DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
RADIATION SAFETY SECTION
IONIZING RADIATION RULES

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PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS

R 325.5701 Purpose and scope.

Rule 701. (1) This part establishes requirements governing the use of computed tomography (CT) scanners in the healing arts.

(2) This part applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.

(3) A CT scanner is exempt from this part if the scanner meets 1 of the following:

- **(a)** Generates a peak power of 5 kilowatts or less as certified by the manufacturer.
- **(b)** Is used only for attenuation corrections and anatomical markers as part of a positron emission tomography (PET/CT) or single photon emission computed tomography (SPECT/CT) study.
- **(c)** Is used as a simulator solely for treatment planning purposes in conjunction with a megavoltage radiation therapy unit.
- **(d)** Is used solely for intra-operative guidance tomography.

(4) In addition to the requirements of this part, all registrants are subject to R 325.5001 to R 325.5665 and the certificate of need review standards for computed tomography scanner services.

History: 2011 AACS.

R 325.5703 Definitions.

Rule 703. (1) As used in this part the definitions in 21 C.F.R. 1020.33, "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909 or via the internet at website: www.michigan.gov/rss and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993 or via the internet at website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

(2) As used in this part the following definitions apply:

- **(a)** "Annual" means a period of 12 consecutive months.
- **(b)** "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Computed tomography includes the capability of producing axial tomograms.
- **(c)** "CT medical event" means an unintended event where a physician determines that actual damage has occurred to an organ or a physiological system of an individual due to or suspected to be due to exposure to diagnostic radiation from a CT scanner.
- **(d)** "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT scanner hybrids if used for CT only procedures.
- **(e)** **"**Medical physicist" means a person trained in evaluating the performance of CT scanners, related equipment, and facility quality assurance programs and who meets the requirements in R 325.5707.
- **(f)** **"**Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body.
- **(g)** **"**Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in R 325.5705.
- **(h)** **"**Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce 3-dimentional images of functional processes in the body.
- **(i)** **"**Tomogram" means the depiction of the attenuation properties of a section through a body.
- **(j)** **"**Traceable to a national standard" means an instrument is calibrated at either the national institute of standards and technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3% of the national standard in the appropriate energy range.

History: 2011 AACS.

R 325.5705 CT operators.

Rule 705. Six months after the effective date of these rules, all CT examinations shall be performed by a radiologic technologist who meets all of the following requirements or by a physician or osteopathic physician licensed under article 15 of the act.

- **(a)** *Initial qualifications*. Before beginning to perform CT examinations independently, a technologist shall meet both of the following:
  - **(i)** Be currently registered by the American registry of radiologic technologists (ARRT) or by the Canadian association of medical radiation technologists (CAMRT).
  - **(ii)** Document at least 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection or have the advanced certification in computed tomography from the ARRT.
- **(b)** *Continuing education*. A technologist shall be in compliance with the ARRT requirements for continuing education for the imaging modality in

which he or she performs services. The continuing education shall include credits pertinent to CT.

History: 2011 AACS.

R 325.5707 Medical physicist.

Rule 707. Each registrant with 1 or more CT scanners shall employ or contract with a medical physicist to review the quality and safety of the operation of the CT scanner. The medical physicist shall meet all of the following:

(a) *Initial qualifications*. Before beginning to independently provide consultation to a CT facility, a medical physicist shall meet 1 of the following:

(i) Be certified in diagnostic radiological physics or radiological physics by the American board of radiology, or in diagnostic imaging physics by the American board of medical physics, or in diagnostic radiology physics by the Canadian college of physicists in medicine.

(ii) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least 1 course in biology or radiation biology and 1 course in anatomy, physiology, or similar topics related to the practice of medical physics, and have 3 years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the U.S.

(iii) During the 3 years immediately following the effective date of this part, a medical physicist that does not meet the requirements of paragraph (i) or (ii) of this subdivision shall be considered qualified if the physicist conducted evaluations of at least 3 CT scanners between January 1, 2007 and January 1, 2010. Three years after the effective date of this part, a medical physicist shall meet the requirements of paragraph (i) or (ii) of this subdivision.

(b) *Continuing experience*. After the second anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have evaluated at least 2 CT scanners in the prior 24-month period.

(c) *Continuing education*. After the third anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have earned at least 15 continuing medical education units, at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.

(d) *Reestablishing qualifications*. A medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:

(i) A medical physicist who fails to meet the continuing experience requirements of subdivision (b) of this rule shall evaluate a sufficient number of CT scanners, under the supervision of a medical physicist, to meet the requirements of subdivision (b) of this rule.

(ii) A medical physicist who fails to meet the continuing education requirements of subdivision (c) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of subdivision (c) of this rule.

History: 2011 AACS.

R 325.5709 Equipment requirements.

Rule 709. (1) The regulations in 21 C.F.R. 1020.33(c), (d), (f), (g), (h), (i), and (j), "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909 or via the internet at website: www.michigan.gov/rss and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993 or via the internet at website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

(2) CT equipment shall be maintained in compliance with the requirements of subrule (1) of this rule.

History: 2011 AACS.

R 325.5711 Enclosures.

Rule 711. (1) A fixed CT scanner enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for a CT scanner enclosure shall be determined by the workload, use, and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and is subject to design approval by the department.

(3) Protective barriers shall be provided in the ceiling, floor, and walls of a fixed CT scanner enclosure.

(4) The control panel for a fixed CT scanner shall be shielded by a protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(5) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with subrule (4) of this rule.

(6) The operator of a fixed CT scanner shall be able to see and communicate with the patient from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier in which it is installed.

(7) Mobile or portable CT scanners used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of subrules (1) to (6) of this rule.

History: 2011 AACS.

R 325.5713 Conditions of operation.

Rule 713. (1) Six months after the effective date of these rules, the CT facility shall establish scanning protocols in consultation with the medical physicist.

(2) The CT operator shall check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the technique and individual patient. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors. Dose indicators or indices outside of expected values shall be documented and reviewed by an interpreting physician or medical physicist.

(3) A fixed CT scanner shall be operated from a shielded position behind a protective barrier pursuant to R 325.5711(4).

(4) Staff personnel routinely working with or around radiation sources shall not be required by the licensee or registrant to restrain patients during CT examinations. If such procedure is permitted personnel exposure shall not exceed the limits in R 325.5205 or the procedure is prohibited.

(5) When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body will be struck by the useful beam and that his or her body is as far as possible from the edge of the useful beam.

(6) Only individuals whose presence is necessary are allowed in a fixed CT scanner room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.

(7) Personnel monitoring is required in controlled areas for each individual occupationally exposed to ionizing radiation from CT scanner equipment. Personnel monitoring devices shall be permanently assigned to each occupationally exposed individual. Monitoring shall be continuous during employment as a radiation worker.

(8) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(9) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with R 325.5222.

(10) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for any medical or dental reason.

(11) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 2011 AACS.

R 325.5715 Report and notification of a CT medical event.

Rule 715. (1) A CT facility shall report any CT medical event.

(2) The registrant shall submit a written report to the department within 15 days after a physician of the CT facility discovers the CT medical event or within 15 days after the CT facility is notified of the CT medical event by another physician, whichever comes first.

(3) The written report shall include all of the following:

- **(a)** The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate.
- **(b)** The name of the physician who determined a CT medical event occurred.
- **(c)** The dates of occurrence and discovery of the CT medical event.
- **(d)** A narrative description of the CT medical event.
- **(e)** The cause of the CT medical event.
- **(f)** The effect on the individual who received the exposure.
- **(g)** A narrative detailing corrective action taken or planned to prevent a recurrence.
- **(h)** Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not.
- **(i)** The name and signature of the person preparing the report.

(4) The report shall not contain the name of the individual who is the subject of the CT medical event or any other information that could lead to identification of the individual.

(5) The registrant shall provide notification of the CT medical event to the referring physician and shall notify the individual who is the subject of the CT medical event not later than 1 week after its discovery, unless the referring physician personally informs the registrant that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring

physician. If the referring physician or the affected individual cannot be reached within 1 week, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the CT medical event, because of any delay in notification. The notification of the individual who is the subject of the CT medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the CT medical event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

History: 2011 AACS.

R 325.5717 Quality control program.

Rule 717. (1) Six months after the effective date of these rules, a CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following:

- **(a)** Image quality.
- **(b)** Patient radiation dose.
- **(c)** Personnel radiation protection.
- **(d)** Compliance with the provisions of this part.
- **(e)** Ongoing quality control.

(2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits.

(3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule.

(4) The ongoing quality control evaluation should include the following:

- **(a)** Image quality, including the following:
  - **(i)** High-contrast resolution.
  - **(ii)** Low-contrast resolution.
  - **(iii)** Image uniformity.
  - **(iv)** Noise.
  - **(v)** Artifact evaluation.
- **(b)** Alignment light accuracy.
- **(c)** Slice thickness.
- **(d)** CT number accuracy.
- **(e)** Dose display devices.

History: 2011 AACS.

R 325.5719 Initial and annual medical physicist performance evaluations.

Rule 719. (1) A medical physicist shall complete an initial performance evaluation of the CT scanner before use on human patients and annually thereafter.

(2) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months and shall be traceable to a national standard as specified in R 325.5703(2)(j).

(3) A performance evaluation should include the following:

- **(a)** Alignment light accuracy.
- **(b)** Alignment of table to gantry.
- **(c)** Table and gantry tilt.
- **(d)** Slice localization from scanned projection radiograph.
- **(e)** Table increment accuracy.
- **(f)** Slice thickness.
- **(g)** Image quality, including the following:
  - **(i)** High-contrast resolution.
  - **(ii)** Low-contrast resolution.
  - **(iii)** Image uniformity.
  - **(iv)** Noise.
  - **(v)** Artifact evaluation.
- **(h)** CT number accuracy and linearity.
- **(i)** Dosimetry, including the following:
  - **(i)** Dose indicator such as computed tomography dose index (CTDI).
  - **(ii)** Patient radiation dose for representative examinations.
- **(j)** Safety evaluation, including the following:
  - **(i)** Visual inspection.
  - **(ii)** Audible and visual signals.
  - **(iii)** Posting requirements.
  - **(iv)** Scattered radiation measurements.
- **(k)** Review of the ongoing quality control program, including test results and corrective action.

(4) The medical physicist shall prepare a report that includes all of the following:

- **(a)** A summary of the performance evaluation required under subrule (1) of this rule.
- **b)** Recommendations for necessary improvements, if any.
- **(c)** Type of dosimetry system used, including the date of the last calibration.

(5) The report required under subrule (4) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation.

History: 2011 AACS.

R 325.5721 Records and report retention.

Rule 721. A CT facility shall maintain records and reports on file and shall make the records and reports available for review by the department as follows:

(a) Records documenting the qualifications of all personnel who worked at the facility as an operator or medical physicist. Records of personnel no longer employed by the CT facility shall be kept on file until the next inspection following the employee's termination has been completed and the department has determined that the facility is in compliance with the CT personnel requirements.

(b) A report of a CT medical event required under R 325.5715 shall be maintained on file for at least 7 years.

(c) Initial and annual medical physicist performance evaluation reports required under R 325.5719(4) shall be maintained on file for at least 5 years.

(d) Records of the results from the ongoing quality control evaluation required under R 325.5717 shall be maintained on file for at least 2 years.

History: 2011 AACS.

PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS

Sections of 21 C.F.R. 1020.33, "Computed tomography (CT) equipment", are adopted by reference. Text that has not been adopted is crossed out.

~~fluoroscopic imaging, the techniques factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.~~

~~(3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.~~

~~(4) The predetermined or selectable options for producing the LIH radiograph shall be described in the information required by §1020.30(h). The information shall include a description of any technique factors applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.~~

~~(k) *Displays of values of AKR and cumulative air kerma.* Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:~~

~~(1) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.~~

~~(2) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.~~

~~(3) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.~~

~~(4) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to §1020.30(h)(6)(iii).~~

~~(i) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in §1020.32(d)(3)(i), (d)(3)(ii), or (d)(3)(v) for measuring compliance with air kerma rate limits.~~

~~(ii) For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.~~

~~(5) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.~~

~~(6) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.~~

~~[70 FR 34039, June 10, 2005]~~

§ 1020.33 Computed tomography (CT) equipment.

~~(a) *Applicability.* (1) The provisions of this section, except for paragraphs (b), (c)(1), and (c)(2) are applicable as specified herein to CT x-ray systems manufactured or remanufactured on or after September 3, 1985.~~

~~(2) The provisions of paragraphs (b), (c)(1), and (c)(2) are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984.~~

(b) *Definitions.* As used in this section, the following definitions apply:

(1) *Computed tomography dose index (CTDI)* means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan; that is:

$$\mathrm{CTDI} = 1/\mathrm{nT} \int_{-7\mathrm{T}}^{+7\mathrm{T}} \mathrm{D}(z)\,dz$$

where:

z=position along a line perpendicular to the tomographic plane.
D(z)=Dose at position z.
T=Nominal tomographic section thickness.
n=Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(2) *Contrast scale* means the change in linear attenuation coefficient per CT number relative to water; that is:

$$\text{Contrast scale} = \frac{\mu_x - \mu_w}{(CT)_x - (CT)_w}$$

where:

μ_w=Linear attenuation coefficient of water.
μ_x=Linear attenuation coefficient of material of interest.
$(CT)_w$=CT number of water.
$(CT)_x$=CT number of material of interest.

(3) *CT conditions of operation* means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in §1020.30(b)(36).

(4) *CT number* means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

(5) [Reserved]

(6) *CT dosimetry phantom* means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. The means used for placement of a dosimeter(s) (i.e., hole size) and the type of dosimeter(s) used is at the discretion of the manufacturer. Any effect 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.

(7) *Dose profile* means the dose as a function of position along a line.

(8) *Modulation transfer function* means the modulus of the Fourier transform of the impulse response of the system.

(9) *Multiple tomogram system* means a CT x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(10) *Noise* means the standard deviation of the fluctuations in CT number expressed as a percent of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n \frac{100 \times CS \times s}{\mu_w}$$

where:

CS=Contrast scale.
μ_w=Linear attenuation coefficient of water.
s=Estimated standard deviation of the CT numbers of picture elements in a specified area of the CT image.

(11) *Nominal tomographic section thickness* means the full-width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

(12) *Picture element* means an elemental area of a tomogram.

(13) *Remanufacturing* means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in this section to ''manufacture'', ''manufacturer'', or ''manufacturing'' includes remanufacture, remanufacturer, or remanufacturing, respectively.

(14) *Scan increment* means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(15) *Scan sequence* means a preselected set of two or more scans performed consecutively under preselected CT conditions of operations.

