Guidance in Bold Text

Rule: 3701:1-66-10 Effective: 12/20/2019

Medical Computed Tomography Radiation-Generating Equipment

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.

This rule applies to mobile and stationary computed tomography equipment except for:

- **Fluoroscopy equipment with computed tomography capability;**
- **Computed tomography equipment used exclusively for radiotherapy simulation; and**
- **Computed tomography equipment combined with linear accelerators.**

Computed tomography means an imaging procedure that uses multiple x-ray transmission measurements and computer programs to generate tomographic images.

Medical purpose or medical use means using radiation-generating equipment to irradiate human beings or animals for diagnostic, localization, or other healing arts purposes.

(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 of greater than 0.5 second duration;

Computed tomography equipment must have the capability for the operator to terminate the x-ray exposure at any time during a scan or series of scans when the exposure time exceeds one-half second.

(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;

If the exposure that would otherwise be delivered via the selected protocol is prematurely terminated by the operator, the CT unit may not allow further x-ray exposure until the CT conditions of operation (i.e. the protocol) have been manually reset by the operator.

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

An 'x-ray on' light or other similar indicator, which is only active when the x-ray is on, must be located on both the x-ray operator control panel and the CT gantry. Please see paragraph (A)(4) of this rule for details regarding visual indicator location and operation.

(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;

The visual indicator specified in paragraph (A)(3) of this rule must activate for at least one half second, even if the duration of the exposure is less than one half second. In

addition, at least one visual indicator must be visible from each side of the CT gantry.

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

A red button or switch imprinted with the universal symbol meets this requirement. This may also be accomplished by labeling each button or switch, "emergency off."

(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;

The computed tomography equipment must indicate the protocol conditions prior to initiating the scan. (i.e. technical parameters including kVp, mA, time per rotation, mAs, mode, etc.)

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

The indicated table increment shall not deviate from the actual table increment by more than 1 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);

Tomographic plane means that geometric plane which is identified as corresponding to the output tomogram.

Reference plane means a plane which is displaced from and parallel to the computed tomographic plane.

A visual indicator of the location of the tomographic plane and/or reference plane must be available. Typically, this is accomplished by projecting light lines onto the patient.

(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; and

The light source which provides visual determination of the location of the tomographic plane or a reference plane must be visible under light conditions 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.

The total error in the indicated location of the tomographic plan or reference plan shall not exceed 5 millimeters.

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(B) In addition to paragraph (G) 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;

Protocols (techniques and CT conditions of operation) based on all applicable sections of this rule must be provided to the operator at the control panel. The protocols may be in the form of a written chart, pre-programmed menu or a combination of the two. Pediatric protocols must be available if there is a potential that pediatric studies will be performed.

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

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

The volume computed tomography dose index (CTDIvol) for a routine adult head scan shall not exceed 80 milligray (8 rad).

Paragraph (C)(5) of this rule requires that the radiation dose measurements be representative of the clinical protocols performed on the CT unit.

Paragraph (C)(1)(a) of this rule requires a radiation expert to perform radiation dose measurements, prior to medical use, upon installation and after any repair that may alter radiation output.

Paragraph (C)(1)(b) of this rule requires a radiation expert to perform radiation dose measurements annually.

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

The volume computed tomography dose index (CTDIvol) for a routine adult abdomen scan shall not exceed 30 milligray (3 rad).

Paragraph (C)(5) of this rule requires that the radiation dose measurements be representative of the clinical protocols performed on the CT unit.

Paragraph (C)(1)(a) of this rule requires a radiation expert to perform radiation dose measurements, prior to medical use, upon installation and after any repair that may alter radiation output.

Paragraph (C)(1)(b) of this rule requires a radiation expert to perform radiation dose measurements annually.

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

pound) abdomen scan; and

The volume computed tomography dose index (CTDIvol) for a routine pediatric abdomen scan shall not exceed 20 milligray (2 rad). Pediatric meaning 5-year-old or 40 pounds.

Paragraph (C)(5) of this rule requires that the radiation dose measurements be representative of the clinical protocols performed on the CT unit.

Paragraph (C)(1)(a) of this rule requires a radiation expert to perform radiation dose measurements, prior to medical use, upon installation and after any repair that may alter radiation output.

Paragraph (C)(1)(b) of this rule requires a radiation expert to perform radiation dose measurements annually.

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

The volume computed tomography dose index (CTDIvol) for a routine pediatric head scan shall not exceed 40 milligray (4 rad). Pediatric meaning 1 year old.

Paragraph (C)(5) of this rule requires that the radiation dose measurements be representative of the clinical protocols performed on the CT unit.

