

Computed Tomography (CT) Proposed Rules for Radiation Safety

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CT – an introduction

- "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.
- Computed axial tomography (CAT) scanning was invented by Godfrey N. Hounsfield in 1972 and independently by Alan Cormack in 1972.
- Hounsfield's CT scanner took several hours to acquire data and days to reconstruct a single image from the data

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CT – an introduction

- Siemens introduced the first commercial CT system in May 1974 called the SIRETOM
- First units could only image a patients head
- These early units took several minutes to acquire image data and several minutes to reconstruct the data

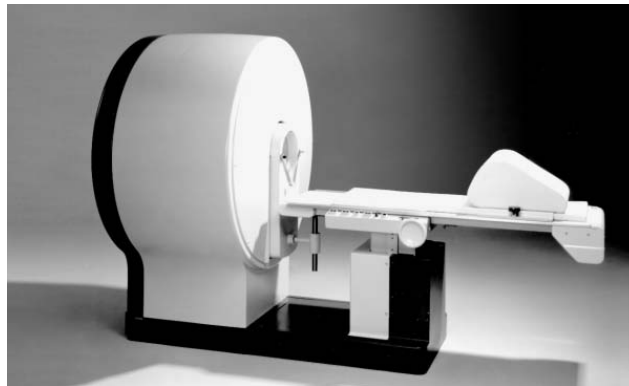
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CT – an introduction

Siemens SIRETOM – circa 1974



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CT – an introduction

- The latest multi-slice CT systems can image an entire chest in less than ten seconds and reconstructs the images in a similar time period
- Faster systems = higher volume of patients
- Faster systems = development of new techniques

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Radiation risk

- Risk is proportional to absorbed dose
- Risk is quantified by determining the “effective dose” and is expressed as millisievert (mSv)
- Atomic bomb survivors who experienced doses that were slightly higher than doses encountered in CT demonstrated increased cancers (5-20 mSv vs 1-10 mSv)

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Effective dose from various diagnostic procedures^{1,2}

- Head x-ray = 0.1 mSv
- Chest x-ray = 0.02 mSv
- Abdomen x-ray = 0.7 mSv
- Upper G.I exam = 5 mSv
- Barium enema = 8 mSv
- CT head = 2 mSv
- CT chest = 7 mSv
- CT abdomen = 10 mSv
- Coronary Angiography (CTA) = 16 mSv

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Growth of CT

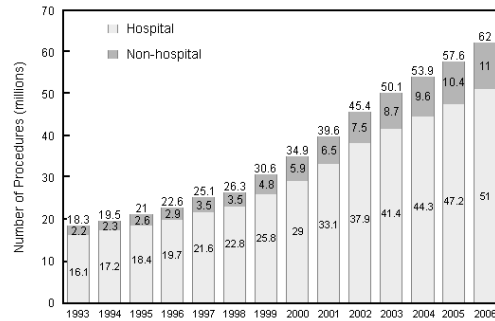
- 1980 ~ 3 million CT exams performed (USA)
- 1993 ~ 18 million CT exams performed (USA)
- 2006 ~ 62 million CT exams performed (USA)
- 1993 -2006 – growth rate ~10-11%/year
- Continued growth is expected ~ 7% per year

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CT procedures per year²

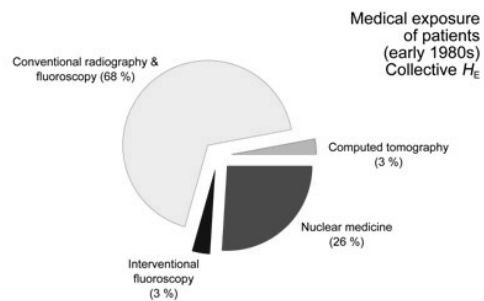


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Medical dose - US population²

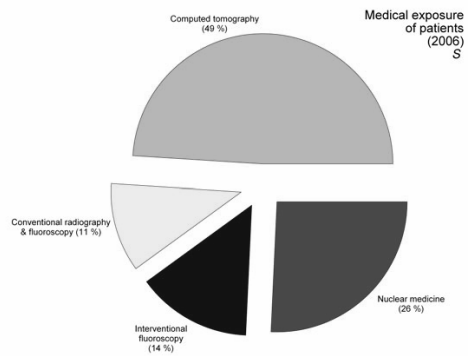


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Medical dose - US population²