(16) *Sensitivity profile* means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

(17) *Single tomogram system* means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

(18) *Tomographic plane* means that geometric plane which the manufacturer identifies as corresponding to the output tomogram.

(19) *Tomographic section* means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(c) *Information to be provided for users.* Each manufacturer of a CT x-ray system shall provide the following technical and safety information, in addition to that required under §1020.30(h), to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution of such information. This information shall be identified and provided in a separate section of the user's instruction manual or in a separate manual devoted only to this information.

(1) *Conditions of operation.* A statement of the CT conditions of operation used to provide the information required by paragraph (c) (2) and (3) of this section.

(2) *Dose information.* The following dose information obtained by using the CT dosimetry phantom. For any CT x-ray system designed to image both the head and body, separate dose information shall be provided for each application. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuating materials present.

(i) The CTDI at the following locations in the dosimetry phantom:

(*a*) Along the axis of rotation of the phantom.

(*b*) Along a line parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom with the phantom positioned so that CTDI is the maximum obtainable at this depth.

(*c*) Along lines parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom at positions 90, 180, and 270 degrees from the position in paragraph (c)(2)(i)(*b*) of this section. The CT conditions of operation shall be the typical values suggested by the manufacturer for CT of the head or body. The location of the position where the CTDI is maximum as specified in paragraph (c)(2)(i)(*b*) of this section shall be given by the manufacturer with respect to the housing of the scanning mechanism or other readily identifiable feature of the CT x-ray system in such a manner as to permit placement of the dosimetry phantom in this orientation.

(ii) The CTDI in the center location of the dosimetry phantom for each selectable CT condition of operation that varies either the rate or duration of x-ray exposure. This CTDI shall be presented as a value that is normalized to the CTDI in the center location of the dosimetry phantom from paragraph (c)(2)(i) of this section, with the CTDI of paragraph (c)(2)(i) of this section having a value of one. As each individual CT condition of operation is changed, all other independent CT conditions of operation shall be maintained at the typical values described in paragraph (c)(2)(i) of this section. These data shall encompass the range of each CT condition of operation stated by the manufacturer as appropriate for CT of the head or body. When more than three selections of a CT condition of operation are available, the normalized CTDI shall be provided, at least, for the minimum, maximum, and midrange value of the CT condition of operation.

(iii) The CTDI at the location coincident with the maximum CTDI at 1 centimeter interior to the surface of the dosimetry phantom for each selectable peak tube potential. When more than three selections of peak tube potential are available, the normalized CTDI

shall be provided, at least, for the minimum, maximum, and a typical value of peak tube potential. The CTDI shall be presented as a value that is normalized to the maximum CTDI located at 1 centimeter interior to the surface of the dosimetry phantom from paragraph (c)(2)(i) of this section, with the CTDI of paragraph (c)(2)(i) of this section having a value of one.

(iv) The dose profile in the center location of the dosimetry phantom for each selectable nominal tomographic section thickness. When more than three selections of nominal tomographic section thicknesses are available, the information shall be provided, at least, for the minimum, maximum, and midrange value of nominal tomographic section thickness. The dose profile shall be presented on the same graph and to the same scale as the corresponding sensitivity profile required by paragraph (c)(3)(iv) of this section.

(v) A statement of the maximum deviation from the values given in the information provided according to paragraph (c)(2) (i), (ii), (iii), and (iv) of this section. Deviation of actual values may not exceed these limits.

(3) *Imaging performance information.* The following performance data shall be provided for the CT conditions of operation used to provide the information required by paragraph (c)(2)(i) of this section. All other aspects of data collection, including the x-ray attenuation properties of the material in the tomographic section, shall be similar to those used to provide the dose information required by paragraph (c)(2)(i) of this section. For any CT x-ray system designed to image both the head and body, separate imaging performance information shall be provided for each application.

(i) A statement of the noise.

(ii) A graphical presentation of the modulation transfer function for the same image processing and display mode as that used in the statement of the noise.

(iii) A statement of the nominal tomographic section thickness(es).

(iv) A graphical presentation of the sensitivity profile, at the location corresponding to the center location of the dosimetry phantom, for each selectable nominal tomographic section thickness for which the dose profile is given according to paragraph (c)(2)(iv) of this section.

(v) A description of the phantom or device and test protocol or procedure used to determine the specifications and a statement of the maximum deviation from the specifications provided in accordance with paragraphs (c)(3)(i), (ii), (iii), and (iv) of this section. Deviation of actual values may not exceed these limits.

(d) *Quality assurance.* The manufacturer of any CT x-ray system shall provide the following with each system. All information required by this subsection shall be provided in a separate section of the user's instructional manual.

(1) A phantom(s) capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or a reference material.

(2) Instructions on the use of the phantom(s) including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and a method to store as records, quality assurance data.

(3) Representative images obtained with the phantom(s) using the same processing mode and CT conditions of operation as in paragraph (c)(3) of this section for a properly functioning system of the same model. The representative images shall be of two forms as follows:

(i) Photographic copies of the images obtained from the image display device.

(ii) Images stored in digital form on a storage medium compatible with the CT x-ray system. The CT x-ray system shall be provided with the means to display these images on the image display device.

(e) [Reserved]

(f) *Control and indication of conditions of operation*—(1) *Visual indication.* The CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to initiation of a scan or a scan sequence. On equipment having all or some of these conditions

of operation at fixed values, this requirement may be met by permanent markings. Indication of the CT conditions of operation shall be visible from any position from which scan initiation is possible.

(2) *Timers*. (i) Means shall be provided to terminate the x-ray exposure automatically by either deenergizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function. A visible signal shall indicate when the x-ray exposure has been terminated through these means and manual resetting of the CT conditions of operation shall be required prior to the initiation of another scan.

(ii) Means shall be provided so that the operator can terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than one-half second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(g) *Tomographic plane indication and alignment*. (1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The relationship of the reference plane to the planes of the tomograms shall be provided to the user in addition to other information provided according to §1020.30(h). This reference plane can be offset from the location of the tomographic planes.

(3) The distance between the indicated location of the tomographic plane or reference plane and its actual location may not exceed 5 millimeters.

(4) For any offset alignment system, the manufacturer shall provide specific instructions with respect to the use of this system for patient positioning, in addition to other information provided according to §1020.30(h).

(5) If a mechanism using a light source is used to satisfy the requirements of paragraphs (g) (1) and (2) of this section, the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(h) *Beam-on and shutter status indicators*. (1) Means shall be provided on the control and on or near the housing of the scanning mechanism to provide visual indication when and only when x rays are produced and, if applicable, whether the shutter is open or closed. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for one-half second. Indicators at or near the housing of the scanning mechanism 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.

(2) For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-ray with a shutter, the radiation emitted may not exceed 0.88 milligray (vice 100 milliroentgen exposure) in 1 hour at any point 5 cm outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements average over an area of 100 square cm with no linear dimension greater than 20 cm.

(i) *Scan increment accuracy*. The deviation of indicated scan increment from actual scan increment may not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass 100 kilograms or less, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(j) *CT number mean and standard deviation*. (1) A method shall be provided to calculate the mean and standard deviation of CT numbers for an array of

picture elements about any location in the image. The number of elements in this array shall be under user control.

(2) The manufacturer shall provide specific instructions concerning the use of the method provided for calculation of CT number mean and standard deviation in addition to other information provided according to § 1020.30(h).

[49 FR 34712, Aug. 31, 1984; 49 FR 37381, Sept. 24, 1984, as amended at 49 FR 47388, Dec. 4, 1984; 56 FR 36098, Aug. 1, 1991; 67 FR 9587, Mar. 4, 2002; 70 FR 34042, June 10, 2005]

~~§ 1020.40 Cabinet x-ray systems.~~

~~(a) *Applicability.* The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x-ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.~~

~~(b) *Definitions.* As used in this section the following definitions apply:~~

~~(1) *Access panel* means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.~~

~~(2) *Aperture* means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.~~

~~(3) *Cabinet x-ray system* means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed *cabinet*) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.~~

~~(4) *Door* means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.~~

~~(5) *Exposure* means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.~~

~~(6) *External surface* means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.~~

~~(7) *Floor* means the underside external surface of the cabinet.~~

~~(8) *Ground fault* means an accidental electrical grounding of an electrical conductor.~~

~~(9) *Port* means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.~~

~~(10) *Primary beam* means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.~~

~~(11) *Safety interlock* means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.~~

~~(12) *X-ray system* means an assemblage of components for the controlled generation of x-rays.~~

CT Accreditation Program Requirements

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Overview

The CT Accreditation Program involves the acquisition of clinical and phantom images, dose measurements, and the submission of scanning protocols. Every unit used to produce diagnostic clinical images for patients must successfully pass accreditation testing for the facility to be accredited. Facilities that use units that have been withdrawn, expired, or failed accreditation testing or facilities that never submit a unit for accreditation testing are subject to revocation of their accreditation. Such revocation could adversely affect reimbursement. Every unit must apply for all modules routinely performed on that unit for a facility to be accredited. For sites that perform only adult CT scanning, clinical images required for submission will be both basic and specialized examinations in the modules routinely performed on that unit. For sites that do occasional pediatric scanning (≤15 years of age) in addition to adult work, an additional exam performed on a child will also have to be selected for submission. Sites that perform only pediatric examinations (***only*** patients ≤15 years of age) will have to submit basic and specialized exams tailored to the pediatric population (see selection list under Clinical Images section for all three patient type scenarios).

Mandatory Accreditation Time Requirements

Submission of all accreditation materials is subject to mandatory timelines. Detailed information about specific time requirements is located in the *Overview for the Diagnostic Modality Accreditation Program*. Please read and be familiar with these requirements.

Withdrawn, Added, or Replacement Units

The CT Accreditation Program is unit based. Consequently, facilities ***must notify the ACR*** if they have permanently ***withdrawn*** (i.e., removed) a unit from service, if they have ***replaced*** that unit with a new one or have ***added*** another unit. The type of accreditation options available for a new unit will depend on the amount of ***time the facility has left on its current accreditation certificate:***

- ***Over 13 months*** – The facility needs to submit only unit information and additional testing materials. Once accreditation is approved, the new unit's expiration date will be the same as the previous expiration date.
- ***Less than 13 months*** - The facility must renew accreditation for all units at the facility including the new one. Once approved, all of the units at the facility will have an expiration date that is three years from the old expiration date.

CT units that receive replacements or upgrades to any of the major subassemblies after accreditation is granted will be treated as new units and follow the procedures above. Facilities are only required to report modifications that change the unit's model number. If the unit changes from an adult- or pediatric-only unit to an adult + pediatric unit, an additional adult or pediatric examination must be submitted. If less than thirteen months are left on the facility's accreditation, it must renew the accreditation of all of its equipment at the same time.

Loaner unit

Accredited facilities may use a "loaner" unit to temporarily replace an accredited unit that is out of service for repairs, etc. for up to six months without submitting clinical and phantom images for evaluation. The accredited facility must immediately notify the ACR of the installation date, manufacturer and model of the loaner. Any loaner unit that is in use for more than one month will be required to submit evidence of testing by a qualified medical physicist within 90 days of installation. If the loaner is in place for longer than six months, the facility

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must submit the unit for accreditation evaluation, including clinical and phantom image assessment and the corresponding fee.

Personnel Qualifications

All interpreting physicians, medical physicists and technologists working in CT (including part-time and locum tenens staff) ***must meet and document*** specific requirements in order for their facility to be accredited by the ACR.

The continuing education and continuing experience requirements are based on previous full calendar years. For example, if a site renews their accreditation in July 2009, the physicians and medical physicists/MR scientists at that site must have met the full requirement for continuing education from January 1, 2006 to December 31, 2008. Likewise, they must have met the full continuing experience requirements from January 1, 2007 to December 31, 2008. If they did not meet these requirements in the given timeframes, the ACR will accept continuing education credits or continuing experience obtained in 2009.

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Physician

All physicians who supervise and/or interpret CT examinations must be a licensed medical practitioner who meets the following minimum criteria

Requirements for all Physicians Supervising and/or Interpreting CT Examinations		
Qualifications	**Radiologists**	**Other Physician**
Initial	• Board certification in radiology or diagnostic radiology by: ○ ABR, ○ American Osteopathic Board of Radiology, ○ Royal College of Physicians and Surgeons of Canada, or ○ Le College des Medicins du Quebec, and • If board certified **before 2008** must also meet the following: ○ Oversight, interpretation and reporting of 300 CT examinations in the past 36 months [1], [2] **OR (Not Board Certified)** • Completion of an Accreditation Council for Graduate Medical Education (ACGME)or American Osteopathic Association (AOA) diagnostic radiology residency, and • Performance of, as well as interpretation and reporting of, 500 CT examinations in the past 36 months.[1, 2] **Occasional Readers** Occasional readers are not required to meet the interpreting physician initial qualifications or continuing experience requirements. However, the reads of all occasional readers combined should not exceed 5% of the total volume of reads per practice and per modality. There must be an active written review process in place at the institution for occasional readers based on each institution's credentialing requirements. Validation of this process will take place during any site visit by the ACR.	• Completion of an accredited specialty residency, and • 200 hours of Category I continuing medical education (CME) in the performance as well as interpretation of CT in the subspecialty where CT reading occurs, and • Interpretation and reporting of 500 cases during the past 36 months in a supervised situation.[2]
Continuing Experience	Upon renewal, physicians reading CT examinations must meet the following: Currently meets the Maintenance of Certification (MOC) requirements for ABR (See ABR MOC) **OR** Physicians reading CT examinations across multiple organ systems must have read 200 exams over the prior 36 months.[3] **OR** For physicians reading organ system specific exams (i.e., body, abdominal, musculoskeletal, head) across multiple modalities they must read a minimum of 60 organ system specific CT exams in 36 months. However, they must read a total of 200 *cross-sectional imaging* (MRI, CT, PET/CT and ultrasound) studies over the prior 36 months.[3]	
Continuing Education	Upon renewal must meet one of the following: 1. Currently meets the Maintenance of Certification (MOC) requirements for the ABR (See ABR MOC) **OR** 2. Completes 150 hours (that includes 75 hours of Category 1 CME) in the prior 36 months pertinent to the physician's practice patterns (See ACR Guideline) **OR** 3. Completes 15 hours CME in the prior 36 months specific to the imaging modality or organ system (half of which must be category 1)	

[1] Completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

[2] The supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised. The supervising interpreting physician does not have to be present at the time of initial interpretation. However, the supervising physician must review and, if necessary, correct the final interpretation. Supervision may also be accomplished through a formal course that includes a lecture format in addition to all of the following: 1) a database of previously performed and interpreted cases, 2) an assessment system traceable to the individual participant, and 3) direct feedback regarding the responses. Examples of suitable assessment systems are an audience response system, a viewbox or monitor based program or an individual CD-ROM or web-based instruction system.

