641—40.8(136C) Computed tomography X-ray systems. In addition to the applicable requirements of this chapter, all computed tomography X-ray systems, except CT used exclusively for radiation therapy, shall meet the requirements for manufacture as specified in 21 CFR 1020.33 and the requirements set forth in this chapter at the time of installation and at all times when in use.

40.8(1) *Requirements for equipment.*

a. Conditions of operation. Computed tomography X-ray registrants shall comply with control and indication of conditions of operation as specified in 21 CFR 1020.33(f).

b. Visual indication. CT X-ray systems shall meet the requirements as specified in 21 CFR 1020.33(f)(1).

c. Timers. CT X-ray systems shall meet the requirements as specified in 21 CFR 1020.33(f)(2).

d. Tomographic plane indication and alignment. CT X-ray registrants shall comply with tomographic plane indication and alignment as specified in 21 CFR 1020.33(g).

e. Beam-on and shutter status indicators and control switches. CT X-ray registrants shall comply with beam-on and shutter status indicators as specified in 21 CFR 1020.33(h).

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed as specified in 21 CFR 1020.33(h)(1).

(2) Each emergency button or switch shall be clearly labeled as to its function.

f. Information to be provided for users. CT X-ray registrants shall comply with information to be provided for users as specified in 21 CFR 1020.33(c).

g. Conditions of operation. CT X-ray registrants shall comply with conditions of operations as specified in 21 CFR 1020.33(c)(1).

h. Dose information. CT X-ray registrants shall comply with dose information as specified in 21 CFR 1020.33(c)(2).

i. Imaging performance information. CT X-ray registrants shall comply with imaging performance information as specified in 21 CFR 1020.33(c)(3).

j. Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

(1) The total error in the indicated location of the tomographic plane or reference plane cannot exceed 5 mm as specified in 21 CFR 1020.33(g)(3).

(2) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible as specified in 21 CFR 1020.33(h)(1).

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 mm with any mass from 0 to 100 kilograms resting on the support device as specified in 21 CFR 1020.33(i).

(4) The patient support device shall 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 as specified in 21 CFR 1020.33(i).

(5) Measurement of actual versus indicated scan increment may be taken anywhere along this travel as specified in 21 CFR 1020.33(i).

(6) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan as specified in 21 CFR 1020.33(f)(2)(ii).

40.8(2) *Facility design requirements.* The location of a mobile and fixed CT X-ray system must be designed and constructed as follows.

a. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

b. Viewing systems.

(1) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(2) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

c. Radiation protection shielding survey. Within 30 days of first use of a mobile or fixed stationary CT X-ray system, the registrant shall complete and keep on file a radiation protection shielding survey of the room and surrounding areas consistent with the National Council on Radiation Protection and Measurements Report #147 (2004) and subrule 40.8(3).

40.8(3) *CT shielding requirements for mobile and stationary fixed CT X-ray systems.* The operator's booth and surrounding occupied areas must be designed and constructed in accordance with the National Council on Radiation Protection and Measurements Report #147 (2004) or other nationally accepted standard.

a. Protective barriers must be provided in the ceiling, floor, and walls of the CT X-ray system enclosure to ensure exposure does not exceed acceptable dose limits established in 641—subrule 37.11(7).

b. The control panel must be shielded by a protective position between the operator and the radiation source during CT X-ray system operation.

c. The registrant shall submit a revised radiation shielding plan for department review in accordance with this rule after replacement of a mobile or fixed stationary CT X-ray system or any change in the CT X-ray system room's construction or surrounding rooms construction.

d. Rooms in which a mobile CT X-ray system is used are exempt from the requirements of paragraphs 40.8(3)*"a," "b,"* and *"c."* However, the operator must be protected to ensure exposure does not exceed dose limits established in 641—Chapter 37 for dose limits to members of the public.

40.8(4) *Surveys, calibrations, and routine QC.*

a. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert within 30 days of installation.

b. Existing systems not previously surveyed shall have a survey made by, or under the direct supervision of, a qualified expert within 12 months of the effective date.

c. Such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

d. The registrant shall obtain a written survey report from the qualified expert. A copy of the report shall be retained and made available to the department upon request for the duration of use and registration of the CT X-ray system.

40.8(5) *System performance evaluation.* The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

a. The calibration of a CT X-ray system shall be performed annually as specified in paragraph 40.4(2)*"b"* by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

b. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system.

(1) The calibration of such system shall be traceable to a national standard.

(2) The dosimetry system shall have been calibrated within the preceding two years.

c. The use of a water equivalent CT phantom shall be incorporated. At a minimum, noise, CT number, and artifacts shall be evaluated.

40.8(6) *Calibration.* Calibration shall meet the following requirements:

a. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable.

b. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness, the CTDI along the two axes specified in paragraph 40.8(5)*"c"* shall be measured for the purpose of determining the CTDI, and the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

c. The CT dosimetry phantom shall be oriented so that the measurement point 1 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified.

d. The CT conditions of operation shall correspond to typical values used by the registrant, and the spot checks specified in subrule 40.8(7) shall be made as specified in 21 CFR 1020.33(c)(2)(iv).