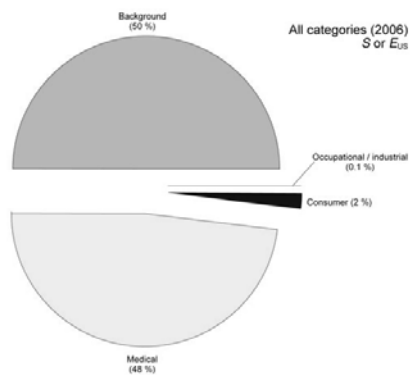


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Average effective dose major sources (US)²

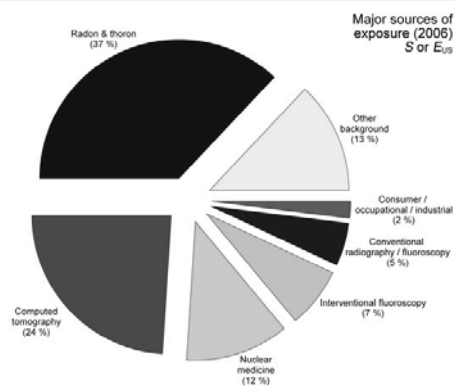


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Average effective dose all sources US²



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Incidents

- Cedars-Sinai Medical Center in Los Angeles³
 - 206 patients receive overexposure during brain scans before the error was noticed
 - Each received 3-4 gray, up to 8 times the maximum dose expected for this exam (0.5 gray)
- Two year old receives CT overdose⁴
 - Technologist subjected a 2 year old to 151 CT scans in the same area of the cervical spine (C1 thru C4)
 - Total dose was estimated to be 2,800 mSv – 11,000 mSv
 - Typical dose is 1.5-4.0 mSv for a normal pediatric CT study
 - Lifetime attributable risk (LAR) is estimated to be 39%

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Why new CT rules

- Current *Ionizing Radiation Rules* (1975)
- Lack rules specifically regulating CT
- Patient dose from CT >> regular x-ray exams
- Higher dose = higher risk of cancer
- Technological advances = increased use
- Use of CT is expected to continue to grow
- 48% of all exposure comes from medical sources
- 49% of medical exposures comes from CT

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What rules are we proposing

- Purpose/Scope/Exemptions
- Personnel requirements
- Equipment requirements
- Quality control program
- Facility design requirements
- Surveys

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Sources

- The Michigan Department of Community Health's Certificate of Need Review Standards for Computed Tomography (CT) Scanner Services
- The *Federal Performance Standards for Ionizing Radiation Emitting Products*, 21 C.F.R. §1020.33 "Computed tomography (CT) equipment" (June 10, 2005)
- The American College of Radiology's CT Accreditation Program Requirements
- The Conference of Radiation Control Program Director's Suggested State Regulations for the Control of Radiation, Part F X-ray in the Healing Arts.
- Reviewing the proposed rules with interested stakeholders

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Exemptions

- Purpose and scope
 - Specify that the rules apply to all registrants who use CT systems for the intentional exposure of humans for the purpose of diagnostic imaging
 - This would exempt PET/CT and SPECT/CT unless the CT portion of the system is used for diagnostic imaging
- Exemptions
 - Specific exemption for CT systems with power ratings of 5 kilowatts or less

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Personnel requirements

- Requirements for:
 - Interpreting physicians
 - Radiological technologists
 - Medical physicist

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Interpreting physicians

- Licensed to practice medicine in Michigan
- Initial qualifications
 - Board certified
 - Radiology or
 - Diagnostic radiology and
 - Read at least 300 CT exams in the last 36 months
 - Or have completed a diagnostic or specialty residency program and have read 500 CT exams in the last 36 months
- Continuing experience
- Continuing education

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Radiologic technologists

- Initial qualifications
 - ARRT registered
 - Hold the advanced certificate in CT from the ARRT or have specialized training (20 hrs)
- Continuing education = ARRT requirements