[3] Double-reading (2 or more physicians interpreting the same examination) is acceptable. Interpreting physicians may also re-interpret a previously interpreted examination and count it towards meeting the continuing experience requirement, as long as he/she did not do the initial interpretation. Examinations that are reviewed and evaluated for RADPEER™ or an alternative physician peer review program may count toward your continuing experience numbers.

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Requirements for Physicians Supervising and Interpreting Cardiac CT Examinations		
Qualifications	**Radiologists**	**Other Physicians**
Initial	• Board certification in radiology or diagnostic radiology by: o ABR, o American Osteopathic Board of Radiology, o Royal College of Physicians and Surgeons of Canada, or o Le College des Medicins du Quebec, and • If board certified **before 2008**, must also meet the following: o Supervision, interpretation and/or review and reporting of 75 Cardiac CT examinations within the last 36 months. [4,5] **OR (Not Board Certified)** • Completion of an Accreditation Council for Graduate Medical Education (ACGME) Radiology Residency Program, AND • Have supervised interpretation of 75 cardiac CT cases in the past 36 months[5] AND • Completion of at least 40 hours of Category 1 Continuing Medical Education (CME) in cardiac imaging, including cardiac CT, anatomy, physiology, and/or pathology or documented equivalent supervised experience in a center actively performing cardiac CT.[5]	**CARDIOLOGISTS[6] (Cardiac Only)** Certification in cardiology by the American Board of Internal Medicine with completion of Level 2 training or higher **Level 2 requirements** • Board certification or eligibility, valid medical license, and completion of a 3-month (cumulative) specialty residency or fellowship in Cardiac CT AND • 150 Cardiac CT examinations in which 50 where the candidate is physically present, involved in the acquisition and interpretation of the case, AND • Completion of 30 hours of courses related to CT in general and/or Cardiac CT in particular **Level 3 requirements** • Board certification or eligibility, valid medical license, and completion of a 12-month (cumulative) specialty residency or fellowship in Cardiac CT AND • 300 Cardiac CT examination in which 100 where the candidate is physically present, involved in the acquisition and interpretation of the case, AND • Completion of 60 hours of courses related to CT in general and/or Cardiac CT in particular **NUCLEAR MEDICINE PHYSICIANS (Cardiac Only)** • Completion of an ACGME approved training program in nuclear medicine AND • Specific training in CT within an ACGME accredited training program OR • 160 hours of category 1 CME in CT to include, but not limited to: CT physics, recognition of artifacts, safety, instrumentation, and 40 hours specific to cardiovascular CT. AND • Interpretation and reporting under the supervision of a qualified physician of at least 75 cases of CT of the cardiovascular system during the past 36 months.[5]
Continuing Experience	Upon renewal, radiologists reading Cardiac CT examinations must have read 50 exams over the prior 24-month period. The cardiac examinations interpreted will count toward the overall continuing experience for other CT modules.[7]	**Upon renewal, cardiologists reading Cardiac CT examinations must have continuing experience in accordance with level 2 requirements or higher – 50 examinations each year.[7]**
Continuing Education	Upon renewal, physicians must have earned at least 15 CME in CT (half of which must be category 1) hours in the prior 36-month period and should include CME in Cardiac CT as is appropriate to the physician's practice needs.	Upon renewal, cardiologists must have earned at least 30 hours of coursework in the prior 36 month period in accordance with level 2 requirements.

[4] Board certification and completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

[5] The supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised. The supervising interpreting physician does not have to be present at the time of initial interpretation. However, the supervising physician must review and, if necessary, correct the final interpretation. Supervision may also be accomplished through a formal course that includes a lecture format in addition to all of the following: 1) a database of previously performed and interpreted cases, 2) an assessment system traceable to the individual participant, and 3) direct feedback regarding the responses. Examples of suitable assessment systems are an audience response system, a viewbox or monitor based program or an individual CD-ROM or web-based instruction system.

[6] 2005 ACCF/AHA Clinical Competence Statement on Cardiac CT and MR.

[7] Double-reading (2 or more physicians interpreting the same examination) is acceptable. Interpreting physicians may also re-interpret a previously interpreted examination and count it towards meeting the continuing experience requirement, as long as he/she did not do the initial interpretation. Examinations that are reviewed and evaluated for RADPEER™ or an alternative physician peer review program may count toward your continuing experience numbers.

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In addition, all physicians interpreting CT examinations must:

- Have completed an accredited diagnostic radiology residency or 80 hours of documented, relevant classroom instruction including diagnostic radiology and radiation safety physics. Otherwise, physicians must demonstrate training in the principles of radiation protection, the hazards of radiation exposure to both patients and radiological personnel, and appropriate monitoring requirements.
- Be thoroughly acquainted with the many morphologic and pathophysiologic manifestations and artifacts demonstrated on computed tomography. Additionally, supervising physicians should have appropriate knowledge of alternative imaging methods.
- Be knowledgeable of patient preparation, and training in the recognition/treatment of adverse effects of contrast materials[8] for these studies.
- Be responsible for reviewing all indications for the examination; specifying the use, dosage, and rate of administration of contrast agents[8], specifying the imaging technique, including appropriate windowing and leveling; interpreting images; generating written reports; and maintaining the quality of both the images and interpretations.
- Be familiar with the meaning and importance to the practice of CT of: total radiation dose to the patient, exposure factors, conscious sedation principles that are performed in the practice, and post-processing techniques and image manipulation on work stations.

In addition to being in compliance with the interpreting physician qualifications stated above, the ***supervising physician*** also has the following responsibilities:

- Develop, implement and enforce policies and procedures related to radiation protection, the hazards of radiation exposure to both patients and radiological personnel, and appropriate monitoring requirements.
- Develop, implement and enforce policies and procedures to address safety issues, including contrast use and sedation, and reduce exposure as much as reasonably possible for pediatric patients.
- Ensure that a physician is present and immediately available when contrast is administered to patients.
- Develop, implement and enforce policies and procedures to identify pregnant or potentially pregnant patients.
- Develop, implement and enforce policies and procedures consistent with ACR's Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Concerns.
- Be responsible for assuring compliance with the recommendations of the medical physicist.
- Be responsible for the oversight and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the CT Accreditation Program.
- Be responsible for notifying the ACR within 15 days of any changes in imaging equipment (units) or changes in the use of equipment that could affect clinical or phantom images (i.e., in CT an adults-only approved scanner being used to scan pediatric patients).
- Ensure that all accreditation criteria are met and that the same standard of performance is maintained during the 3-year accreditation period.
- Provide immediate written notice to the ACR upon the termination of any accredited services provided by the Practice Site or a change in ownership of the operating location.
- Ensure that all physicians providing services at this facility are actively participating in a formal peer review program that meets the stated accreditation requirements.

[8] See the ACR Practice Guideline for the Use of Intravascular Contrast Media.

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Radiologic Technologist

Qualifications	Radiological Technologist
Initial	• ARRT registered (RT) and radiography (R) and/or computed tomography (CT) certified and/or unrestricted state license[9], and • Documented training and experience in CT, and • Documented training and experience in operating CT equipment and radiation physics and protection. • Passing the advanced examination for CT certification is recommended.
Continuing Education	• Registered technologists – In compliance with the CE requirements of their certifying organization for the imaging modality in which they perform services – CE includes credits pertinent to the technologist's ACR accredited clinical practice • State licensed technologists – 24 hours of CE every 2 years – CE is relevant to imaging and the radiologic sciences, patient care – CE includes credits pertinent to the technologist's ACR accredited clinical practice • All others – 24 hours of CE every 2 years – CE is relevant to imaging and the radiologic sciences, patient care – CE includes credits pertinent to the technologist's ACR accredited clinical practice

Medical Physicist

The qualified medical physicist:

- Must be familiar with the principles of imaging physics and of radiation protection; the guidelines of the National Council on Radiation Protection and Measurements; laws and regulations pertaining to the performance of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments used for performance testing.
- The qualified medical physicist should be available for consultation regarding patient dosimetry issues within a reasonable period of time.

The qualified medical physicist is responsible for the conduct of all surveys of the CT equipment. The medical physicist may be ***assisted*** by properly trained individuals in obtaining data. These individuals must be approved by the medical physicist in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The medical physicist ***must be present*** during the surveys; review, interpret, and approve all data; and provide a report of the conclusions ***with his/her signature***. Effective ***January 1, 2010***, all medical physicists providing these services ***must*** meet the following minimum criteria:

[9] Except where prohibited by state law or regulation, for initial accreditation and accreditation renewal, registered nuclear medicine technologists who have had appropriate training in CT with documentation as defined by the supervising physician at the site will be considered to be qualified to perform PET/CT exams. However, they are not considered qualified to perform stand-alone diagnostic CT. Registered CT technologists who have appropriate training (see http://www.nmtcb.org/specialty/petExam.php) in nuclear medicine are also considered qualified to do PET/CT. However, they are not considered qualified to perform stand-alone PET or other nuclear medicine studies. At the time of any site survey by the ACR, the site must provide documentation of training and experience.

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Qualifications	Medical Physicist
Initial	**<u>Board Certified</u>** Certified in Diagnostic Radiological Physics or Radiological Physics by the American Board of Radiology; in Diagnostic Imaging Physics by the American Board of Medical Physics; or in Diagnostic Radiology Physics by the Canadian College of Physicists in Medicine **OR** **<u>Not Board Certified in Required Subspecialty</u>** • Graduate degree in medical physics, radiologic physics, physics, or other relevant physical science or engineering discipline from an accredited institution, ***and*** • Formal coursework in the biological sciences with at least – 1 course in biology or radiation biology, and – 1 course in anatomy, physiology, or similar topics related to the practice of medical physics • 3 years of documented experience in a clinical CT environment **OR** **<u>Grandfathered</u>** Conducted surveys of at least 3 CT units between January 1, 2007 and January 1, 2010
Continuing Experience	Upon renewal, 2 CT unit surveys in prior 24 months
Continuing Education	Upon renewal, 15 CEU/CME (1/2 Cat 1) in prior 36 months (must include credits pertinent to the accredited modality)

Equipment

CT equipment specifications and performance shall meet state and federal requirements and applicable ACR Practice Guidelines and Technical Standards.

Quality Control

A quality control (QC) program must be established and implemented under the supervision of a qualified medical physicist. Initial performance testing (acceptance testing) is required upon installation. Effective one year from the publication of the *2012 ACR CT Quality Control* Manual (12/01/2012), all facilities applying for accreditation must maintain a documented quality control (QC) program and must comply with the minimum frequencies of testing outlined in the manual.

Annual Medical Physicist Survey

All facilities applying for accreditation or renewal must demonstrate compliance with ACR QC requirements by including a copy of the facility's most recent Annual CT System Performance Evaluation with their accreditation testing materials. The medical physicist must evaluate the performance of each CT unit at least annually. ACR realizes that surveys cannot usually be scheduled exactly on the anniversary date of the previous survey. Therefore, a period of up to 14 months between surveys is acceptable. Effective December 2013 this evaluation should include, but not be limited to, the following:

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- Review of Clinical Protocols
- Scout Prescription and Alignment Light Accuracy
- Image Thickness
- Table Travel Accuracy
- Radiation Beam Width
- Low-Contrast Performance
- Spatial Resolution
- CT Number Accuracy
- Artifact Evaluation
- CT Number Uniformity
- Dosimetry
- Gray Level Performance of CT Acquisition Display

Monitors

- Other tests as required by state or local regulations

Continuous Quality Control

A continuous quality control (QC) program must be established for all CT units with the assistance of a qualified medical physicist. An on-site radiological technologist should be identified to be responsible for conducting routine quality control.

The continuous QC program should include, but not be limited to, the following:

- Water CT Number & Standard Deviation- Daily
- Artifact Evaluation- Daily
- Wet Laser Printer Quality Control- Weekly
- Visual Checklist- Monthly
- Dry Laser Printer Quality Control- Monthly
- Display Monitor Quality Control- Monthly

All quality control testing must be carried out in accordance with written procedures and methods. Preventive maintenance must be scheduled, performed, and documented by a qualified service engineer on a regular basis. The results of the QC program must be monitored annually by the qualified medical physicist. If the results of a QC test fall outside the control limits, corrective action should be taken. A qualified medical physicist should be available to assist in prescribing corrective actions for unresolved problems. All deficiencies must be documented and service records maintained by the CT facility.

Quality Assurance

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control and Patient Education Concerns. The site will have a quality assurance program that incorporates the following two elements:

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Physician Peer-Review Requirements

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed and reported as required, and periodically reviewed in order to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.[10]

All sites initially applying for ACR accreditation and all sites renewing their accreditation must actively participate in a physician peer review program that performs the following functions:

- Includes a double reading (2 MDs interpreting the same study) assessment.
- Allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the actual clinical practice of each physician.
- Reviewer assessment of the agreement of the original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (One example is a 4-point scoring scale).
- Policies and procedures for action to be taken on significant discrepant peer review findings for the purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by imaging modality.
- Summary data for each facility/practice by modality.

There are several options available to meet this requirement. Sites may develop their own peer review program, use a vendor product or RADPEER, a peer review process developed by the ACR.

For information about RADPEER or eRADPEER please visit the ACR web site at: http://www.acr.org/Quality-Safety/RADPEER.

Appropriateness/Outcome Analysis

The results of an appropriateness/outcomes analysis and the actions taken to correct any deficiencies should be maintained as quality assurance records at the facility. Policy and procedures must be in place to look at the diagnostic accuracy, and complication rate and outcome of CT-guided interventional procedures. Documentation may be requested as part of an on-site survey.

[10] 2005 ACR Guidelines and Technical Standards. ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns. Page IV.

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Accreditation Testing

Clinical Images

The clinical examinations will be of the head/neck, chest, cardiac and abdomen regions. Three to four examinations and your ***facility's protocol*** for that examination must be submitted from each unit. The exact number of examinations depends on the number of modules for which the unit is used. If the unit is a specialty unit, and does not perform examinations from all four modules, at least three exams are still required from that unit.

