to patient use;

C. That the cone beam CT equipment for use in a medical office must meet the requirements of part 4732.0890, as applicable. The equipment must not be used if:

(1) The positioning markers are not functional;

(2) Any acceptance tests or initial calibration tests exceed a parameter;

(3) Manufacturer's recommended quality control tests or periodic maintenance exceeds a parameter.

D. The operators of cone beam CT must meet the requirements in 4732.0861-4732.0862;

E. That site-specific staff training is conducted initially and if there is a change in equipment that would affect the radiation output or dose or a change in software;

F. Ensure that the operating and emergency procedures are in the control area and the staff have completed training on the procedures;

G. Ensure all training is documented according to 4732.0330; and

H. The utilization log, retake analysis, are annual audit are performed according to this chapter.

**Subp. 3. Quality assurance program.** The registrant must ensure that the quality assurance program includes:

A. Quality control test procedures;

B. Annual audit;

C. Utilization log;

- D. Retake reject analysis;
- E. Installation calibration reports;
- F. Equipment performance reports;
- G. Individual monitoring reports, if applicable; and
- H. Any other information pertaining to the use of the equipment.

Subp. 4. **Records.** All records must be maintained according to 4732.0330.

**4732.0895 DENTAL CONE BEAM COMPUTED TOMOGRAPHY**

**SYSTEMS.** Refer to part 4732.0865, cone beam computerized tomography designed for visualization of the head and soft tissues of the neck.

**Subp. 1. Requirements for dental use of cone beam computed tomography.** In addition to other applicable parts of this chapter, the registrant must ensure:

- A. That a shielding plan has been completed and reviewed;
- B. That the cone beam CT equipment for use in a dental office meets the requirements of part 4732.0890, as applicable. The equipment should not be used if:
  - (1) The positioning markers are not functional;
  - (2) Any acceptance tests or initial calibration tests exceed a parameter;
  - (3) Manufacturer's recommended quality control tests or periodic maintenance exceeds a parameter.
- C. That the operators of cone beam CT meet the requirements in 4732.0861-4732.0862; or

D. Be a dental hygienist, dental assistant, advanced oral practitioner, licensed or registered with the Minnesota Board of Dentistry or an individual who had completed the MN x-ray operator examination prior to 2008;

E. That site-specific staff training must be conducted initially and if there is a change in equipment or software that would affect the radiation output or dose;

F. That training on the following items is completed:

(1) At least 4 hours of training on cross-sectional anatomy and positioning; and

(2) At least 4 hours of computed tomography equipment training by the manufacturer, the radiation safety officer, or qualified registered service provider. This must include appropriate computer software training; and

(3) At least 2 months experience under the general supervision of an individual qualified in computed tomography or a licensed practitioner of the healing arts.

G. That all training is documented according to 4732.0330; and

H. That the utilization log, retake analysis, are annual audit are performed according to this chapter.

**Subp. 2. Quality assurance program.** The registrant must ensure that the quality assurance program includes:

I. Quality control test procedures, either written manufacturer's recommended tests or written procedures by the radiation safety officer;

A. Annual audit;

- B. Utilization log;
- C. Retake reject analysis;
- D. Installation calibration reports;
- E. Equipment performance reports;
- F. Individual monitoring reports, if applicable; and
- G. Any other information pertaining to the use of the equipment.

Subp. 3. **Records.** All records must be maintained according to 4732.0330.

#### **4732.0900. CONE BEAM O-ARM IMAGING SYSTEMS.**

Subp. 1. Requirements for medical use of cone beam O-arm computed tomography must follow the requirements for cone beam CT scanners in this chapter.

Subp. 2. Records. All records must be maintained according to 4732.0330.

#### **4732.1100. INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.**

##### **Subpart 1. Tests required.**

A. Installation calibration tests or acceptance tests must be conducted prior to any patient use. Any adjustments must be made to bring the equipment up to a nationally recognized standard such as the Code of Federal Regulations, title 21, section 1020 or manufacturer's specifications, with a copy left on site, and to ensure compliance with this chapter prior to first use.

B. Equipment performance tests must be conducted over all clinical ranges, when applicable. For equipment performance tests, any adjustments must be made to bring equipment to a nationally recognized standard or manufacturer's specifications; and to ensure compliance with this chapter prior to using the equipment again.

Subp. 2. **Frequency of tests.** The tests in this part are to be made at the time of installation and whenever the following occurs plus at the specified intervals thereafter:

- A. Major maintenance is performed;
- B. Replacement of an x-ray tube;
- C. A major change in equipment operation; or
- D. Introduction of a new software package, is accomplished.