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Medical physicist

- Initial qualifications
 - Be board certified or hold a graduate level degree in an approved discipline
 - Have 3 years clinical experience in CT
- Continuing experience
- Continuing education

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Equipment

- Plan to adopt by reference the FDA's CT requirements for Computed tomography
 - 21 C.F.R. §§1020.33 (June 10, 2005)
 - Must be maintained in compliance with those regulations

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Quality control program

- Shall be established and implemented under the supervision of the medical physicist (MP)
- MP must perform an initial or acceptance test of each CT system prior to use on patients
- MP must perform an annual evaluation of the CT system and quality control program
- Facility conducts a continuous quality control program designed/overseen by the MP

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Facility design requirements

- Enclosure must meet the requirements of R325.5331
- Operator must be able to operate the equipment from a shielded position
- Operator must be able to communicate with the patient from the control panel
- Operator must be able to see the patient from the control panel
- Electronic viewing systems must remain operational or must be repaired before any further examinations are performed

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Surveys

- Requires a radiation shielding survey by a medical physicist prior to use on patients for newly installed systems or within 1 year for existing systems
- Medical physicist must provide a written report to the facility

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References

- 1- Average effective dose in millisieverts (mSv) as compiled by Fred Mettler, Jr., et al., "Effective Doses in Radiology and Diagnostic Nuclear Medicine: A catalog," *Radiology* Vol 248, No 1, pp 254-263, July 2008.
- 2 - NCRP Report 160, *Ionizing Radiation Exposure of the Population of the United States*, 2009
- 3 – FDA Medical Devices Alerts and Notices
- 4 – "California technologist faces testimony in CT overdose case", AuntMinnie.com, September 18, 2009

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**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
RADIATION SAFETY SECTION
IONIZING RADIATION RULES**

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PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS**R325.5701. Purpose and scope.**

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

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

(3) CT systems with power ratings of 5 kilowatts or less are exempt from this part. CT scanners used only for attenuation corrections and anatomical markers are also exempt from this part.

(4) In addition to the requirements of this part, all registrants are subject to the applicable provisions of R325.5001 to R325.5665.

R325.5703. 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 and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

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

(a) "Annual" means a period of twelve 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) "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.

R325.5705. Interpreting physicians.

Rule 705. The following requirements apply to all physicians involved in the interpretation of CT images.

(a) Initial qualifications. Before beginning to interpret CT examinations independently, a physician shall be licensed under article 15 of the act and shall meet one of the following:

- (i)** Be board certified in radiology or diagnostic radiology by the American board of radiologists, the American osteopathic board of radiology, the royal college of physicians and surgeons of Canada, or le college des medecins du Quebec and have interpreted or reviewed 300 CT examinations in the past 36 months; or
- (ii)** Have completed an accredited diagnostic radiology residency and have interpreted or reviewed 500 CT examinations in the past 36 months under supervision; or
- (iii)** Have completed an accredited specialty residency, have a combined total of 200 hours of category I continuing medical education (CME) in the performance of and

interpretation of CT in the subspecialty where CT reading occurs, and have interpreted or reviewed 500 CT examinations in the past 36 months under supervision.

(b) *Continuing experience.* Following the second anniversary date in which the requirements of subrule (a) of this rule were completed, the interpreting physician shall have interpreted or multi-read at least an average of 9 CT examinations per month over the prior 24-month period. This equates to interpreting at least 216 CT examinations in the prior 24-month period.

(c) *Continuing education.* Following the third anniversary date in which the requirements of subrule (a) of this rule were completed, the interpreting physician shall have earned at least 15 continuing medical education units in CT, at least half of which shall be category I, in the prior 36-month period.

R325.5707. Radiologic technologists.

Rule 707. The following requirements apply to all radiologic technologists involved in the operation of CT systems.

(a) *Initial qualifications.* Before beginning to perform CT examinations independently, the technologist shall:

- (i) Be currently registered by the American registry of radiological technologists (ARRT); and
- (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.* The technologist shall be in compliance with the ARRT requirements for continuing education appropriate to his or her practice needs, which are 24 credits in a 2-year period.

R325.5709. Medical physicist.

