4732.0865 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;

B. the manufacturer's specifications; or

C. part 4731.1100.

Subp. 2. **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. 3. **Radiation surveys.** All computed tomography systems installed 90 days after November 5, 2007, and those systems not previously surveyed, 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. 4. **Equipment performance measurements.**

A. The registrant must ensure that the equipment performance measurement procedures 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) processing requirements in 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 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. 5. **Spot checks.** The registrant must ensure the spot checks for the computed tomography equipment 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. All spot checks must be included in the equipment performance measurements and at time intervals and system conditions specified by the manufacturer or a registered service provider.

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

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

E. 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.

F. Documentation of the spot checks must be maintained according to part 4732.0330.

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. 7. **Program review.** The registrant or radiation safety officer must review, sign, and date the operator's equipment performance measurements at intervals not to exceed 12 months.

Subp. 8. **Operating procedures.** 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 equipment manufacturer or equivalent; and

(3) has training on appropriate positioning and anatomy for the 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 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. 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;

(2) the manufacturer's specifications; or

(3) part 4732.1100.

B. The equipment must not be used 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; or

(3) by a registered service provider.

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

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