The facility may choose which examinations it will submit for accreditation (see selection list below). At least one of the examinations chosen for each unit must be a specialized examination. For units applying for cardiac, at least one CTA examination must be submitted, unless the unit is only used for patients 15 years of age and under, in which case the pediatric cardiac examination is required for the cardiac module. ***Asterisks denote the specialty examinations.*** If the unit is also used for pediatric patients, at least one of the examinations must also be from a child between the ages of 0 and 15. ***Pediatric images should clearly reflect that the site has taken into account the child's age and body habitus in selecting the scanning parameters and contrast dosage. Please refer to the "FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients." All of the FDA health notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html.***

Facilities may not submit images performed on models or volunteers. All clinical images **must** be from actual patients. **Use of volunteers or models may result in withholding, denial or revocation of accreditation.** Patient films will be returned with the final report. ***The reviewers assume that the images submitted are examples of your best work. All images must demonstrate adequate positioning, film contrast and exposure level, resolution, noise, patient and facility identification, and lack of artifacts.***

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Pediatric Examination Choices			
Head/Neck	**Chest**	**Abdomen**	**Cardiac**
• Pediatric head CT (such as for headaches, seizures, or suspected mass) • Pediatric sinus for infection • Pediatric cervical spine* • Pediatric temporal bones*	• Pediatric chest (such as for detection of metastatic disease, trauma, infection, or cough) • Pediatric high-resolution CT of chest (HRCT) for evaluation of diffuse lung disease*	• Pediatric abdomen (such as for blunt trauma, acute abdominal pain, or infection) • Pediatric CT for adrenal/renal mass*	• Pediatric Cardiac such as for Congenital Disease

Adult Examination Choices			
Head/Neck	**Chest**	**Abdomen**	**Cardiac**
• Head (such as for headaches and to exclude neoplasm) • Temporal bones* • Cervical spine for known or suspected fracture*	• Chest (such as for evaluation of known or suspected lung cancer or cough) • Suspected pulmonary embolus* • High-resolution CT of chest (HRCT) for evaluation of diffuse lung disease* • Assessment of possible aortic dissection*	• Abdomen (such as for detection of possible liver metastases or lymphoma) • Known cirrhosis (R/O hepatoma)* • Evaluation of ***known*** renal mass (including ROI measurements)* • Evaluation of a patient with suspected pancreatic carcinoma*	• Calcium Scoring (No more than one exam) • CTA (Required)* • Pulmonary Vein Mapping • Cardiac Function and Morphology, such as, for tumor, congenital heart disease, aortic valve or cardiomyopathy

See the table below for the number of examinations required based on the number of modules your site selected on the application:

Number of modules on application	**Number of examinations per module**	**Total exams per unit**
One module	Three examinations are required, at least one of which must be a specialty examination. If adult and pediatric, at least one of the examinations must be a pediatric examination.	Three
Two modules	Select one specialty examination from either module and one routine examination from each module. If adult and pediatric, at least one of the examinations must be a pediatric examination.	Three
Three modules	Select one specialty examination from *one* module, *and* select one examination from *each* of the other two modules. If adult and pediatric, at least one of the examinations must be a pediatric examination.	Three
Four modules	The CTA examination from the cardiac module is required in addition to, one examination from each of the other three modules. If adult and pediatric, at least one of the examinations must be a pediatric examination.	Four

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Exam Identification and Labeling

Required Identification Labeling for Each Adult or Pediatric CT Image	
Identifying Demographic Data	**Scan and Display Parameters**
• Patient's first and last name • Medical record number • Institution name • Date and time of examination • Date of birth or age of patient • Gender of patient	• Anatomic orientation label • mA/kV • Table speed (pitch) • Scan time • Series number (if applicable) or image number • Size scale • Slice thickness • Table position • Window width/level

Recommended Identification and Labeling for CT	
On each image	**On at least one image of the exam**
• Contrast use • Field of view • Reconstruction algorithm	• Technologist's identification number, name, or initials

Clinical Protocols

The typical scanning protocols for the submitted images will be required for accreditation; the submitted clinical images should reflect use of those protocols. The facility should submit its protocols in the format that it normally uses on site, but they need to be readily understandable by a reviewer charged with correlating those protocols with the submitted images.

A typical protocol should include at least the following elements:

- Indication
- Scanner settings
- Phase of respiration
- Slice thickness
- Table speed (pitch)
- Reconstruction algorithm
- Reconstruction interval
- Cranio-caudal extent
- IV contrast (with injection rate and scan delay)
- Necessity for preliminary non-contrast scans.

There are many published sources of information on scanning protocols and procedures in ACR documents and in radiological journals and textbooks.

Phantom Testing: Image Quality and Dose

A single ACR phantom (Gammex 464) must be used for all units accredited at a facility. When the testing materials are sent, the applicant will receive instructions on how to order the phantom directly from the manufacturer.

Specific performance criteria evaluated using the phantom include:

- CT number accuracy
- Low-contrast resolution
- Image uniformity

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A complete set of phantom images, along with dose measurements, from every CT unit at the facility must be submitted.

For accreditation purposes, it is necessary for your medical physicist to perform CTDI testing on every CT unit at your facility. Using these CTDI measurements, your physicist will be able to calculate various descriptors of dose for your adult head, pediatric head (1 year old), pediatric abdomen (5 year old, ~40 lbs.), and adult abdomen examinations (depending on the modules and patient types performed on that unit). These calculations will use the average technique factors provided by your facility. You can access the appropriate calculation spreadsheet at http://www.acr.org/Quality-Safety/Accreditation/CT.

In order to be accredited with the ACR, a CT unit must pass both the clinical and phantom image quality tests. The phantom will fail (and, the unit will fail ACR accreditation) if the dose from the CT unit exceeds the pass/fail criteria. The facility must repeat the entire phantom portion of the accreditation testing, *and pass*, for the unit to be granted accreditation.

The ACR has also updated the dose reference levels for the phantom submission. Reference levels help identify situations where doses are above expected values and should be investigated. Units exceeding these reference levels (but remaining below the pass/fail criteria) will ***not*** fail accreditation. However, even if the unit is granted accreditation, the ACR strongly urges the facility to consult with its medical physicist to determine if it is possible to reduce the examination dose without sacrificing image quality. Corrective action for exceeding dose reference values will be checked by a survey team if your facility is chosen for a validation on site survey.

These new pass/fail criteria and reference levels are based on a detailed analysis of the dose data and image quality collected during the first three years of the accreditation program. The new requirements and recommendations consider the amount of radiation necessary for adequate image quality. Because multislice CT units are more prevalent since the accreditation program started, the new dose criteria and levels also incorporate a more appropriate dose descriptor ($CTDI_{vol}$). These changes are being made to help facilities reduce unnecessary radiation dose to patients undergoing CT examinations while still maintaining sufficient radiation levels necessary for appropriate diagnoses.

Note: The pediatric head and abdomen dose reference values and pass/fail criteria have been adjusted and are effective July 1, 2013.

ACR CT Accreditation Dose Pass/Fail Criteria and Reference Levels

Examination	Pass/Fail Criteria $CTDI_{vol}$ (mGy)	Reference Levels $CTDI_{vol}$ (mGy)
Adult Head	80	75
Adult Abdomen	30	25
Pediatric Head	40	35
Pediatric Abdomen (40 lb.)	20	15

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Accreditation Fees

Checks should be made payable to the American College of Radiology (include modality accreditation ID#, if available). American Express, MasterCard, and Visa are accepted. The charge for the phantom is paid directly to the manufacturer.

Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$2400 for first unit up to three modules $2500 for first unit for all four modules $2300 each additional unit at one site location up to three modules $2400 for each additional unit for all four modules
Repeat	$800 per scanner for clinical or phantom images $1600 per scanner if repeating both
Reinstate/Corrective Action Plan	$2400 per unit up to three modules $2500 per unit for all four modules
Add Units (mid cycle) **Add Module/Patient Type**	$1600 each unit $1600 each unit
Replacement Certificate	$50 per certificate.
Phantom	$3315 for phantom. $321 for carrying case and stand (optional).

Note: Fees subject to change without notice.

For Additional Information

For further information log on to the ACR Web site at www.acr.org, click on "Accreditation" and click on "Computed Tomography". A link to "Frequently Asked Questions" is available in the CT menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR CT Accreditation Program office by phone, dial (800) 770-0145.

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ACR Practice Guidelines and Technical Standards

The following ACR Practice Guidelines and Technical Standards are pertinent to achieving and maintaining CT Accreditation. These guidelines and standards form the basis of the accreditation program.

ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation

ACR Practice Guideline for the Use of Intravascular Contrast Media

ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT)

ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Brain

ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Extracranial Head and Neck in Adults and Children

ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Spine

Practice Guideline for the Performance of High-Resolution Computed Tomography (HRCT) of the Lungs in Adults

ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Abdomen and Computed Tomography (CT) of the Pelvis

ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment

ACR Practice Guideline for Communication of Diagnostic Imaging Findings

ACR Practice Guideline for the Performance and Interpretation of Cardiac Computed Tomography (CT)

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BILL NUMBER: SB 1237 CHAPTERED
BILL TEXT

CHAPTER 521
FILED WITH SECRETARY OF STATE SEPTEMBER 29, 2010
APPROVED BY GOVERNOR SEPTEMBER 29, 2010
PASSED THE SENATE AUGUST 30, 2010
PASSED THE ASSEMBLY AUGUST 26, 2010
AMENDED IN ASSEMBLY AUGUST 20, 2010
AMENDED IN ASSEMBLY JUNE 23, 2010
AMENDED IN SENATE APRIL 28, 2010

INTRODUCED BY Senator Padilla
(Coauthor: Senator Alquist)

FEBRUARY 19, 2010

An act to add Sections 115111, 115112, and 115113 to the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, Padilla. Radiation control: health facilities and clinics: records.

Under existing law, the State Department of Public Health licenses and regulates health facilities and clinics, as defined.

Under existing law, the Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law the department may also require registration and inspection of sources of ionizing radiation, as defined. Violation of these provisions is a crime.

This bill would, commencing July 1, 2012, require hospitals and clinics, as specified, that use computed tomography (CT) X-ray systems for human use to record, if the CT systems are capable, the dose of radiation on every CT study produced during the administration of a CT examination, as specified. The bill would require the dose to be verified annually by a medical physicist, as specified, unless the facility is accredited.

This bill would, commencing July 1, 2013, require facilities that furnish CT X-ray services to be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health. The bill would also require the facility to report certain information to the department, the affected patient, and the patient's treating physician.

Because this bill expands the definition of a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 115111 is added to the Health and Safety Code, to read:

115111. (a) Commencing July 1, 2012, subject to subdivision (e), a person that uses a computed tomography (CT) X-ray system for human use shall record the dose of radiation on every CT study produced during a CT examination.

(b) The facility conducting the study shall electronically send each CT study and protocol page that lists the technical factors and dose of radiation to the electronic picture archiving and communications system.

(c) The displayed dose shall be verified annually by a medical physicist to ensure the displayed doses are within 20 percent of the true measured dose measured in accordance with subdivision (f) unless the facility is accredited.

(d) Subject to subdivision (e), the radiology report of a CT study shall include the dose of radiation by either recording the dose within the patient's radiology report or attaching the protocol page that includes the dose of radiation to the radiology report.

(e) The requirements of this section shall be limited to CT systems capable of calculating and displaying the dose.

(f) For the purposes of this section, dose of radiation shall be defined as one of the following:

(1) The computed tomography index volume (CTDI vol) and dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).

(2) The dose unit as recommended by the American Association of Physicists in Medicine.

SEC. 2. Section 115112 is added to the Health and Safety Code, to read:

115112. Commencing July 1, 2013, facilities that furnish CT X-ray services shall be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health.

SEC. 3. Section 115113 is added to the Health and Safety Code, to read:

115113. (a) Except for an event that results from patient movement or interference, a facility shall report to the department an event in which the administration of radiation results in and of the following:

(1) Repeating of a CT examination, unless otherwise ordered by a physician or a radiologist, if the following dose values are exceeded:

(A) 0.05Sv (5 rem) effective dose equivalent.

(B) 0.5 Sv (50 rem) to an organ or tissue.

(C) 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(2) CT X-ray irradiation of a body part other than that intended by the ordering physician or a radiologist if one of the following dose values are exceeded:

(A) 0.05 Sv (5 rem) effective dose equivalent.

(B) 0.5 Sv (50 rem) to an organ or tissue.

(C) 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(3) CT or therapeutic exposure that results in unanticipated permanent functional damage to an organ or a physiological system,

hair loss, or erythema, as determined by a qualified physician.

(4) A CT or therapeutic dose to an embryo or fetus that is greater than 50 mSv (5 rem) dose equivalent, that is a result of radiation to a known pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by a qualified physician.

(5) Therapeutic ionizing irradiation of the wrong individual, or wrong treatment site.

(6) The total dose from therapeutic ionizing radiation delivered differs from the prescribed dose by 20 percent or more. A report shall not be required pursuant to this paragraph in any instance where the dose administered exceeds 20 percent of the amount prescribed in a situation where the radiation was utilized for palliative care for the specific patient. The radiation oncologist shall notify the referring physician that the dose was exceeded.

(b) The facility shall, no later than five business days after discovery of an event described in subdivision (a), provide notification of the event to the department and the referring physician of the person subject to the event and shall, no later than 15 business days after discovery of an event described in subdivision (a) provide written notification to the person who is subject to the event.

(c) The information required pursuant to this section shall include, but not be limited to, information regarding each substantiated adverse event, as defined in Section 1279.1, reported to the department, and may include compliance information history.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

INTERSOCIETAL ACCREDITATION COMMISSION

CT | ICACTL

The IAC Standards and Guidelines for CT Accreditation

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Introduction

The Intersocietal Accreditation Commission (IAC) accredits imaging facilities specific to Computed Tomography (CT). IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

A CT facility (i.e., imaging center, physician office, hospital) is a unit under the overall direction of a Medical Director with a Technical Director who is appointed and responsible for direct supervision of the technical staff members and the daily operations of the facility.

The intent of the accreditation process is two-fold. It is designed to recognize facilities that provide quality CT services. It is also designed to be used as an educational tool to improve the overall quality of the facility.

The following are the specific areas of CT for which accreditation may be obtained:

- coronary calcium scoring CT
- coronary CTA
- neurological CT [brain, spine, CTA]
- sinus and temporal bone CT
- body CT [chest (non-coronary), abdomen, pelvis, extremity]
- vascular/other CTA [chest (non-coronary), abdomen, pelvis, peripheral/extremity]

In addition to all standards listed below, the facility, including all staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

These accreditation Standards and Guidelines are the minimum standards for accreditation of CT facilities. Standards are the minimum requirements to which an accredited facility is held accountable. *Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.*

Standards are printed in regular typeface in outline form. *Guidelines are printed in italic typeface in narrative form.*

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician and certified by the American Board of Medical Specialties (ABMS), in a relevant specialty, or board certified in a relevant specialty recognized by the American Osteopathic Association, Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec.

1.1.1A Medical Director Required Training and Experience

The Medical Director must demonstrate an appropriate level of training and experience by meeting one or more of the following:

1.1.1.1A Cardiac CT

Completion of Level 2 or equivalent training meeting ACCF/AHA/ACP guidelines (*See Appendix*) for cardiovascular CT with SCCT letter of verification or a letter of verification from the program director and independent interpretation of at least 50 CT examinations.