40.8(7) *Routine QC (spot checks).* Spot check procedures shall be in writing and shall have been verified by a qualified expert.

a. The spot check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing 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 CTN for water or other reference material as specified in 21 CFR 1020.33(d)(1).

b. All spot checks shall be included in the calibration required by subrules 40.8(5) and 40.8(6) and at time intervals and under system conditions specified by a qualified expert.

c. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by subrules 40.8(5) and 40.8(6).

d. The images shall be retained until a new calibration is performed and retained in two forms:

(1) Photographic copies of the images obtained from the image display device; and

(2) Images stored in digital form on a storage medium compatible with the CT X-ray system.

e. Written records of the spot checks performed shall be retained and made available to the department upon request as specified in subrule 40.4(15).

40.8(8) *CT operating procedures.* The CT X-ray system cannot be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 38. The following information shall be readily available to the CT operator:

a. Instructions on performing routine QC;

b. Scanning protocols for operators;

c. A record of radiation output information, maintained by the registrant, so the radiation dose may be estimated in accordance with established protocols in accordance with the utilization log requirements of this chapter.

40.8(9) *CT systems used for radiation therapy, including PET CT, SPECT CT and CT simulation systems.*

a. PET CT and SPECT CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements of this chapter.

b. Operators must meet the requirements of 641—Chapter 38 and be specifically trained in the operation of the PET CT or SPECT CT system.

c. CT systems used exclusively for radiation therapy simulation treatment planning shall be subject to the requirements of this chapter.

40.8(10) *Remote CT scanning requirements.*

a. Operator requirements. Each person who seeks to operate CT X-ray systems in Iowa from a remote location outside of Iowa must possess a current Iowa permit to practice in accordance with 641—Chapter 38 before engaging in remote CT procedures.

b. Facility requirements. Facilities utilizing remote CT scanning shall ensure qualified operators meet the following requirements:

(1) The facility shall maintain documentation demonstrating that each remote operator of a CT system meets the qualification requirements specified in 641—Chapter 38, applicable to the location of the CT system.

(2) The facility shall verify that each operator meets the qualifications outlined in 641—Chapter 38, including operators located out of state, to ensure compliance with Iowa requirements.

c. On-site personnel. Each on-site personnel shall receive training specific to the personnel's assigned responsibilities in the operation of the remote CT system. Training shall include, at a minimum, both of the following:

(1) Patient positioning;

(2) Administration of contrast.

d. Procedures. Procedure review to ensure safe operation and compliance with state regulations will include, at a minimum, all of the following:

(1) Patient ID procedures;

(2) Protocol management procedures;

(3) Emergency procedures.

e. Radiation safety program elements for remote CT. The facility shall ensure all of the following are met. In addition, records should be maintained and made available upon request to the department.

(1) Use only remote CT systems and components that can adequately protect patient information and to establish policies and procedures for ensuring patient information is protected at the imaging facility, remote imaging locations, and locations where other members of the medical team will view or access patient information.

(2) Maintain a list of the remote operating locations and associated imaging sites. The list must contain the name of the facility, location, and a contact person.

(3) Define the roles and responsibilities and develop procedures for the remote CT technologist and the on-site personnel.

(4) Ensure the on-site personnel completes annual radiation safety training related to the personnel's CT responsibilities.

(5) Ensure the on-site personnel maintains constant surveillance of the patient throughout the CT imaging procedure and performs only one CT imaging procedure at a time.

(6) Ensure remote CT will not be performed if communications (verbal and virtual) or connectivity between the remote site and the imaging facility are not functioning properly or are otherwise unreliable.

(7) Perform checks of the communication system (verbal and visual) and the functionality and connectivity between the remote location and the imaging facility prior to initiating each CT imaging procedure.

(8) Develop procedures for responding to emergencies and situations where there may be a loss of connectivity between the remote site and the imaging facility.

(9) Ensure the remote CT technologist maintains constant surveillance via vocal and visual communications throughout a CT imaging procedure and performs only one CT imaging procedure at a time.

(10) Develop policies and procedures to ensure adequate management oversight of remote operations, including all of the following:

1. Audits to evaluate the effectiveness and safety of the remote CT operations;
2. Reportable radiation incidents;
3. Observations of work being performed at both the imaging facility and the remote location;
4. Processes to identify, track, investigate, and implement corrective actions for incidents where CT examinations are incomplete or repeated.

40.8(11) *Cone-beam CT (CBCT) X-ray systems; equipment requirements.* The CBCT X-ray system must meet the applicable requirements of this chapter.

a. The X-ray field in the plane of the image receptor may not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

b. The registrant shall document and follow QC recommendations in accordance with manufacturer recommendations or as established by a qualified expert in accordance with nationally recognized guidelines.

c. The registrant shall document and implement imaging protocols and a policy addressing deviations from established protocols.

d. The CBCT X-ray system shall only be operated by an individual who meets the requirements of 641—Chapter 38 or rule 481—575.4(153) and who has been specifically trained in the operation of the CBCT X-ray system.

e. The registrant shall maintain documentation of the established protocols, policies, and QC testing until the X-ray system is removed from the facility for inspection by the department.

f. The CBCT operator shall have instructions on all of the following:

(1) Instructions on performing routine QC;

(2) Scanning protocols for operators;

(3) CT systems, including CBCT systems, solely used in nonhuman imaging refer to rule 641—40.10(136C).

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