

3701:1-66-10 Computed tomography radiation-generating equipment.

As used in this rule, "computed tomography (CT) radiation-generating equipment" means CT units as defined in paragraph (B)(12) of rule 3701:1-66-01 of the Administrative Code and used for medical purpose, except for fluoroscopy units with CT capability, CT units used exclusively for radiotherapy simulation and CT units integrated with linear accelerators. In addition to other applicable rules adopted pursuant to Chapter 3748. of the Revised Code and Chapter 3701:1-66 of the Administrative Code, handlers of CT radiation-generating equipment that includes either mobile or stationary installations shall comply with the following:

- (A) CT radiation-generating equipment shall be maintained to meet the following equipment standards:
- (1) The operator shall be able to terminate x-ray exposure at any time during a scan, or series of scans under CT radiation-generating equipment control 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 shall require the operator to reset CT conditions of operation prior to the initiation of another scan.
 - (3) The CT x-ray control and gantry shall 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 shall be actuated for at least 0.5 second. Visual 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.
 - (5) Each emergency button or switch shall be clearly labeled as to its function.
 - (6) The CT radiation-generating equipment shall 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 shall not deviate from the actual table increment by more than one millimeter.
 - (8) Means shall 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 shall 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.
 - (10) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.
 - (11) Mobile CT radiation-generating equipment permanently mounted on a base with

wheels or castors for moving while completely assembled shall be provided with curtains of not less than 0.25 millimeter lead equivalent that completely surrounds the gantry bore during exposures.

- (B) In addition to paragraph (H) of rule 3701:1-66-02 of the Administrative Code, handlers of CT radiation-generating equipment shall meet the following radiation safety requirements:
- (1) Techniques shall 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 shall not exceed a volume computed tomography dose index (CTDI_{vol}):
 - (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 shall be limited to those uses permitted by written instruction of a radiation expert.
 - (4) Operators of CT radiation-generating equipment used on humans shall possess an Ohio radiologic license in accordance with Chapter 3701-72 of the Administrative Code or hold an appropriate license or certificate in accordance with Chapter 4715. of the Revised Code for dental imaging.
- (C) In addition to other applicable quality assurance requirements in rule 3701:1-66-04 of the Administrative Code, handlers of CT radiation-generating equipment shall comply with the following quality assurance requirements:
- (1) The registrant shall designate and utilize a radiation expert who shall:
 - (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 patient use, a radiation expert shall 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 shall be specified by a radiation expert in the quality assurance program; and
 - (C) The radiation expert's approval of the test results shall be documented.
- (b) Perform measurements of radiation dose annually, not to exceed a fourteen month period.
 - (c) Develop written procedures to include system conditions and tolerance limits for the evaluation of image quality. The procedures shall incorporate the use of a CT phantom which has the capability of providing an indication of CT number accuracy for at least three materials, noise, image thickness, alignment light accuracy, and the resolution capability of the system for low and high contrast objects.
 - (d) Perform evaluations of image quality according to the written procedures upon installation and prior to scanning patients and at least annually, not to exceed a fourteen month period, thereafter.
 - (e) Approve the quality control program conducted by the CT technologist including the image quality evaluations appropriate for the system and allowable variations for the indicated parameters.
- (2) Written records of all image quality evaluations and radiation dose measurements shall be maintained between inspections for review by the department's inspector.
 - (3) The images for quality shall 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 must include perfusion studies, if performed. The written program shall be audited by a radiation expert on an annual basis, not to exceed a fourteen month period.
 - (5) Radiation dose measurements shall be performed using clinical protocols representative of the utilization of the CT unit. If protocols are estimated,

measurements must be based on a sample of actual patient data. The specific CT conditions of operation shall be documented for each protocol;

- (a) Radiation dose measurements shall be expressed in terms of CTDIvol;
 - (b) Radiation dose measurements shall be performed using a CT dosimetry phantom that meets the following specifications and conditions of use:
 - (i) The CT dosimetry phantom shall be a right circular cylinder of a material having approximate tissue equivalence of one gram per cubic centimeter. The phantom shall be at least fourteen centimeters in length and shall 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 shall 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 shall 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 shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present; and
 - (c) Radiation dose measurements shall be performed with a calibrated dosimetry system. The calibration of such system shall 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 shall be readily available for review upon inspection. The dosimetry system shall have been calibrated within the preceding two years.
 - (d) Requirements 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 shall 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 shall comply with the following rules:
- (1) Under the guidance of a radiation expert, handlers of CBCT units shall develop and implement a written quality control testing program to include test procedures, test frequencies, and tolerance limits.
 - (2) The written quality control program must include an annual testing component to be performed by a radiation expert. This annual testing component must be performed upon installation of new CBCT units and annually thereafter, not to

exceed fourteen months.

- (3) The annual tests to be performed by a radiation expert must include an assessment of radiation dose and an evaluation of image quality.
 - (4) Records of all quality control tests shall be documented and retained between inspections.
 - (5) CBCT scanners are exempt from paragraphs (B)(2) and (C)(5) of this rule.
 - (6) SPECT/CT and PET/CT units used exclusively for hybrid imaging shall 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 shall be exempt from paragraphs (A) to (D) of this rule, and shall comply with the requirements set forth in paragraph (H)(2) of rule 3701:1-68-03 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 (I)(4) and (I)(5) of rule 3701:1-66-02 of the Administrative Code.

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