Rule 709. Each registrant with one or more CT systems 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 the following:

(a) *Initial qualifications.*

- (i) Be certified in diagnostic radiological physics or radiological physics by the American board of radiology or by the Canadian college of physics in medicine; or
- (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 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.

(b) *Initial Experience.* Have 3 years documented experience in a clinical CT environment.

(c) *Continuing experience.* Following the second anniversary date of when the requirements of subrules (a) and (b) of this rule were completed, the medical physicist shall have surveyed at least 2 CT units in the prior 24-month period.

(d) *Continuing education.* Following the third anniversary date in which the requirements of subrules (a) and (b) of this rule were completed, the medical physicist shall have earned at least 15 continuing medical education units in CT, at least half of which shall be category I, in the prior 36-month period.

Rule 710. Record retention for personnel.

Rule 710. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the department. Records of personnel no longer employed by the facility should not be discarded until the next inspection has been completed and the department has determined that the facility is in compliance with the CT personnel requirements.

R325.5711. Equipment requirements.

Rule 711. (1) The regulations 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 and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

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

R325.5713. Quality control program.

Rule 713. (1) A quality control program shall be established and implemented under the supervision of the medical physicist.

(2) Initial performance testing of the CT system shall be completed by the medical physicist before use on human patients.

(3) Measurements of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated within the preceding 24 months and the calibration shall be traceable to a national standard. During the calendar year in which the dosimetry system is not calibrated, an inter-comparison to a system calibrated within the previous 12 months shall be performed.

R325.5715. Annual medical physicist evaluation.

Rule 715. (1) The performance of each CT machine shall be evaluated by the medical physicist at least annually. This evaluation should include the following:

- (a) Alignment light accuracy
- (b) Alignment of table to gantry
- (c) Table/gantry tilt
- (d) Slice localization from scanned projection radiograph
- (e) Table increment accuracy
- (f) Slice thickness
- (g) Image quality
 - (i) High-contrast resolution
 - (ii) Low-contrast resolution

- (iii) Image uniformity
- (iv) Noise
- (v) Artifact evaluation
- (h) CT number accuracy and linearity
- (i) Display devices
 - (i) Video display
 - (ii) Hard-copy display
- (j) Dosimetry
 - (i) Dose indicator such as computed tomography dosimetry index (CTDI)
 - (ii) Patient radiation dose for representative examinations
- (k) Safety evaluation
 - (i) Visual inspection
 - (ii) Audible/visual signals
 - (iii) Posting requirements
 - (iv) Scattered radiation measurements
- (l) Review of the continuous quality control program

(2) The medical physicist shall prepare a survey report that includes a summary of this evaluation and recommendations for necessary improvements. The report shall include the type and date of the last calibration or inner comparison of the dosimetry system used.

(3) The survey report shall be sent to the facility within 30 days of the date of the survey and shall be maintained on file by the facility for a period of at least 5 years. Copies of the survey report shall be made available to the department for review.

R325.5717. Continuous quality control.

Rule 717. (1) The CT facility shall establish a continuous quality control program with the assistance of the medical physicist. The medical physicist shall determine the frequency of each test and who should perform the test. An on-site radiological technologist should be identified to be responsible for conducting routine quality control.

(2) The quality control tests shall be performed in accordance with written procedures and methods. If the results of a quality control test fall outside of the control limits, corrective action shall be taken.

(3) The continuous quality control testing should include the following:

- (a) Image quality
 - (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) Display devices

(4) Records of the results from the continuous quality control program shall be maintained on file at the facility for a period of at least 2 years.

R325.5721. Facility design requirements

Rule 721. (1) A CT equipment enclosure shall be in compliance with the requirements of R325.5331.

(2) The operator shall be able to operate the equipment from a shielded position.

(3) Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(4) 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.

(5) If the primary viewing system is by electronic means and that system stops functioning properly, the system must be replaced or paired before any further examinations are performed.

R325.5723. Surveys.

Rule 723. (1) All CT x-ray systems installed after *[insert effective date of the regulations]* shall have a survey as defined in R325.5221 made initially before use on human patients. Those systems not previously surveyed shall have a survey made within one year of *[insert effective date of the regulations]*. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. The surveys required by this subrule shall be made by, or under the direct supervision of, a medical physicist.

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