OR

Diplomat of the Certification Board of Cardiovascular Computed Tomography (CBCCT) or Certificate of Advanced Proficiency in Cardiac CT offered through the American College of Radiology (ACR).

OR

1.1.1.2A Non-cardiac CT – Interpretation of at least 150 studies (with at least 50 where the candidate is physically present and involved in the acquisition and interpretation of the case) and attendance in at least 20 hours of CT classes relevant to the specialty with a letter of verification from the program director and independent interpretation of at least 50 CT examinations.

OR

1.1.1.3A Established Practice – A physician, who has been interpreting CT studies for at least five years, has acquired a minimum of 150 hours Category I Continuing Medical Education (CME) (obtained over the course of their professional experience) and has interpreted a minimum of 500 CT examinations relative to the organ system(s) with self attestation.

AND for all training and experience pathways listed above 40 hours of CT relevant CME. A minimum of three hours of documented continuing education must be in radiation safety.

(*See Guidelines on Page 11 for further recommendations.*)

1.1.2A Medical Director Responsibilities

The Medical Director responsibilities include but are not limited to:

1.1.2.1A all clinical services provided and for the determination of the quality and appropriateness of care provided;

1.1.2.2A supervising the entire operation of the facility or delegate specific operations to associate Medical Directors, medical staff and the Technical Director;

1.1.2.3A arranging for qualified providers in the absence of medical staff for contrast administration, drug administration and patient and staff safety;

1.1.2.4A assuring compliance of the medical and technical staff to the standards outlined in this document and the supervision of their work;

1.1.2.5A must be an active participant in the interpretation of exams performed in the facility; Comment: If not generating final reports, the Medical Director must provide documentation of review and acceptance, or amendment of findings.

1.1.2.6A the Medical Director, in consultation with the medical physicist and/or qualified expert, may delegate the operation of the CT scanner to a qualified physician as outlined in 1.2.1.3A based on potential dose to the patient and technical complexity of the CT system as long as the state permits physicians to operate x-ray producing equipment.

1.1.3A Continuing Medical Education (CME) Requirements

1.1.3.1A The Medical Director must document at least 15 hours of Category I American Medical Association (AMA) or Physician Recognized Award (PRA) CME credits in CT over a period of three years.

i. A minimum of three hours of the documented 15 hours of CME must be related to radiation safety.
ii. Yearly accumulated continuing education must be kept on file and available to the IAC, when requested.

Comment: If the Medical Director has completed training or certification, as specified under 1.1.1A in the past three years, the CME requirement will be considered fulfilled.

STANDARD – Technical Director

1.2A The Technical Director (i.e., supervisor, chief technologist, manager, etc.) designated to the facility must be a qualified CT technologist or a physician as described in 1.2.1.3A. The Technical Director must have appropriate training, technical certification as noted and documented experience in the field of computed CT imaging.

Comment: In a facility with no technologists, the Medical Director or a member of the medical staff may serve as Technical Director. In this case, the Medical Director or Medical staff must meet the requirements of the Technical Director and submit appropriate documentation of radiation safety and scanner training.

1.2.1A Technical Director Required Training and Experience

The Technical Director must meet one of the following criteria:

1.2.1.1A American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) certification in computed tomography imaging (i.e., RT (CT)).

OR

1.2.1.2A An appropriate nationally recognized credential in another medical imaging field to include radiation safety training (i.e., CNMT, RT (MR), RT).

AND

One year of full-time equivalent experience as a CT technologist and performance of a minimum of 100 CT examinations.

OR

1.2.1.3A A qualified licensed physician may operate a volume or cone beam CT scanner (for sinus and temporal bone imaging only) if that person has received a minimum of at least three hours of documented, specific training in radiation safety provided by a medical physicist or qualified expert and received a 100% score on a written examination administered by the provider of the radiation safety training program.

AND

Received a minimum of at least four hours of documented, specific training in the operation of the scanner.

1.2.2A Technical Director Responsibilities

1.2.2.1A The Technical Director reports directly to the Medical Director or his/her delegate. Responsibilities include, but are not limited to:

i. all facility duties delegated by the Medical Director;
ii. performance of CT examinations in the facility;
iii. supervision of the technical staff and/or ancillary staff (if applicable);
iv. the delegation, when warranted, of specific responsibilities to the technical staff and/or the ancillary staff;
v. daily technical operation of the facility (i.e., facility record keeping, calibration log, quality assurance, scanning protocols, etc.);
vi. operation and maintenance of facility equipment;
vii. the compliance of the technical staff to the IAC CT Standards outlined within this document;
viii. working with the Medical Director, medical staff and technical staff to ensure quality patient care;
ix. technical training (if applicable); and
x. monitoring radiation exposure for both patients and staff.

1.2.3A Continuing Education (CE) Requirements

1.2.3.1A The Technical Director must document at least 15 hours of Category I AMA or Recognized Continuing Education Evaluation Mechanism (RCEEM) approved CT-related CE over a period of three years.

i. A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.

ii. Yearly accumulated CE must be kept on file and available to IAC, when requested.

Comment: If the Technical Director has successfully acquired an appropriate CT credential within the past three years, the continuing education requirement will be considered fulfilled.

STANDARD – Medical Staff

1.3A All members of the medical staff must be licensed physicians and American Board of Medical Specialties (ABMS) board certified in a relevant specialty or board certified in a relevant specialty recognized by the American Osteopathic Association, Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec.

1.3.1A Medical Staff Required Training and Experience

The medical staff must meet one of the following criteria:

1.3.1.1A Cardiac CT

Completion of Level 2 or equivalent training meeting ACCF/AHA/ACP guidelines for cardiovascular CT (which includes attendance in at least 20 hours of CT classes relevant to the specialty, a portion of which are in radiation safety) with SCCT letter of verification or a letter of verification from the program director. *(See Appendix)*

OR

Diplomat of the Certification Board of Cardiovascular Computed Tomography (CBCCT) or Certificate of Advanced Proficiency in Cardiac CT offered through the American College of Radiology (ACR).

OR

1.3.1.2A Non-cardiac CT – Interpretation of at least 150 studies (with at least 50 where the candidate is physically present and involved in the acquisition and interpretation of the case) and attendance in at least 20 hours of CT classes relevant to the specialty, a portion of which are in radiation safety, with a letter of verification from program director.

OR

1.3.1.3A Established Practice – A physician who has been interpreting CT studies for at least five years, has acquired a minimum of 150 hours Category I CME (obtained over the course of their professional experience) and has interpreted a minimum of 500 CT examinations relative to the organ system(s) with self attestation.

AND

40 hours of CT relevant CME. A minimum of three hours of documented continuing education must be in radiation safety.

(See Guidelines on Page 11 for further recommendations.)

1.3.2A Medical Staff Responsibilities

Medical staff responsibilities include but are not limited to:

1.3.2.1A The medical staff interprets and/or performs clinical CT examinations in compliance with the requirements established by the Medical Director. If not generating final reports, the medical staff member must provide documentation of review and acceptance or amendment of findings.

1.3.3A Continuing Medical Education (CME) Requirements

1.3.3.1A The medical staff must document at least 15 hours of Category I AMA or PRA CME credits in CT over a period of three years.

i. A minimum of three hours of the documented 15 hours of CME must be related to radiation safety.
ii. Yearly accumulated continuing education must be kept on file and available to the IAC CT, when requested.

Comment: If the medical staff has completed training or certification as specified 1.3.1.1A or 1.3.1.2A in the past three years, the CME requirement will be considered fulfilled.

STANDARD – Technical Staff

1.4A All members of the technical staff must be qualified imaging technologists or a qualified physician (as outlined) for cone beam CT performing sinus and temporal bone CT imaging only).

1.4.1A Technical Staff Required Training and Experience

All members of the technical staff must meet one or more of the following criteria:

1.4.1.1A American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) certification in CT imaging (i.e., RT (CT)).

OR

1.4.1.2A An appropriate nationally recognized credential in another medical imaging field (i.e., CNMT, RT (MR), RT).

OR

1.4.1.3A Completion of 12 months full-time (35 hours/week) clinical CT experience under direct supervision of a credentialed technologist plus ONE of the following:

i. Completion of a formal two-year program or equivalent in another medical imaging profession, with concentration in radiation physics.
ii. Completion of a bachelor's degree in another medical imaging specialty, with concentration in radiation physics.

OR

1.4.1.4A In a facility with no technologists, a qualified licensed physician may operate a volume or cone beam CT scanner (for sinus and temporal bone imaging only) if that person has received a minimum of at least three hours of documented, specific training in radiation safety provided by a medical physicist or qualified expert and received a 100% score on a written examination administered by the provider of the radiation safety training program.

AND

Received a minimum of at least four hours of documented, specific training in the operation of the scanner.

1.4.2A Technical Staff Responsibilities

Technical staff responsibilities include but are not limited to:

1.4.2.1A reports to the Technical Director; and

1.4.2.2A assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical CT examinations and other tasks assigned.

1.4.3A Continuing Education (CE) Requirements

1.4.3.1A The technical staff must document at least 15 hours of Category I AMA or RCEEM approved CT-related CE over a period of three years.

i. A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.
ii. Yearly accumulated continuing education must be kept on file and available to IAC CT, when requested.

Comment: If the technical staff member has successfully acquired an appropriate CT credential within the past three years the continuing education requirement will be considered fulfilled.

STANDARD – Medical Physicist or Qualified Expert

1.5A The medical physicist must be board certified by the American Board of Radiology, the American Board of Medical Physics, or the Canadian College of Medical Physics in a discipline that includes diagnostic imaging.

Comment: In states where medical physicists or qualified experts are licensed, registered or otherwise state-approved to measure dose and evaluate image quality at CT scanning facilities, these credentials are acceptable.

1.5.1A Responsibilities

1.5.1.1A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, are permitted to assist the medical physicist or qualified expert in data collection.

1.5.2A Continuing Education (CE) Requirements

1.5.2.1A The medical physicist must document at least 15 hours of Category I AMA, Commission on Accreditation of Medical Physicists Educational Programs (CAMPEP) or the American College of Radiology (ACR) Medical Education for Physicists (MEP) approved physics related CE over a period of three years.

i. A minimum of three hours of the documented 15 hours of CE must be related to radiation safety.
ii. Yearly accumulated continuing education must be kept on file and available to IAC CT, when requested.

STANDARD – Supervising Personnel for Contrast and/or Medication Administration

1.6A If the Medical Director or medical staff are not present during the CT examination, delegation of contrast and/or medication administration supervision and safety duties may be relegated to alternative licensed providers (i.e., RN, NP, or PA) that meet the following criteria:

1.6.1A Are knowledgeable of patient preparation, and training in the recognition/treatment of adverse effects of contrast materials for these studies.

1.6.2A Are responsible for supervising the use, dosage, and rate of administration of contrast agents, per the facility's protocol.

1.6.3A Possess familiarity with radiation safety, and the conscious sedation policies and procedures (if used) that are performed relative to CT.

1.6.4A Are responsible for supervising the administration of beta-blockers, nitrates, and/or other cardio active and/or other medications per the facility's protocol.

STANDARD – Support Services

1.7A Ancillary personnel (i.e., clerical, nursing, transport, etc.) necessary for safe and efficient patient care are provided.

1.7.1A Clerical and administrative support must be sufficient to ensure efficient operation and record keeping.

1.7.2A Nursing and ancillary services must be sufficient to ensure quality patient care and are available when necessary.

1.7.3A Supervision: The Medical Director must ensure that appropriate support services are provided in the best interest of patient care.

(See Guidelines on Page 11 for further recommendations.)

Section 1A: Personnel and Supervision
Guidelines

1.1.1A Medical Director required training and experience: The majority of the 40 required CME hours should be Category I.

1.3.1A Medical staff required training and experience: The majority of the 40 required CME hours should be Category I.

1.6A The use of a qualified medical physicist is encouraged for initial acceptance testing, to establish and monitor the quality control program and radiation safety policies and procedures.

Section 2A: Facility

STANDARD – Examination Areas

2.1A Examinations must be performed in a setting providing patient and technical staff safety, comfort and privacy.

2.1.1A The adequate performance of a CT examination requires the proper positioning of the patient. For this reason, adequate spacing is required for inclusion of a CT imaging system and patient privacy.

2.1.1.1A Patient privacy must be assured with the use of appropriate curtains or doors.

2.1.1.2A A sink and antiseptic soap must be readily available and used for hand washing in accordance with the infection control policy of the facility.

2.1.1.3A Direct visualization and audible monitoring of the patient must be available through a leaded glass window, while protecting the personnel from radiation exposure.

2.1.1.4A Post testing area must be available for patient observation, as indicated clinically.

STANDARD – Interpretation Areas

2.2A Adequate designated space must be provided for the interpretation of the CT examination and the preparation of reports.

(See Guidelines on Page 12 for further recommendations.)

STANDARD – Storage Space

2.3A Space permitted for storage of records and supplies must be sufficient for the patient volume of the facility.

Section 2A: Facility
Guidelines

2.2A Space should be provided for data evaluation, interpretation, and discussion of the study with the technologist and/or referring physician.

Section 3A: Examination Reports and Records

STANDARD – Records

3.1A Provisions must exist for the generation and retention of examination data for all CT examinations performed.

3.1.1A A system for recording and archiving CT data (images, measurements and final reports) obtained for diagnostic purposes must be in place.

3.1.2A A permanent record of the images and interpretation must be made and retained in accordance with applicable state or federal guidelines for medical records. Critical reconstructed CT data should be readily retrievable for comparison with new examinations. A complete series of digital axial images, reconstructed in at least one phase for gated studies, must be permanently stored in a format that will allow future multi-planar reformatting.

3.1.3A Archiving media must include loss-less digital storage and a system for long-term, offline digital storage.

STANDARD – Examination Interpretation and Reports

3.2A Provisions must exist for the timely reporting of examination data.

3.2.1A All CT examinations must be reviewed promptly after the study is completed, as appropriate for the risk of clinically significant results at least within one working day. Results of examinations with critical findings must be communicated to the referring physician as quickly as clinically indicated.

3.2.2A A mechanism for communicating any significant changes must be defined for those situations in which the final interpretation differs significantly from the preliminary report.

3.2.3A CT examinations must be interpreted and reported by the Medical Director or by a member of the medical staff of the CT facility. Final physician interpretations of routine CT examinations must be available within two working days. An interpretation can be in the form of paper, digital storage or an accessible voice system.

3.2.4A The final verified, signed report must be available in a timely fashion, generally within four working days.

(See Guidelines on Page 14 for further recommendations.)

3.3A CT examination reporting must be standardized in the facility. All physicians interpreting CT examinations in the facility must agree on a standardized report format.