Paragraph (C)(1)(a) of this rule requires a radiation expert to perform radiation dose measurements, prior to medical use, upon installation and after any repair that may alter radiation output.

Paragraph (C)(1)(b) of this rule requires a radiation expert to perform radiation dose measurements annually.

(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;

If a test result exceeds a tolerance limit established by the radiation expert, the CT unit may not be used for any medical purpose, except those permitted by written instruction of the radiation expert.

Compliance is verified by comparing equipment evaluation records, such as those provided by a radiation expert/service personnel and daily QC tests, to the tolerance limits specified in the written QC program. If a test result has exceeded the associated tolerance limit, the clinical use of the CT unit is reviewed to determine if the CT unit was used for any medical purpose other than those permitted by written instruction of a medical physicist.

Paragraph (C)(1)(d) of this rule requires the radiation expert to develop a written quality control program to include the tests and allowable tolerance limits performed by the CT technologist.

(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, shall 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

A mobile computed tomography unit must be provided with lead curtains that surrounds the gantry bore unless the protective curtains interfere with the sterile field of a surgical procedure.

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

If an individual other than the patient needs to be in the room during a CT procedure, they must wear a lead apron of not less than 0.25 millimeter lead equivalent or stand behind a whole body protective barrier such as a mobile lead equivalent shield.

(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 handler shall designate and utilize a radiation expert who shall:

A radiation expert is an individual defined in Ohio administrative Code 3701:1-66-01.

The handler (facility) must designate and use a radiation expert.

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

(i) Upon installation;

Prior to medical use:

- **A radiation expert must measure radiation dose and record that dose in terms of $CTDI_{vol}$ in accordance with paragraph (C)(5) of this rule; and**
- **A radiation expert must measure and evaluate image quality according to paragraph (C)(1)(c) of this rule.**

Installation includes original installation of a new CT unit or re-installation of an existing CT unit in another location.

(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 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 radiation expert shall perform and document, prior to patient use, measurements of radiation output and image quality after any repair or replacement of any component that may alter the radiation output or image quality of the computed tomography equipment, unless in the documented determination of a radiation expert, as part of the quality assurance program, the repair or replacement will not cause a significant change in radiation output or degradation of image quality.

(a) The radiation expert may designate qualified individuals to perform and document the measurements specified in paragraph (C)(1)(a)(ii) of this rule;

The radiation expert may designate qualified individuals to perform and document radiation output testing and image quality evaluations following the repair or replacement of any component of the CT equipment. The measurements must be performed and documented, prior to medical use and in accordance with paragraphs (C)(1)(a)(ii) of this rule.

The radiation expert can either designate individuals by name and qualification, or a group of individuals by credentials. The radiation expert must document his/her qualification criteria in the quality assurance program as required by paragraph (C)(1)(a)(ii)(b) 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

The radiation expert shall provide the criteria that an individual or individuals must meet to perform radiation output and image quality measurements following post-repair or replacement of any component that may alter the radiation output or image quality of the computed tomography equipment. These measurements must be made prior to medical use, and the radiation expert must document the qualifying criterion for the designees in the written quality assurance program.

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

If a designee performs the post-repair or replacement measurements, the radiation expert must provide documented approval of the designee's measurements within 30 days. Electronic documentation is acceptable.

(b) Perform measurements of radiation dose annually;

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The radiation expert must perform radiation dose measurements annually. The dose measurement must be performed in accordance with (C)(5) of this rule.

Annually means at intervals not to exceed one year, plus or minus one month.

(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 shall 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

The radiation expert must perform image quality evaluations at least annually.

The image quality evaluation must be done using a CT phantom capable of providing CT number accuracy for at least three materials and include:

- **CT number accuracy and uniformity;**
- **Noise;**
- **Artifacts;**
- **Radiation beam width;**
- **Resolution for low and high contrast,**
- **Alignment light accuracy; and**
- **Table travel accuracy.**

(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 shall 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 shall be at a minimum completed weekly;

The radiation expert must develop written quality control procedures to be conducted by computed tomography (CT) technologist appropriate to evaluate the CT system.

The image quality control procedures must include the tests to be performed and the allowable tolerance limits for those tests.

The image quality control tests must be done using a water equivalent phantom and at minimum include the evaluation of:

- **Artifacts;**
- **Noise; and**
- **CT number accuracy.**

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

The image quality evaluation and radiation dose measurement records must be kept from the last radiation-generating equipment inspection by the Ohio Department of Health inspector to the next radiation-generating equipment inspection by the Ohio

Department of Health inspector. All record formats (electronic or hard copy) are acceptable if it contains all the required information.