Subp. 3. Test result documentation must contain all numerical information and is required to be kept either in paper form or as computer data which can be retrieved at the time of inspection by the commissioner according to 4732.0330.

**Subp. 6. For facilities with fluoroscopes and C-arm fluoroscopes, manufactured before May 19, 1995.**

TESTS	FREQUENCY	TOLERANCES
Maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and every tube change	< 5 R (1.3 mC/kg) per minute for manual; < 10 R (2.6 mC/kg) per minute for automatic exposure rate control systems

High level control maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and every tube change	< 20 R (5.0 mC/kg <sup>-1</sup> ) per minute
Fluoroscopic image size	At intervals not to exceed 12 months and every tube change	Error between fluoroscopic beam size and observed image size must be no more than ± 3% of SID for all modes and at any tower height
Spot-film size vs. indicated	At intervals not to exceed 12 months	Error between actual fluoroscopic beam size at image receptor and indicated image size must be no more than ± 3% of SID for all modes and at any tower height
Spot-film reproducibility	At intervals not to exceed 12 months	± 5% of average exposure
Phototimer reproducibility, if present	At intervals not to exceed 12 months	± 5% of average exposure
Fluoroscopic high contrast resolution and distortion	At intervals not to exceed 12 months	Six inch (15 centimeter) intensifier: center 30 and edge 24 (wires per inch)

		copper mesh; nine inch (23 centimeter) intensifier
Half-value layer	At intervals not to exceed 12 months and after every tube change	± 5% for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer's specified limits

**Subp. 7. For facilities with fluoroscopes and C-arm fluoroscopes, manufactured on or after May 19, 1995.**

TESTS	FREQUENCY	TOLERANCES
Maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and at every tube change	> 5 R/min must have automatic exposure rate control;> 10 R/min must have high level control; if not high level control maximum is < 10 R/min
High level control maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and at every tube change	< 20 R/min
All other tests as indicated in subpart 5	At intervals not to exceed <u>12</u> months	See criteria in subpart 5

Subp. 9. For facilities with computed tomography scanners.

TESTS	FREQUENCY	TOLERANCES
Accuracy of scout localization view	At intervals not to exceed 12 months	$\pm 1$ millimeters
Accuracy of distance measurements	At intervals not to exceed 12 months	$\pm 1$ millimeters
CT dose index	At intervals not to exceed 12 months	$\pm 20\%$ from manufacturer's recommendations
CT number dependence on slice thickness	At intervals not to exceed 12 months	Mean $\pm 3$ CT numbers averaged over 100 pixels
CT number calibration and noise	Daily and charted <u>either in paper form or a computer data base</u>	Water: $0 \pm 5$ CT numbers; Noise: $\pm 3$ standard deviations of the mean of the baseline noise variance measurements
CT number uniformity and artifacts	Monthly for mobile units. At intervals not to exceed 12 months for fixed base units.	Variation $\pm 5$ CT numbers between the mean values of measurements made at center and edge of phantom that is at least 20 cm. In diameter among a mean of 100 pixels. Artifacts: no noticeable artifacts.
Hard copy output and	Daily	Luminance and contrast not significantly different

visual display		
Table indexing	At intervals not to exceed <u>12</u> months	$\pm 0.5$ millimeter for each increment
Table backlash	At intervals not to exceed <u>12</u> months	$\pm$ one millimeter
<u>CTDI vol</u>	<u>At intervals not to exceed 12 months</u>	<u>Manufacturers recommendations/ 20% of measured value</u>

**Subpart 9a. For computed tomography scanners that are PET/SPECT dedicated.**

TESTS	FREQUENCY	TOLERANCES
Accuracy of scout localization view	At intervals not to exceed 12 months	$\pm 1$ millimeters
Accuracy of distance measurements	At intervals not to exceed 12 months	$\pm 1$ millimeters
CT dose index	At intervals not to exceed 12 months	$\pm 20\%$ from manufacturer's recommendations
CT number dependence on slice thickness	At intervals not to exceed 12 months	Mean $\pm 3$ CT numbers averaged over 100 pixels
CT number calibration and noise	Daily	Water: $0 \pm 5$ CT numbers; Noise: $\pm 3$ standard deviations of the mean of the baseline noise variance measurements
Table indexing	At intervals not to exceed six months	$\pm 0.5$ millimeter for each increment

Table backlash	At intervals not to exceed six months	$\pm 1.0$ millimeter
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