3.3.1A The final report must accurately reflect the content and results of the study. The report must include, but is not limited to:

3.3.1.1A date of the examination;

3.3.1.2A clinical indications leading to the performance of the examination; and

3.3.1.3A an adequate description of the test performed including the:

i. patient date of birth or age;
ii. patient ID or name;

iii. name of the examination;
iv. protocol used in the examination;
v. quality of the study;
vi. details of drug and/or medication administration (include the name, dose administered and route); and
vii. administration of contrast, if used (include the name, type, and amount of IV contrast administered).

(See Guidelines on Page 14 for further recommendations.)

3.3.1.4A an overview of the results of the examination including pertinent findings;

Comment: This must include localization and quantification of abnormal findings (where appropriate).

3.3.1.5A appropriate recommendation for follow up of incidental findings;

3.3.1.6A the reasons for limited examinations (if performed);

3.3.1.7A a summary of the test findings;

3.3.1.8A comparison with previous studies (if available);

3.3.1.9A reports must be typewritten;

3.3.1.10A physician signature line (the printed name of the interpreting physician);

3.3.1.11A manual and/or electronic interpreting physician signature; and

3.3.1.12A date of interpreting physician signature and/or verification.

(See Guidelines on Page 14 for further recommendations.)

Section 3A: Examination Reports and Records
Guidelines

3.2.1A A record of the communication should be maintained.

3.2.2A If preliminary results are provided by an interpreting physician, the final report should be generated within two working days.

3.3.1A Documentation of dose reduction technique if used (e.g., prospective gating, low energy and/or dose modulation) is recommended in the report.

3.3.1.3A Details of any non-standard patient preparation or treatment, if required, should be included in the final report.

Section 4A: Facility Safety

STANDARD – Patient and Facility Safety

4.1A Written policies and procedures must exist to ensure patient and personnel safety. Safety policies must be enforced, reviewed and documented annually by the Quality Improvement (QI) Committee or the Medical Director.

Comment: If a facility performs CT imaging for patients presenting with acute stroke symptoms, refer to the Acute Stroke Appendix for details.

(See Guidelines on Page 17 for further recommendations.)

4.1.1A Patient Identification Policy – For all clinical procedures there must be a process that assures accurate patient identification prior to initiating the procedure. Two independent patient-specific identifiers must be used.

(See Guidelines on Page 17 for further recommendations.)

4.1.2A There must be at least one BLS certified staff member on site for all CT exams.

4.1.3A Standard CT examinations must be safe to both patients and technologists. The facility must have a written procedure in place for handling acute medical emergencies.

4.1.4A Radiation Safety

4.1.4.1A All CT facility professionals must have an understanding of the radiation exposure involved in CT to advise patients undergoing CT imaging.

4.1.4.2A A separate, radiation shielded control room or area must be used by staff during acquisitions. No staff should routinely enter the CT room or area when the x-ray tube is active.

4.1.4.3A Staff radiation exposure must be monitored, and reviewed by the Quality Improvement (QI) Committee. The results must be communicated to the staff member. The facility must comply with the currently published ALARA recommendations for personnel.

4.1.4.4A There must be restriction of the public to radiation areas.

4.1.4.5A Separate pediatric protocols must be established based on patient age or weight. Pediatric protocols must be modified to reduce radiation exposure where appropriate or possible. The use of higher than recommended radiation doses must be justified.

4.1.4.6A Use of appropriate radiation dose reduction devices OR techniques for appropriate moderation of exposure must be documented or their lack of use justified when applicable. Dose reduction techniques include but are not limited to prospective gating, tube modulation (kVp and/or mAs), manufacturer dose reduction protocol and/or dose modulation.

i. The facility must subscribe to dose optimization to patients.
ii. Radiation dose for CT acquisition must be set at the lowest values that are consistent with satisfactory image quality for the study ordered.
iii. Modifications to the manufacturer's default protocols that increase patient dose above the site appointed physicist recommendation must be reviewed by a medical physicist prior to implementation of the proposed change(s) in order to assess impact on radiation dose and image quality.

iv. If the physicist deems that the proposed change(s) is appropriate, the facility must maintain documentation of the protocol change(s) that includes the rationale for the change, including the details of the change (exactly what changes were made to the technical parameters for the scans), and the physicist review of impact on dose and image quality.

4.1.5A Incident Report/Adverse Events Policy – A policy for documentation of adverse events (i.e., contrast reactions, patient falls, emergencies) must be in place.

4.1.6A Patient Pregnancy Screening Policy – For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and contain the signature/initials of the patient and/or technologist verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant.

4.1.6.1A If a diagnostic CT examination is needed for a patient who is pregnant, knowledgeable staff (i.e., Medical Director or other designee) must discuss the potential risk to the fetus and document the general content of the discussion.

4.1.6.2A If determined that the study will not be performed, then the patient must receive options for alternative care.

4.1.7A Patient Pre-test Preparation Policy – There must be a policy in place for determining and administering any necessary pre-test preparations including:

4.1.7.1A education/instructions such as dietary or medication restrictions, examination specific preparation or other relevant information;

4.1.7.2A sufficient time must be allowed for adequate patient preparation; and

4.1.7.3A any other types of necessary pre-test preparation must be assessed prior to the start of the examination.

4.1.8A Contrast/Medication Administration and Supervision Policy

4.1.8.1A A CT facility providing CT procedures that require the administration of contrast, drug administration and/or exams requiring sedation, must have the following emergency supplies readily available:

i. posting of emergency phone number(s);
ii. an Automated External Defibrillator (AED) or a fully-equipped cardiac arrest cart (crash cart);
iii. equipment for starting and maintaining intravenous access;
iv. oxygen tank or wall-mounted oxygen sources with appropriate cannulae and/or masks; and
v. personnel trained and available to use the above emergency equipment.

4.1.8.2A The policy must address the steps taken to identify patients with documented or possible sensitivity to contrast and/or at increased risk for renal toxicity.

4.1.8.3A The policy must address medication and contrast administration procedures and the oversight of the contrast/medication administration and must include, but is not limited to:

i. IV access including location of insertion site and size of catheter;
ii. medications, including contrast, used in the procedure (i.e., beta blockers, conscious sedation);
iii. dosage, timing, route of administration;

iv. patient instruction;
v. patient monitoring;
vi. any precautions or restrictions needed;
vii. treatment of adverse reactions; and
viii. consent form (if required);

4.1.8.4A The Medical Director or delegated qualified personnel must administer medications and contrast and meet the Standards as listed in 1.6A to 1.6.4A.

(See Guidelines on Page 17 for further recommendations.)

Section 4A: Facility Safety
Guidelines

4.1A *Imminent life threatening situations may override the patient preparation and identification at the discretion of the treating physician.*

4.1.1A *Examples of patient-specific identifiers include the patient's identification bracelet, hospital identification card, driver's license, or asking the patient to state his or her full name or birth date avoiding procedures in which the patient can answer "yes" or "no."*

4.1.8A *All facilities conducting contrast-enhanced studies should be equipped with remote infusion devices.*

4.1.8.2A *If contrast is used serum creatinine and BUN should be obtained if clinically indicated and the results reviewed prior to the CT examination.*

Section 5A: Administrative

STANDARD – Patient Confidentiality

5.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

5.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the facility and how the facility handles complaints/grievances.

STANDARD – Primary Source Verification

5.3A There must be a policy in place identifying how the facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as, the certification and training of all technical staff members and any other direct patient care providers.

Section 5A: Administrative
Guidelines

Sample documents are available for each of the required policies listed in Section 5A on the IAC CT website at www.intersocietal.org/ct/seeking/sample_documents.htm.

Section 6A: Multiple Sites (Fixed and/or Mobile)

STANDARD – Multiple Sites

6.1A When testing is performed at more than one physical facility, the facility may be eligible to apply for a single accreditation as a multiple site facility if the following criteria are met:

6.1.1A all facilities have the same Medical Director;

6.1.2A all facilities have the same Technical Director;

6.1.3A all CT examinations are interpreted by medical staff included in the application;

6.1.4A all facilities utilize the same medical physicist or qualified expert;

6.1.5A all CT examinations are performed by technical staff included in the application; and

6.1.6A technical and interpretive quality assessment, as outlined in Section 2C: QI Measures must be evaluated for all CT testing sites.

Section 6A: Multiple Sites (Fixed and/or Mobile) *Guidelines*

Facilities needing complete details on adding a multiple site should review the current IAC Policies and Procedures available on the IAC website at www.intersocietal.org/iac/legal/policies.htm.

Part B:
Examinations and Procedures

Section 1B: Instrumentation and Equipment

STANDARD – Instrumentation

1.1B All CT imaging devices in use must be appropriate for the organ systems being imaged, and must be FDA approved for the specific imaging task.

1.1.1B Equipment specifications and performance must meet all state, federal and local requirements, as well as the manufacturer's published performance specifications and current standards of medical practice for the types of examinations performed.

1.1.2B The CT systems utilized for diagnostic studies must include, at a minimum, adequate hardware and software to perform and store organ specific procedures.

1.1.2.1B Coronary Calcium Scoring – CT scanners that will be used for coronary calcium scoring must meet the following minimum specifications:

i. Electron Beam CT Systems

- ≤ 100msec

OR

ii. Multi-detector CT Systems

- 4 slice system or greater

Comment: ≤ 0.5 sec rotation speed is recommended.

1.1.2.2B Coronary Computed Tomography Angiography (CTA) – CT scanners used for coronary arteries and coronary bypass grafts must meet the following minimum specifications:

i. Multi-detector CT Systems

- 64 slice system or greater
- ≤ 0.5 sec rotation speed
- Dual auto injector system

1.1.2.3B Vascular or Other CTA – CT scanners that will be used for CTA (abdomen; pelvis; chest (non coronary); neurovascular (including carotids); and peripheral vascular) and meet the following minimum specifications:

i. Multi-detector CT Systems:

- 16 slice system or greater is recommended
- Automatic infusion injector system

Comment: ≤ 0.5 sec rotation speed is recommended.

ii. Electron Beam CT

1.1.2.4B Neurological CT (excluding CTA) – CT scanners that will be used for neurological imaging must meet the following minimum specifications:

i. Single or Multi-detector CT Systems

Comment: ≤ 0.5 sec rotation speed is recommended.

1.1.2.5B Sinus and Temporal Bone CT – CT scanners that will be used for dedicated sinus and temporal bone imaging must meet the following minimum specifications:

i. Volume or Cone Beam CT System
ii. Single or Multi-detector CT Systems

Comment: ≤ 2 sec rotation speed is recommended.

1.1.2.6B Body CT (Chest, Abdomen, Pelvis, Extremities, excluding CTA) – CT scanners that will be used for body imaging (excluding CTA), must meet the following minimum specifications:

i. Single, Electron Beam or Multi-detector CT Systems

Comment: ≤ 2 sec rotation speed is recommended.

1.1.3B The computer software and reconstruction systems used for CT procedures must be appropriate for the study performed and meet the following minimum specifications:

1.1.3.1B Coronary Calcium Scoring:

i. must be capable of providing a visual representation of coronary calcium exceeding protocol thresholds;
ii. must be capable of quantitating coronary calcium using Agatston, mass and/or volume scoring methodologies; and
iii. must be capable of providing user interaction with quantitative program to allow for selecting or de-selecting coronary calcifications based on visual inspection.

1.1.3.2B Coronary CTA:

i. must be capable of displaying data as Maximum Intensity Projection (MIP), thick or thin slices;
ii. must be able to display data as multi-planar reformat;
iii. must be able to display data in a curve plane reformat;
iv. must be able to present data in a three dimension format with the ability to display data rotated about all three axes;
v. must be able to extract relevant measurements as described in facility specific protocol;
vi. must be able to load simultaneously multiple phases; and
vii. must be able to perform quantification of coronary calcium.

1.1.3.3B Vascular or Other CTA (Abdomen, Pelvis, Chest (non-coronary), Neurovascular (including carotids) and Peripheral Vascular):

i. must be capable of displaying data as Maximum Intensity Projection (MIP), thick or thin slice;
ii. must be able to display data as multi-planar reformat data;
iii. ability to present data in a three dimension fashion to display data rotated about all three axes; and
iv. must be able to extract relevant measurements as described in the facility specific protocol.

1.1.3.4B Neurological CT (excluding CTA):

i. must be capable of image processing appropriate to the imaging task.

1.1.3.5B Sinus and Temporal Bone CT:

i. must be capable of image processing appropriate to the imaging task.

1.1.3.6B Body CT (Chest, Abdomen, Pelvis, Extremities, excluding CTA):

i. must be capable of image processing appropriate to the imaging task.

1.1.4B For all systems:

1.1.4.1B all data are to be reviewed in a digital, on-screen medium;

1.1.4.2B monitor specifications must be sufficient to prevent any loss of resolution of CT images and to display the thinnest reconstructed images available;

1.1.4.3B must have capability to display data in standard contrast settings (lung field, bone, chest, etc.);

1.1.4.4B must have capability to adjust brightness and contrast settings manually;

1.1.4.5B datasets used for archiving must be DICOM compatible; and

1.1.4.6B must have the capability to optimize the field of view based on patient size and protocol implemented.

(See Guidelines on Page 24 for further recommendations.)

STANDARD – Equipment Quality Control

1.2B The Quality Improvement (QI) Program must consist of equipment quality control (QC) testing, CT system installation acceptance testing, and acceptance testing after a major upgrade to include: image quality, dose assessment and post installation shielding verification. *(Refer to Physicist Guidance Document in Appendix)*

1.2.1B Acceptance testing must include a comprehensive evaluation of the system components, the QC parameters included in 1.3B and 1.4B, image performance, and system performance as outlined in 21 CFR and applicable FDA guidance documents and performance of a radiation survey to verify the adequacy of installed lead shielding, if applicable.

1.2.2B The system parameters must be compared to the manufacturer's system specifications and reviewed by the QI Committee and/or the Medical Director.

1.2.3B The medical physicist or qualified expert must perform the shielding design to ensure that occupational workers and members of the public are shielded according to NCRP Report 147, state regulation, or other equivalent industry standards.

1.2.3.1B This must be performed prior to installation of each new scanner.

1.2.3.2B A post installation survey must be performed by a medical physicist or qualified expert to verify the shielding.

1.2.4B Dose and image quality review of representative exams as compared to professional standards must be performed.

(See Guidelines on Page 24 for further recommendations.)

1.3B Routine (daily and periodic) QC tests are to be conducted according to performance measurements as outlined by the manufacturer. Federal standards require that CT manufacturers provide QC testing instructions, recommended testing frequency, a QC test phantom appropriate for the scanner and acceptable variations in parameter measurements.

