Ohio Administrative Code

Rule 3701:1-66-10 Medical computed tomography radiation-generating equipment.

Effective: December 13, 2024

This rule applies to mobile and stationary computed tomography (CT) radiation-generating equipment, except for fluoroscopy units with CT capability, CT units used exclusively for radiotherapy simulation, and CT units integrated with linear accelerators.

(A) CT radiation-generating equipment will be maintained to meet the following equipment standards:

(1) The operator will be able to terminate x-ray exposure at any time during a scan or series of scans of greater than 0.5 second duration;

(2) In the case of premature termination of the x-ray exposure by the operator, the CT radiation-generating equipment will need the operator to reset CT conditions of operation prior to the initiation of another scan;

(3) The CT x-ray control and gantry will provide visual indication whenever x-rays are produced;

(4) If the x-ray production period is less than 0.5 second, the indication of x-ray production will be actuated for at least 0.5 second. Visual indicators at or near the gantry will 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;

(5) Each emergency button or switch will be clearly labeled as to its function;

(6) The CT radiation-generating equipment will be designed such that the CT conditions of operation are indicated prior to the initiation of a scan or a scan sequence;

(7) The indicated table increment will not deviate from the actual table increment by more than one millimeter;

(8) Means will be provided to permit visual determination of the location of the tomographic plane or a reference plane. A reference plane may be offset from the location of the tomographic plane(s);

(9) If a device using a light source is used to satisfy paragraph (A)(8) of this rule, the light source will provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to five hundred lux; and

(10) The total error in the indicated location of the tomographic plane or reference plane will not exceed five millimeters.

(B) In addition to paragraph (G) of rule 3701:1-66-02 of the Administrative Code, handlers of CT radiation-generating equipment will meet the following radiation safety obligations:

(1) Techniques will be provided in the vicinity of the control panel or on a pre-programmed menu, based on patient age, weight, body mass index, or patient dimensions, as appropriate, that specifies for each routine examination the CT conditions of operation, including techniques specific to pediatric patient examinations, if applicable;

(2) The limits of radiation dose will not exceed a volume computed tomography dose index (CTDIvol):

(a) Eighty milligray (eight rad) for the facility's routine adult head scan;

(b) Thirty milligray (three rad) for the facility's routine adult or seventy kilogram (one hundred fifty-four pound) abdomen scan;

(c) Twenty milligray (two rad) for the facility's routine pediatric five-year old or eighteen kilogram (forty pound) abdomen scan; and

(d) Forty milligray (four rad) for the facility's routine (one-year old) pediatric head scan;

(3) If the results of the quality control tests, the image quality evaluations, or the radiation dose

measurements exceed a tolerance limit established by a radiation expert, use of the CT radiation-generating equipment on patients will be limited to those uses permitted by written instruction of a radiation expert;

(4) Mobile CT radiation-generating equipment, except for stationary CT radiation-generating equipment installed in a van, trailer, or mobile vehicle and operator behind a protective control booth, will be provided with protective curtains of not less than 0.25 millimeter lead equivalent that completely surrounds the gantry bore during exposures, unless the protective curtains interfere with the sterile field of a surgical procedure; and

(5) Any individual who is in the room during a CT exposure will stand clear of the gantry bore, and will stand behind a whole body protective barrier or wear a protective lead apron of not less than 0.25 millimeter lead equivalent.

(C) In addition to other applicable quality assurance obligations in rule 3701:1-66-04 of the Administrative Code, handlers of CT radiation-generating equipment will comply with the following quality assurance obligations:

(1) The handler will designate and utilize a radiation expert who will:

(a) Perform measurements of the radiation dose and image quality prior to medical use:

(i) Upon installation;

(ii) After repair or replacement of any component of the CT equipment which may alter the radiation output or image quality, prior to medical use, a radiation expert will perform and document measurements of radiation output, using a method specified by a radiation expert in the quality assurance program, and image quality as specified in paragraph (C)(1)(c) of this rule unless in the documented determination of a radiation expert, the repair or replacement will not cause a significant change in radiation output or significant degradation of image quality as defined in the quality assurance program according to paragraph (C)(1)(c) of this rule.

