

ICACTL STANDARDS FOR COMPUTED TOMOGRAPHY (CT) LABORATORY OPERATIONS

PART I

ORGANIZATION

These standards list the requirements and recommendations for laboratories performing diagnostic CT examinations. **All absolute requirements appear in bolded text.**

SECTION 1

Personnel and Supervision

STANDARD - Medical Director(s)

1.1 The Medical Director must be a licensed physician and ABMS board certified in a relevant specialty.

1.1.1 Medical Director Required Training and Experience:

The Medical Director must meet at least one of the following criteria:

A) **Cardiac CT** - Completion of Level 2 or equivalent training meeting ACCF/AHA/ACP guidelines 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

B) **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

C) **Established Practice** – A physician who has been interpreting computed tomography studies for at least five years, has acquired 150 hours Category I CME and has interpreted a minimum of 500 computed tomography examinations relative to the organ system (s) with self attestation.

AND

40 hours of CT relevant CME, a portion of which are in radiation safety. The majority of the 40 hours should be Category I. If 15 of the 40 hours are within 3 years the CME requirement in 1.1.3 will be considered met.

1.1.2 Medical Director Responsibilities:

- 1.1.2.1 The Medical Director is responsible for all clinical services provided and for the determination of the quality and appropriateness of care provided.**
- 1.1.2.2** The Medical Director may supervise the entire operation of the laboratory or may delegate specific operations to associate medical directors, medical staff and the Technical Director.
- 1.1.2.3 The Medical Director is responsible for arranging for qualified providers in the absence of medical staff for contrast administration, drug administration and patient and staff safety.**
- 1.1.2.4 The Medical Director is responsible for assuring compliance of the medical and technical staff to the standards outlined in this document and the supervision of their work.**
- 1.1.2.5 The Medical Director must be an active participant in the interpretation of examinations performed in the laboratory. If not generating final reports, the medical director must provide documentation of review and acceptance, or amendment of findings.**
- 1.1.2.6 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 C 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.**

1.1.3 Continuing Medical Education (CME) Requirements:

- A) The Medical Director must document at least 15 hours of Category I AMA CME credits in CT over a period of three (3) years.**
- B) Yearly accumulated continuing education must be kept on file and available to the ICACTL, when requested.**

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

STANDARD - Technical Director

1.2 The Technical Director must be a qualified CT technologist or a physician as described in 1.2.1 C.

Note: In a laboratory with no technologists, the Medical Director or a member of the medical staff may serve as Technical Director. In this case, in addition to submitting the Medical Director or Medical staff forms, they must also submit all forms required for the Technical Director including documentation of radiation safety and scanner training. Effective January 1, 2011 all technical directors must be qualified imaging technologists.

A qualified Technical Director (i.e.: supervisor, chief technologist, manager, etc.) is designated for the laboratory.

The Technical Director must have appropriate training, technical certification as noted and documented experience in the field of computed tomography imaging.

1.2.1 Technical Director Required Training and Experience:

The Technical Director must meet ONE OF the following criteria:

A) 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

B) An appropriate credential in another medical imaging field as well as 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

C) A qualified licensed physician may operate a dedicated limited use CT scanner (i.e. [volume or cone beam](#)) if that person has received a minimum of at least 3 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 (4) hours of documented, specific training in the operation of the scanner.

The Technical Director, [including a physician technical director](#), **must** have an appropriate imaging credential for CT as outlined in 1.2.1 A and/or B by January 1, 2011.

1.2.2 Technical Director Responsibilities:

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

- 1.2.2.1 All laboratory duties delegated by the Medical Director**
- 1.2.2.2 Performance of CT examinations in the laboratory**
- 1.2.2.3 Supervision of the technical staff and/or ancillary staff, if applicable**
- 1.2.2.4 The delegation, when warranted, of specific responsibilities to the technical staff and/or the ancillary staff
- 1.2.2.5 Daily technical operation of the laboratory (e.g.: laboratory record keeping, calibration log, quality assurance, scanning protocols, etc.)**
- 1.2.2.6 Operation and maintenance of laboratory equipment**
- 1.2.2.7 The compliance of the technical staff to the ICACTL *Standards* outlined within this document**
- 1.2.2.8 Working with the Medical Director, medical staff and technical staff to ensure quality patient care**
- 1.2.2.9 Technical training, if applicable**
- 1.2.2.10 Monitoring radiation safety**

1.2.3 Continuing Education Requirements:

- A) The Technical Director must document at least 15 hours of Category I AMA or RCEEM approved CT related continuing education over a period of three (3) years.**
- B) Yearly accumulated continuing education must be kept on file and available to ICACTL, when requested.**

Comment: If the Technical Director has successfully acquired an appropriate credential within the past three (3) years, the continuing education requirement will be considered fulfilled.

STANDARD - Medical Staff

1.3 All members of the medical staff must be licensed physicians and **ABMS** board certified in a relevant specialty.

1.3.1 Medical Staff Required Training and Experience:

The Medical Staff must meet **ONE OF** the following criteria:

A) **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

OR

B) **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

C) **Established Practice** – A physician who has been interpreting computed tomography studies for at least five years, has acquired 150 hours Category I CME with at least 40 hours relevant to CT, a portion of which are in radiation safety and has interpreted a minimum of 500 computed tomography examinations relative to the organ system(s) with self attestation.