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

The most recently evaluated test images must be maintained in at least one of the following formats.

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

A laser printed or chemically processed photographic image may be maintained.

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

A digital image may be stored directly in the CT unit memory, on a removable digital storage device, in the PACS, or on any other compatible storage medium.

(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;

The facility in consultation with a radiation expert must implement a written program for radiation dose optimization and scan protocol review. The radiation must audit the written program for radiation dose optimization annually.

Annually means at intervals not to exceed one year, plus or minus one month.

(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:

The radiation dose measurements must be based on clinical protocols performed on the computed tomography (CT) unit.

If protocols are estimated, the radiation dose measurements must be based on a sample of actual patient data.

The specific CT conditions of operation shall be documented (part of the record) such as kVp, mA, time per rotation, scan FOV, reconstruction algorithm and image (slice) thickness based on patient age, weight, body mass index, or patient dimensions.

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

The radiation dose measurement required by this rule are to be expressed in terms of volume computed tomography dose index (CTDIvol).

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

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The facility must keep some documentation on the CT dosimetry phantoms used. This could be a copy of the phantom specifications or a statement on the dose measurement report that the measurement was made with a phantom meeting the specifications of this rule.

(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;

The Computed Tomography (CT) dosimeter phantom must:

- **Be a right circular cylinder with an approximate tissue equivalence of 1 gram per cubic centimeter.**
- **Be at least 14 centimeters in length.**
- **Have diameters of 32 centimeters for measuring radiation dose of adult abdomens, and 16 centimeters for measuring radiation dose for pediatric heads and abdomens.**

(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;

The Computed Tomography (CT) dosimeter phantom must have a means for the dosimeter to be placed along the axis of the rotation and along a line parallel to the axis of rotation on the outer surface or within 1 centimeter from the outer surface and within the phantom. Other placement locations may also 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

Any dose effects due to the removal of the phantom material to accommodate dosimeters must be accounted for with appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(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;

The dose measurements must be with the CT phantom on the patient couch or support device without additional attenuation materials present.

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(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; and

The calibration of the dosimetry system used to measure radiation dose be must be traceable to a national standard.

The calibration of the dosimetry system must be within the two years preceding the last time the dosimetry system was used to measure radiation dose on a computed tomography unit.

The calibration records for the dosimetry system must be available for review at the time of the Ohio Department of Health radiation-generating equipment inspection.

(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.

This paragraph provides an option of implementing an alternative method of measuring radiation dose and/or expressing dose test results based on an established nationally-recognized standard for CT dosimetry. Sources of such a nationally-recognized standard may include publications from the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), or a federal regulatory agency such as the United States Food and Drug Administration (FDA).

If an alternate dosimetry method is used, a radiation expert must document the procedures, either directly or by reference, in the written quality assurance program. In the case an alternate dosimetry method is documented by reference, a copy of the actual method must be made part of the 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;

Handlers (facilities) must develop a written quality control testing program under the direction of a radiation expert.

The written quality control testing program shall include:

- **Test procedures**
- **Testing frequency**
- **Tolerance limits for the tests**

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(2) The written quality control testing 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;

The written QC testing program must include an annual testing component to be performed by the radiation expert. This testing must be performed:

- **Upon installation, and**
- **Annually thereafter.**

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

The annual testing performed by the radiation expert required in paragraph (D)(2) of this rule must include an assessment of radiation dose and an image quality evaluation.

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

The quality control test must be documented and the records available for review at the time of the Ohio Department of Health radiation-generating equipment inspection.

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

$CTDI_{vol}$ measurement limits are not applicable to CBCT equipment.

(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.

The dose from SPECT/CT and PET/CT units used exclusively for hybrid image to san the head must not exceed 80 milligray (8 rad) as required by paragraph (B)(2)(a) of this rule.

The dose from SPECT/CT and PET/CT units used exclusively for hybrid image to scan the abdomen must not exceed 30 milligray (8 rad) as required by 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 rule 3701:1-68-06 of the Administrative Code.

Micro-Computed Tomography units are except from Ohio Administrative Code 3701:1-66-10 but must meet the requirements of Ohio Administrative Code 3701:1-68-06.

(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

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(H)(5) of rule 3701:1-66-02 of the Administrative Code.

Mobile computed tomography equipment mounted on a base with wheels or castors and not used in one place does not need to provide a window, mirror or television monitoring system to view the patient from behind the protective barrier.

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

Veterinary computed tomography units are exempt from the volume computed tomography dose index (CTDIvol) limits and the dose optimization and scan protocol review with the radiation expert.