1.3.1B Daily QC tests must include (where appropriate to the scanner):

1.3.1.1B mean CT number for water of representative components;

1.3.1.2B mean CT number of other reference material;

1.3.1.3B image noise;

1.3.1.4B artifact assessment; and

1.3.1.5B proper function of audible and visual patient safety equipment.

1.3.2B Periodic QC tests must include all from Section 1.3B and the following (where appropriate to the scanner):

1.3.2.1B spatial resolution for high and low contrast objects;

1.3.2.2B image uniformity;

1.3.2.3B slice thickness;

1.3.2.4B alignment light accuracy;

1.3.2.5B image display and storage devices; and

1.3.2.6B air calibration, if required.

1.4B Annual system performance measures must be evaluated using an appropriate phantom(s), determined by the medical physicist or qualified expert. *(Refer to Physicist Guidance Document in Appendix.)*

1.4.1B Annual system performance by a medical physicist or qualified expert must include the measurement and assessment of patient dose for representative examinations using CT dosimetry phantom(s) and instrumentation, in accordance with current professional standards and regulatory guidelines.

1.4.2B The annual system performance QC measures must include (where appropriate to the scanner):

1.4.2.1B contrast scale;

1.4.2.2B mean CT number of water and reference materials;

1.4.2.3B linearity;

1.4.2.4B internal and external laser light alignment;

1.4.2.5B gantry tilt (tilt gantry systems only);

1.4.2.6B slice localization;

1.4.2.7B table incrementation accuracy;

1.4.2.8B slice thickness;

1.4.2.9B image quality (as noted in 1.3B);

1.4.2.10B image display and storage devices; and

1.4.2.11B safety analysis including an inspection of audible and visual equipment.

1.5B The QI Committee and/or the Medical Director must evaluate the medical physicist or qualified expert's recommendations for which quality control tests should be performed on the CT scanner and ancillary equipment, the frequency of the testing, and designate personnel to perform the test(s).

1.5.1B Preventive maintenance (PM) service is required per the manufacturers' recommendations but not less than annually for each CT scanner at the facility.

(See Guidelines on Page 24 for further recommendations.)

STANDARD – Quality Control Documentation

1.6B All QC results must be documented and reviewed.

1.6.1B A written report of the acceptance tests must be maintained at the CT facility. The report must be signed and dated by the person performing the tests.

1.6.2B A complete log of PM, quality control tests and service records for all CT scanners and ancillary equipment must be maintained at the CT facility. The reports must be signed and dated by the person(s) performing the tests.

1.6.3B Results of all QC tests must be documented, archived and stored on film, in digital format, or on other suitable media according to state requirements if applicable.

(See Guidelines on Page 24 for further recommendations.)

Section 1B: Instrumentation and Equipment
Guidelines

1.2B The CT site-appointed medical physicist or qualified expert should perform the acceptance testing.

1.1.4B If images are transmitted to another location for interpretation, the original resolution should be maintained

1.5B Scanner ancillary equipment inspection (e.g., ECG gating, other monitoring equipment, injectors, processors, workstations, PACS, etc.) should also be included in the PM.

1.6B Quality control tests, standards, thresholds, timelines and results should be reviewed and discussed on a quarterly basis by the QI Committee and/or the Medical Director.

Section 2B: Protocols

STANDARD – Procedure Volumes

2.1B The annual procedure volume must be sufficient to maintain proficiency in examination performance and interpretation.

(*See Guidelines on Page 27 for further recommendations.*)

STANDARD – Indications, Ordering Process and Scheduling

2.2B CT testing is performed for appropriate indications.

2.2.1B Verification of the Indication – A process must be in place in the facility for obtaining and recording the indication. Before a CT study is performed, the indication must be verified and any additional information needed to direct the examination must be obtained.

Comment: For patients presenting with acute stroke symptoms refer to the Acute Stroke Appendix.

2.3B CT testing is appropriately ordered and scheduled.

2.3.1B Ordering Process – The CT order and requisition must clearly indicate the type of study to be performed, the reason(s) for the study and the clinical question(s) to be answered. The order/requisition must be present in the medical record of the patient.

2.3.2B Sufficient time for patient assessment, preparation and testing must be allotted for each study according to the procedure type.

STANDARD – Techniques

2.4B Examination performance must include proper technique.

2.4.1B All procedures must be explained to the patient and/or parents or guardian and informed consent obtained, if required.

2.4.2B Elements of examination performance include as appropriate, but are not limited to:

2.4.2.1B proper patient positioning;

2.4.2.2B optimization of image acquisition parameters inclusive of dose reduction techniques, if appropriate;

2.4.2.3B utilization of the appropriate protocol; and

2.4.2.4B appropriate protocol selection based on:

i. clinical diagnosis;
ii. patient age;
iii. body habitus/weight;
iv. surgical history;
v. patient clinical presentation; and
vi. contraindications.

2.4.3B The facility must have a complete, written description of each protocol that is being utilized for each CT examination and the protocol(s) must include (as appropriate):

2.4.3.1B indication for the study;

2.4.3.2B anatomical region(s) to be imaged;

2.4.3.3B utilization of the correct scanner for the indication;

2.4.3.4B clear criteria for deviating from protocols;

2.4.3.5B adherence to established practice guidelines (there may be allowance for exceptions if validated);

2.4.3.6B all orientations/views that will be displayed;

2.4.3.7B filming instructions to include window level and contrast settings, views, format, magnification;

2.4.3.8B reconstruction algorithm and filter;

2.4.3.9B reconstruction interval;

2.4.3.10B phase(s) of cardiac cycle reconstructed;

2.4.3.11B indication for IV contrast to include: type of contrast, amount, injection rate and scan delay protocol;

2.4.3.12B other medications used including dose and route of administration;

2.4.3.13B instruction on data archiving and transmission of images including what files are to be stored/transmitted; and

2.4.3.14B scanner settings or acquisition parameters to include (where appropriate to the scanner):

i. acquisition mode;
ii. patient orientation;
iii. KV;
iv. mA/mAs;
v. dose modulation, if used;
vi. collimation;
vii. rotation time;
viii. slice thickness;
ix. increment;
x. table speed/pitch;
xi. FOV;
xii. gantry angle; and
xiii. representative exposure or dose as recorded by the CT system.

Section 2B: Protocols
Guidelines

2.1B *A facility should perform a minimum of 300 CT examinations annually. Each member of the medical staff should interpret a minimum of 300 CT examinations annually. Each member of the technical staff should perform a minimum of 300 CT examinations annually. The total volume of studies interpreted and performed by each staff member may be combined from sources other than the applicant facility. Lower volumes than those recommended here, however, should not dissuade a facility that is otherwise compliant with the IAC CT Standards from applying for accreditation.*

Part C:
Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

1.1C A Quality Improvement (QI) Program must be in place in the CT facility.

1.1.1C QI procedures must be designed to provide a standard of measurement of the technical and interpretive components of facility performance and the documentation of any variance thereof. A QI Committee and/or the Medical Director must provide oversight to these procedures.

1.1.2C The use of a site appointed medical physicist or qualified expert is required for an annual survey to include: image quality evaluation, representative patient dose assessment and for oversight of the QI Program.

(See Guidelines on Page 28 for further recommendations.)

STANDARD – QI Documentation

1.2C QI documentation (policies, reports, records, etc.) must be maintained at the CT facility and made available to all personnel.

1.2.1C QI Record Keeping

1.2.1.1C Records must be maintained of the QI process.

1.2.1.2C The records must include a description of how the information is used to improve quality in the CT facility.

(See Guidelines on Page 28 for further recommendations.)

Section 1C: Quality Improvement Program
Guidelines

1.1C *The QI Committee should, at minimum, consist of the Technical Director, Medical Director, service engineer and/or site-appointed medical physicist.*

The QI Program should also include a process for evaluating indicators such as backlog for scheduled examinations, late reporting, long patient waiting times and utilization review.

1.2C *QI records should include, but not be limited to, image quality evaluation, dose assessment, peer review, correlation data and information gained from the areas outlined in Section 2C.*

Section 2C: Quality Improvement Measures

STANDARD – QI Measures

2.1C The QI Program must include:

(See Guidelines on Page 30 for further recommendations.)

2.1.1C Technical Quality Assessment – Under the supervision of the Medical Director and the Technical Director, and with the guidance of the Medical Physicist or qualified expert, the facility must have a defined QI program that evaluates the ongoing technical quality and radiation dose information (i.e., Computed Tomography Dose Index (CTDI), Dose Length Product (DLP)), of the CT procedures performed in the facility.

2.1.1.1C Each facility must document the available dose reduction techniques and clinical indications/contraindications for their use.

2.1.1.2C Technical indicators must include, but are not limited to:

i. image quality (i.e., field of view; contrast enhancement; artifacts; extent of coverage; adherence to protocol); and
ii. documentation of dosimetry data ranges (DLP; CTDIvol or dose (mGy) per sequence or cumulative per examination) for protocols used in the facility based on patient age and habitus.

2.1.1.3C Radiation dose review and assessment (patients and staff) must be included in the program.

2.1.1.4C Thresholds are determined for each indicator.

(See Guidelines on Page 30 for further recommendations.)

2.1.2C Interpretive Quality Assessment – Under the supervision of the Medical Director, the facility must have a defined QI Program that evaluates the ongoing quality of the interpretation of the CT examinations.

2.1.2.1C Correlation and Confirmation of Results: For those patients who have undergone cardiac CT examinations and other diagnostic procedures (such as cardiac catheterization, invasive angiography, nuclear perfusion examinations or other diagnostic imaging) or surgical intervention, the results of CT examination and other procedures must be routinely compared. A process for reviewing variations between CT examination results and results of other procedures must be in place.

(See Guidelines on Page 30 for further recommendations.)

Section 2C: Quality Improvement Measures Guidelines

2.1C *Appropriate Use Criteria (AUC): As part of the ongoing QI Program, facilities providing computed tomography should incorporate the measurement of the appropriate use of this diagnostic imaging examination based on criteria published and/or endorsed by professional medical organization(s).*

- *Overall results should be documented. The percentage of appropriate, inappropriate and uncertain indications for testing should be measured.*
- *A program for education and reporting should be developed and may include but is not limited to:*
  - *Patterns of adherence to AUC*
  - *Baseline rates of adherence*
  - *Goals for improvement of adherence to appropriate use criteria*
  - *Measurement of improvement rate*
  - *Confidential comparison reports on patterns of adherence in aggregate by ordering physician, ordering practice, and interpreting practice.*

2.1.1C *Technical Quality Assessment: The program should have predefined indicators of technical quality and predefined thresholds that indicate the need for corrective action. The facility should maintain reports of quality assessment evaluations and corrective actions taken. Technical indicators may include, but not limited to:*

- *Adverse effects (i.e., contrast reactions, repeat exams, patient incidents)*
- *Reproducibility of image quality and computer processing (i.e., reformats; electronic transfers)*

2.1.3C *Interpretive Quality Assessment: This program should have predefined indicators of quality and predefined thresholds that indicate the need for corrective action. The Medical Director should maintain reports, as necessary, of quality assessment evaluations and document, if applicable, corrective measures taken.*

- *Peer review: Intermittent peer review of both the performance and interpretation of examinations should be performed to determine the quality, accuracy and appropriateness of the examination. Peer review may also be used to compare reproducibility of interpretation with previous interpretation, or with interpretation of the same study by other qualified interpreting physicians. Both physicians and technologists should be involved in the peer review process in order to achieve standardized protocols and reporting. Results of peer review should be discussed in an appropriate manner to assure correction of negative results as well as to preserve physician, technologist and patient confidentiality. (Strict attention must be paid to physician, staff and patient confidentiality as required by federal, state, local or institutional policy or regulation).*

Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

3.1C Quality Improvement (QI) meetings must be documented.

3.1.1C QI Review and Documentation – The results of the technical and interpretive quality assessments must be reviewed and disseminated to the medical and technical staff at a minimum of two times per year.

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Appendix

Table 3. Requirements for CCT Study Performance and Interpretation to Achieve Level 1, 2, and 3 Clinical Competence

	Cumulative Duration of Training	Minimum Number of Mentored Examinations Performed	Minimum Number of Mentored Examinations Interpreted
Level 1	4 weeks*	—	50†
Level 2—non-contrast	4 weeks*	50	150†
Level 2—contrast	8 weeks*	50	150†
Level 3	6 months*	100	300†

*This represents cumulative time spent interpreting, performing, and learning about CCT, and need not be a consecutive block of time, but at least 50% of the time should represent supervised laboratory experience. In-lab training time is defined as a minimum of 35 h/week. †The case load recommendations may include studies from an established teaching file, previous CCT cases, journals and/or textbooks, or electronic/on-line courses/CME.

Table 5. Documentation and Maintenance of Clinical Competence in CCT

Documentation of Competence	Training Guidelines	Proof of Competence
Training completed after July 1, 2008	Level 2 or Level 3 training as outlined	Letter of certification from training supervisor OR letter attesting to competence from Level 2- or 3-trained physician
Training completed before July 1, 2008	Level 2 training OR interpretation of at least 150 studies (in which 50 where the candidate is physically present, involved in the acquisition and interpretation of the case) and attendance in at least 20 h of devoted CCT classes Level 3 training OR interpretation of at least 300 studies (in which 100 where the candidate is physically present, involved in the acquisition and interpretation of the case) and attendance in at least 40 h of classes devoted to CCT	
Maintenance of competence	Contrast CCT examinations per year be performed and interpreted: Level 2: 50 Level 3: 100	

Acute Stroke Appendix

Requirements for Emergent CT Studies for Patients Presenting With Acute Stroke Symptoms

The following criteria are required for those facilities performing CT studies for patients presenting with acute stroke symptoms:

1. Qualified board certified physicians are required to interpret the study.

2. A written procedure must be available outlining the identification of these emergent CT studies (i.e., code stroke) on the study request so that a timely interpretation is done.

3. A written preliminary report of the CT head should be sent to the treating physician within 45 minutes of the patient's arrival to the facility. Alternatively, a direct verbal report to the treating physician can be done within 45 minutes of the patient's arrival to the facility with a follow up written preliminary report documenting the time of this verbal report exchange. A goal of reading the CT head within 15 minutes of the completion of the study is recommended. If the interpreting and treating physician is the same, a preliminary written report should be noted within the medical record.

4. The written preliminary report should include comments on major CT head findings (at a minimum, presence or absence of hemorrhage, mass lesion, or acute infarction must be mentioned) as well as whether this study fulfills neurological imaging criteria for inclusion or exclusion of acute stroke therapies based on available published neurological imaging guidelines.

5. The physician providing the preliminary interpretation must be the same person providing the final official interpretation of the CT study.

6. When the CT interpreter and the treating physician are different individuals who both render written opinions regarding neurological imaging criteria for inclusion or exclusion of acute stroke therapies, the CT facility must track this information as a part of quality improvement.

