DEPARTMENT OF COMMUNITY HEALTH

DIRECTOR'S OFFICE

BUREAU OF HEALTH SYSTEMS - RADIATION SAFETY SECTION

IONIZING RADIATION RULES PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS

(By authority conferred on the director of the department of community health by section 13521, 1978 PA 368, MCL 333.13521 and Executive Reorganization Order Nos. 1996-1, 1996-2, and 2003-01, MCL 330.3101, 445.2001, and 445.2011)

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.