(A) The radiation expert may designate qualified individuals to perform and document the

measurements specified in paragraph (C)(1)(a)(ii) of this rule;

(B) The criteria for qualifying the designees specified in paragraph (C)(1)(a)(ii)(a) of this rule will be specified by a radiation expert in the quality assurance program; and

(C) The radiation expert's approval of the designee's test results will be documented within thirty days;

(b) Perform measurements of radiation dose annually;

(c) Perform evaluations of image quality at least annually using a CT phantom which has the capability of providing an indication of CT number accuracy for at least three materials. The evaluation of image quality will include CT number accuracy and uniformity, noise, artifacts, radiation beam width, resolution for low and high contrast, alignment light accuracy, and table travel accuracy; and

(d) Develop the written quality control program conducted by the CT technologist appropriate for the evaluation of the CT system that includes the tests and allowable tolerance limits. The quality control evaluation for image quality will include the use of a water equivalent phantom, and at a minimum, the evaluation of artifacts, noise, and CT number accuracy. The evaluation of image quality will be at a minimum completed weekly;

(2) Written records of all image quality evaluations and radiation dose measurements will be maintained between inspections for review by the department's inspector;

(3) The images for quality will be retained until a new image quality evaluation is performed as follows:

(a) Photographic copies of the images obtained from the image display device; or

(b) Images stored in digital form on a storage medium compatible with the CT x-ray system;

(4) In consultation with a radiation expert, develop and implement a written program for radiation

dose optimization and scan protocol review. The protocol review will include perfusion studies, if performed. The written program will be audited by a radiation expert on an annual basis;

(5) Radiation dose measurements will be performed using clinical protocols representative of the utilization of the CT unit. If protocols are estimated, measurements will be based on a sample of actual patient data. The specific CT conditions of operation will be documented for each protocol:

(a) Radiation dose measurements will be expressed in terms of CTDIvol;

(b) Radiation dose measurements will be performed using a CT dosimetry phantom that meets the following specifications and conditions of use:

(i) The CT dosimetry phantom will be a right circular cylinder of a material having approximate tissue equivalence of one gram per cubic centimeter. The phantom will be at least fourteen centimeters in length and will have diameters of thirty-two centimeters for measuring radiation dose from the adult abdomen scan protocol and sixteen centimeters for measuring radiation dose from the head and pediatric abdomen scan protocols;

(ii) The CT dosimetry phantom will provide a means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation on the outer surface or within one centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters will be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

(iv) All dose measurements will be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present;

(c) Radiation dose measurements will be performed with a calibrated dosimetry system. The calibration of such system will be traceable to a national standard, or cross-calibrated with a dosimetry system whose calibration is traceable to a national standard. Records of these calibrations

will be readily available for review upon inspection. The dosimetry system will have been calibrated within the preceding two years; and

(d) Obligations of paragraphs (C)(5)(a) and (C)(5)(b) of this rule may be satisfied by an alternative nationally-recognized standard for CT dosimetry. If an alternate dosimetry method is used, a radiation expert will document the procedures in the written quality assurance program.

(D) Cone beam computed tomography (CBCT) scanners and hybrid imaging systems, with the exception of CBCT units integrated with linear accelerators, will comply with the following rules:

(1) Under the guidance of a radiation expert, handlers of CBCT units will develop and implement a written quality control testing program to include test procedures, test frequencies, and tolerance limits;

(2) The written quality control testing program will include an annual testing component to be performed by a radiation expert. This annual testing component will be performed upon installation of new CBCT units and annually thereafter;

(3) The annual tests to be performed by a radiation expert will include an assessment of radiation dose and an evaluation of image quality;

(4) Records of all quality control tests will be documented and retained between inspections;

(5) CBCT scanners are exempt from paragraphs (B)(2) and (C)(5) of this rule; and

(6) SPECT/CT and PET/CT units used exclusively for hybrid imaging will be in compliance with paragraph (B)(2) of this rule if protocols used to scan the head satisfy the limits of paragraph (B)(2)(a) of this rule and protocols used to scan the abdomen satisfy the limits of paragraph (B)(2)(b) of this rule.

(E) Micro-CT units equipped with an x-ray tube enclosure designed to exclude personnel from its interior during x-ray generation will be exempt from paragraphs (A) to (D) of this rule, and will comply with the obligations set forth in rule 3701:1-68-06 of the Administrative Code.

(F) Mobile CT radiation-generating equipment permanently mounted on a base with wheels or castors for moving while completely assembled and not used in one place are exempt from paragraphs (H)(4) and (H)(5) of rule 3701:1-66-02 of the Administrative Code.

(G) Handlers of CT radiation-generating equipment used for veterinary purposes are exempt from the obligations of paragraphs (B)(2) and (C)(4) of this rule.