7. The final CT interpretation must conform to available published acute stroke neurological imaging guidelines (at a minimum for head CT's, presence or absence of hemorrhage, mass lesion, or acute infarction must be mentioned and the inclusion or exclusion of acute stroke therapies based on neurological imaging criteria).

8. The final CT study interpretation must be dictated within 24 hours of completion of the study.

** The above guidelines are applicable to any CT study used to guide emergent treatment decisions.

Acute Stroke Bibliography

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Medical Physicist or Qualified Expert Report Guidance Document

IAC CT Guidance for Radiation Protection Survey, Image Quality and Dose Assessment

1. Radiation Protection Surveys (RPS) must be performed upon installation of new equipment, or after major changes in room configuration, equipment location, or usage of areas adjacent to the CT scanner. These are typically done upon acceptance, and are not required annually thereafter. Hence, it may be necessary to locate the original acceptance test report of the CT scanner to find the RPS. IAC CT requires that a RPS be submitted, to demonstrate that the safety of the installation and the surrounding areas has been assessed. A complete RPS must include:

    a. A sketch showing the layout of the equipment in the room, and identifying the surrounding areas (e.g., toilet, corridor, outside wall, exam room, office, etc.).

    b. Measurements of exposure (or exposure rate) obtained with an appropriately sensitive radiation measurement system.

    c. Calculations to demonstrate compliance with weekly or annual exposure limits, which must include a determination of workload, identification of occupancy of each adjacent area, and identification of the applicable exposure limit (controlled and non-controlled areas).

    d. Note that shielding designs are not required to be submitted.

2. CT Dosimetry Reports for all scanners, including volume CT (VCT) or cone-beam CT (CBCT) scanners, must include:

    a. Measurements of exposure, and calculations of dose or dose index (or other appropriate dosimetry metric) which include comparison with some applicable reference standard, using the same units as the reference standard. The report must be clear about whether the results are acceptable, and identify corrective actions if the results are not acceptable.

    b. Dosimetry should be in units of pitch-corrected CTDI, point dose at the central ray, or MSAD for typical clinical protocols. The clinical protocol factors must be listed.

    c. Although CTDI is not rigorously defined for VCT or CBCT scanners, CTDI is also not rigorously defined for multislice CT scanner with beam thickness more than 1.0 cm. While imperfect, CTDI is the only metric for which reference standards currently exist. If possible, VCT or CBCT systems should be configured to use a z-axis collimation that is less than the length of the pencil chamber (if such a chamber is used). For example, temporal bone imaging protocols found on ENT scanners often meet this criterion. As new techniques for CT dosimetry are published, more rigorous methods should be used.

    d. The report must identify the phantom and radiation detection system used.

1.	Report must be signed and dated by the medical physicist or qualified expert: IAC CT Standards for medical physicist or qualified expert: Board certified medical physicist or qualified expert. Is the medical physicist or qualified expert licensed by the state or otherwise authorized to perform dose measurements and evaluate CT image quality?	*IAC CT Standards Reference Section 1.2B – 1.6B*
2.	Report must indicate if acceptance test	
3.	Report must indicate if annual survey	
4.	Report must document recommended corrective actions	
5.	Dose report to include:	*Refer to Standard 1.4B*
	a. Dose reported for typical clinical protocols	
	b. Comparison of measured dose with some reference standard, using the same dose units. Report must include if results acceptable.	
	c. Dose should be in units of pitch corrected CTDI (preferably) or point dose at the central ray for cone-beam systems or MSAD.(or IAC approved acceptable methology)	*Refer to page 36*
	d. The ion chamber/electrometer manufacturer/model must be documented	
	e. Phantom used for dose analysis must be documented on report.	
6.	Image quality report to include:	*Refer to Standard 1.4B*
	a. Low-contrast resolution (n/a cone beam CT)	
	b. High-contrast spatial resolution	
	c. Reconstructed slice thickness accuracy (n/a cone beam CT)	
	d. Alignment of laser light (if available on system)	
	e. CT number accuracy	
	f. Noise (not CBCT)	
	g. Are parameters compared with a reference standard or manufacturer's specification? (Some may be N/A.)	
	h. QC phantom for quality analysis must be documented on the report	
7.	Confirmation of Shielding Plan or completion at installation: The Radiation Protection Survey at installation should include:	*Refer to Standard 1.2B*
	a. Layout showing equipment location in the room and type of occupancy for adjacent areas (i.e., office, toilet, outside, corridor, etc.)	
	b. Exposure (mR, mSV or uR, uSV) or exposure rate (mR/hr or mSv /hr) measurements at multiple locations including at least the	

	operator position and areas adjacent to (but outside of) the scanner room. Measurements outside may be omitted under some situations.	
	c. Determination of weekly workload (mAs per scan x # patients per week) or some other accept methodology	
	d. Occupancy factors specified for surrounding areas	
	e. Calculation weekly exposure to persons inside and outside the room, corrected for occupancy factor	
	f. Final assessment of results as "Acceptable," "ALARA," within restricted vs. unrestricted guidelines	
	g. Report is signed and dated by the qualified medical physicist	
	h. Recommendations, actions needed, or issues to be addressed to the facility must be included on the report, if applicable	
	Comment: The IAC CT accreditation program outlines the training and experience requirements that the medical physicist/qualified expert must meet in order to perform CT quality assurance testing. The analysis and evaluation of the quality control testing is left to the judgment of the qualified medical physicist. The primary purpose of the submission of the phantom images with the results is to verify/document the image quality analysis.	

q. Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

Sec. F.7 - Intraoral Dental Radiographic Equipment. In addition to the applicable provisions of F.3, F.4, and F.6, the requirements of F.7 apply to x-ray equipment and associated facilities used for dental intraoral radiography. Requirements for extraoral dental radiographic systems are covered in F.6.

a. Radiation Exposure Control. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

b. Exposure Control Location and Operator Protection.

i. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

ii. Mobile and portable x-ray systems which are:

(1) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.7a.;

(2) Used for less than one week in the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly while making exposures.

c. kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

d. Administrative Controls.

i. Patient and film holding devices shall be used when the techniques permit.

ii. The tube housing and the PID for a permanently mounted intraoral dental system shall not be hand-held during an exposure. Appendix B specifies requirements for the use of intraoral dental radiographic units designed to be hand-held during patient examination.

iii. Dental fluoroscopy without image intensification shall not be used.

Sec. F.11 - Computed Tomography Equipment.

a. Definitions. In addition to the definitions provided in A.2 and F.2 of these regulations, the following definitions shall be applicable to F.11:

"Computed tomography dose index" (CTDI) means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n\,T} \int_{-7T}^{+7T} D(z)\,dz$$

where:

z	=	Position along a line perpendicular to the tomographic plane;
D(z)	=	Dose at position z;
T	=	Nominal tomographic section thickness;
n	=	Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x	=	Linear attenuation coefficient of the material of interest;
μ_w	=	Linear attenuation coefficient of water;
$\overline{CTN}_x$	=	of the material of interest;
$\overline{CTN}_w$	=	of water.

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in F.2.

"CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means

for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Any effect 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.

"CT Number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image:

$$\overline{CTN} = \frac{k\,(\mu_x - \mu_w)}{\mu_w}$$

where:

k	=	A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;
μ_x	=	Linear attenuation coefficient of the material of interest;
μ_w	=	Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Modulation transfer function" means the modulus of the Fourier transform of the impulse response of the system.

"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

$\overline{CS}$	=	Linear attenuation coefficient of the material of interest.
μ_w	=	Linear attenuation coefficient of water.
s	=	Standard deviation of the CTN of picture elements in a specified area of

the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

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

"Remanufacturing" means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in this subsection to “manufacture,” “manufacturer,” or “manufacturing” includes remanufacture, remanufacturing, respectively.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Sensitivity profile" means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

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

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

b. Requirements for Equipment.

i. Termination of Exposure.

(1) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Subdivision F.11b.i.(1).

(3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

ii. Tomographic Plane Indication and Alignment.

(1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(3) If a device using a light source is used to satisfy the requirements of Subdivisions F.11b.ii.(1) or (2), 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 500 lux.

iii. Beam-On and Shutter Status Indicators and Control Switches.

(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.

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

iv. Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

v. Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by F.4c.

vi. Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

vii. 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 shall not exceed 5 millimeters.

(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.

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. 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. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(4) 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.

c. Facility Design Requirements.

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

ii. 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.

d. Surveys, Calibrations, Spot Checks, and Operating Procedures.

i. Surveys.

(1) All CT x-ray systems installed after [insert the effective date of the regulations] and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant [licensee] shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the Agency upon request.

ii. Radiation Calibrations.

(1) The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified medical physicist who is physically present at the facility during such calibration.

(2) The calibration of a CT x-ray system shall be performed after initial installation and before use on human patients, annually or at intervals specified by a qualified medical physicist, and after any change or replacement of components which, in the opinion of the qualified medical physicist, could cause a change in the radiation output.

(3) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

(4) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(a) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(b) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(c) 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;

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

(5) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(6) 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. Where less than 3 nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(b) The CTDI[2/] along the two axes specified in Subdivision F.11d.ii.(4)(b) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter 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. The CT conditions of operation shall correspond to typical values used by the registrant;

(c) The spot checks specified in F.11d.iii. shall be made.

(7) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

iii. Spot Checks.

(1) The spot-check procedures shall be in writing and shall have been developed by a qualified medical physicist.

(2) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which 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.

(3) All spot checks shall be included in the calibration required by F.11d.ii. and at time intervals and under system conditions specified by a qualified medical physicist.

(4) 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 F.11d.ii. The images shall be retained, until a new calibration is performed, in two forms as follows:

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

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[2/] *For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.*

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

(5) Written records of the spot checks performed shall be maintained for inspection by the Agency.

iv. Operating Procedures.

(1) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(2) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(b) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(c) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(d) 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.

(3) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.

Sec. F.12 - Mammography Requirements for States Without FDA Certifying Authority.

Requirements for Certification.

a. Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900, shall be used for screening and diagnostic mammography.

b. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

BOARD OF DIRECTORS POSITION

Relating to: Computed Tomography Protocol Reviews

A recent safety investigation by the U.S. Food and Drug Administration (FDA) of radiation overexposures during brain perfusion CT imaging was conducted at one hospital. Over 200 patients at the particular facility received radiation doses that were approximately eight times the expected level, and in some cases, this excessive dose resulted in hair loss and erythema. The overexposures were determined to be due to a patient protocol being improperly adjusted.

The recent incident of patients receiving unnecessary radiation from CT perfusion brain studies have caused concern and raised awareness in the medical community. In response, the CRCPD's Committee on Computed Tomography has offered recommendations on quality assurance improvement and prevention of such overexposures in the use of CT imaging.

It is the position of the Board of Directors of the Conference of Radiation Control Program Directors, Inc. (CRCPD) that hospitals and CT facilities should review their CT protocols to ensure that their current protocols are appropriate to allow them to provide the best possible CT studies while assuring they are keeping patient exposures as low as reasonably achievable.

The following items should be reviewed and implemented as applicable by hospitals and other CT facilities to improve quality assurance and prevent overexposures in the use of CT imaging:

- Each facility should review all of their CT default protocols to ensure they are correct and are the intended protocol. Comparison should be made to the initial dose assessments that were made at the time of installation and those made during the last annual review by the medical physicist.
- The protocols should be evaluated by the CT interpreting radiologists, CT medical director or section chief in consultation with the medical physicist and chief CT technologist. The evaluation should determine whether the volume computed tomography dose index ($CTDI_{vol}$) dose from the current protocols is appropriate or whether there is an opportunity to reduce the technique and lower the $CTDI_{vol}$. Care must be taken to ensure any dose reductions do not result in an unacceptable sacrifice in image quality.

- The approved techniques must ensure that image quality remains acceptable and results in acceptable dose levels. Once approved, the techniques should be recorded and guidelines of variability established. The limits of the variability range should be approved by the CT medical director. Technologists are permitted to adjust protocols as long as they remain within the approved limits of variability.

- Procedures or engineering protocols such as password protection should be in place that prohibits anyone from changing protocols without approval from the CT medical director.
- Procedures should be set up to have the lead CT technologist review the protocols on a monthly basis, to ensure that they are correct. The protocols should be reviewed by the medical physicist at least once per year. If the $CTDI_{vol}$ dose for each exam is kept as a log at the control panel, the review can be done easily and as needed if any changes in dose trends are noticed.
- All CT technologists should be aware of the normal dose indices that are displayed during exams. Dose indices are normally displayed as volume computed tomography dose index (abbreviated $CTDI_{vol,}$ in units of "milligray" or "mGy") and the dose-length product (*DLP*, in units of "milligray-centimeter" or "mGy-cm"). The technologist should ensure that $CTDI_{vol}$ dose values are forwarded on the images to the PAC workstation. The CT technologists should be able to retrieve the information for the interpreting radiologist's review.
- It is important to review the control parameters of the Automatic Exposure Control (AEC) system, which are unique for each manufacturer. If your CT system has AEC or Dose Reduction capability, one should check that the parameters are correct. The qualified medical physicist in consultation with the medical director and the CT equipment manufacturer should ensure that these control parameters are correct with respect to the imaging requirements of each type of CT study.
- $CTDI_{vol}$ is often misunderstood by CT technologists and interpreting physicians. Each facility should ensure that all interpreting physicians and technologists are properly educated on what the $CTDI_{vol}$ dose numbers mean. The site medical physicists can be consulted to review the $CTDI_{vol}$ methodology and interpretation of the values. These should be reviewed by the interpreting physicians on a case by case basis and the information should be recorded as part of the patient's medical record.
- The CT operator technologists should monitor the dose indices for each patient to ensure that the displayed value falls within an acceptable range. The CT operator technologists should understand the AEC features of the CT scanner. If the technologists are not familiar with the AEC features of the CT scanner, additional training should be provided.

- Consider establishing a threshold to investigate radiation doses above certain dose values. This could be done by selecting common and/or high dose CT studies for $CTDI_{vol}$ radiation dose review.

  Suggested $CTDI_{vol}$ Reference levels are:

  CT Head <75mGy, (7.5 rad)
  CT Abdomen <25mGy, (2.5 rad)
  CT Chest <25mGy (2.5 rad)
  Pediatric Abdomen <20mGy (2.0 rad)
  CT Brain Perfusion study <500mGy (50.0 rad) – Suggested value

  The American College of Radiology and the American Association of Physicists in Medicine are excellent sources for other reference levels.

- Suggestion for state inspectors: Consider using the above items to develop a checklist to ensure that CT departments are aware of the need to establish procedures and protocols that monitor the doses their patients are receiving.

Approved by the Board of Directors October 20, 2009.

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