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;

(2) the manufacturer's specifications; 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 90 days after November 5, 2007, and those systems not previously surveyed, 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 hazard. 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 24 months according to:

(1) nationally recognized standards, such as Code of Federal Regulations, title 21, section 1020;

(2) the manufacturer's specifications; or

(3) part 4732.1100; and

(4) 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.

C. The equipment performance measurements of a CT system must be performed at intervals not to exceed 24 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. 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.

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. **Spot checks.** The registrant must ensure the spot checks for the computed tomography equipment specified in this part are performed at intervals not to exceed 12 months to verify the system's integrity.

A. The spot check procedures must be written procedures developed by the manufacturer or a registered service provider.

B. The spot check procedures must incorporate the use of a CT image quality phantom to provide an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean computed tomography noise (CTN) for water or other reference material.

C. Spot checks must include acquisition of images obtained with the CT image quality phantoms using the same processing mode and CT conditions of operation as are used to perform equipment performance measurements in part 4732.1100. The images must be maintained, until a new equipment performance test is performed.

D. Records must be retained as:

(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 system.

E. Documentation of the spot checks must be maintained according to part 4732.0330 for inspection by the commissioner.

Subp. 8. **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 part 4732.0510; and

B. acquisition of images obtained with the CT dosimetry 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. 9. **Program review.** The registrant or radiation safety officer must review, sign, and date the operator's equipment performance measurements at least quarterly.

Subp. 10. **Operating procedures.** Information about the operation, radiation surveys, and equipment performance measurements of the system must be available for the employees and for the commissioner at the time of an inspection. The registrant must ensure that:

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

(1) after January 1, 2008, 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 manufacturer or equivalent; and

(3) has had training in appropriate CT positioning and anatomy for procedures performed at the facility; and

B. information about the system must be available at the control panel regarding the operation. The information must include the following:

(1) a current technique chart available at the control panel, which specifies for each routine examination the CT conditions of operation and the number of scans per examination; and

(2) instructions on the use of the CT dosimetry or image quality phantoms including the allowable variations for the indicated parameters.

Subp. 11. **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 1030, the manufacturer's specifications, or part 4732.1100.

B. Corrective action must take place if the equipment performance measurements or spot checks of the CT system indicate that a system operating parameter has exceeded a tolerance established:

(1) in part 4732.1100;

(2) by the manufacturer; or

(3) by a registered service provider.

When an operating parameter has been exceeded, the CT system equipment on patients must not be used or must be limited to those uses permitted by established written instructions until the corrective actions have been taken and verification of the correction has been made and documented.

Subp. 12. **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. 13. **Records.** The registrant will ensure that the required documentation is maintained according to part 4732.0330.

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