1.3.2 Medical Staff Responsibilities:

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.**

1.3.3 Continuing Medical Education (CME) Requirements:

A) **The medical staff must document at least 15 hours of Category I AMA CME credits in CT over a period of three (3) years.**

B) **Yearly accumulated continuing education must be kept on file and available to the ICACTL, when requested.**

Comment: If the Medical staff has completed training or certification as specified under 1.3.1(A or B) in the past three years, the CME requirement will be considered fulfilled.

STANDARD - Technical Staff

1.4 All members of the technical staff must be qualified imaging technologists.

Note: In a laboratory with no technologists, the Medical Director or a member of the medical staff may serve as Technical Director or technical staff. In this case, in addition to submitting the Medical Director or Medical staff forms, they must also submit all forms required for the Technical Director including documentation of radiation safety and scanner training. Effective January 1, 2011 all technical directors must be qualified imaging technologists.

1.4.1 Technical Staff Required Training and Experience:

All members of the technical staff must meet ONE OR MORE of the following criteria:

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

OR

B) An appropriate credential in another medical imaging field (i.e.: CNMT, RT (MR), RT).

OR

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

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

OR

D) A qualified licensed physician may operate a dedicated limited use CT scanner (i.e. volume or cone beam scanner) if that person has received a minimum of at least 3 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 (4) hours of documented, specific training in the operation of the scanner.

- E) An individual who is an employee of the laboratory for the purpose of performing CT imaging and does not meet at least one of the above criteria will be considered a “trainee”. The number of trainees must not exceed the number of technical staff members and all trainees must be under direct supervision of a credentialed technologist.

1.4.2 Technical Staff Responsibilities:

- 1.4.2.1 The technical staff member(s) reports to the Technical Director. The technical staff member(s) assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical CT examinations and other tasks assigned.

1.4.3 Continuing Education Requirements:

- A) The technical staff must document at least 15 hours of Category I AMA or RCEEM approved CT related continuing education over a period of three (3) years.**
- B) Yearly accumulated continuing education must be kept on file and available to ICACTL, when requested.**

Comment: If the technical staff member has successfully acquired an appropriate CT credential within the past three (3) years the continuing education requirement will be considered fulfilled.

STANDARD – Medical Physicist or Qualified Expert

1.5 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. 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.

- 1.5.1 Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist or qualified expert in the collection of data.

STANDARD –Supervising Personnel for Contrast **and/or Medication Administration**

1.6 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:**

- 1.6.1 Are knowledgeable of patient preparation, and training in the recognition/treatment of adverse effects of contrast materials for these studies.
- 1.6.2 Are responsible for supervising the use, dosage, and rate of administration of contrast agents, per the laboratory’s protocol.
- 1.6.3 Possess familiarity with radiation safety, and the conscious sedation policies and procedures (if used) that are performed relative to CT.
- 1.6.4 Are responsible for supervising the administration of beta-blockers, nitrates, and/or other cardio active and/or other medications per the laboratory’s protocol.

STANDARD - Support Services

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

1.7.1 Supervision:

1.7.1.1 The Medical Director must ensure that appropriate support services are provided in the best interest of patient care.

1.7.2 Support Services:

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

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

1.7.2.3 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 2

Physical Facilities

(Laboratory Space)

STANDARD - Examination Areas

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

2.1.1 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.

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

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

2.1.1.3 Direct visualization of the patient is available through a leaded glass window, while protecting the personnel from radiation exposure.

2.1.1.4 Adequate space post testing is available for patient observation, as indicated clinically.

Note: All examinations, regardless of the location, must be performed with adequate room for patient positioning and equipment use.

STANDARD - Interpretation and Storage Space

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

Space should be provided for data evaluation, interpretation, and discussion of the study with the technologist and/or referring physician, as needed. **Space permitted for storage of records and supplies must be sufficient for the patient volume of the laboratory.**

SECTION 3

Examination Data Archiving, Examination Reports, and Laboratory Records

STANDARD - CT Examination Data

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

- 3.1.1 A system for recording and archiving CT data (images, measurements and final reports) obtained for diagnostic purposes must be in place.**
- 3.1.2 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 multiplanar reformatting.**
- 3.1.3 Archiving media must include loss-less digital storage and a system for long-term, off-line digital storage.**

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

- 3.2.1 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. A record of the communication should be maintained.**
- 3.2.2 If preliminary results are provided by an interpreting physician, the final report should be generated within two working days. A mechanism for communicating any significant changes must be defined for those situations in which the final interpretation differs significantly from the preliminary report.**
- 3.2.3 CT examinations must be interpreted and reported by the Medical Director or by a member of the medical staff of the CT laboratory. Final physician interpretations of routine CT examinations must be available within two working days.**

Comment: An interpretation can be in the form of paper, digital storage or an accessible voice system. The final verified, signed report must be available in a timely fashion, generally within four working days.

SECTION 4 Laboratory Safety and Patient Confidentiality

STANDARD - Laboratory Safety

4.1 Patient and employee safety is ensured by written policies and procedures, approved by the Medical Director.

- 4.1.1 All CT laboratory professionals must have an understanding of the radiation exposure involved in CT to advise patients who may be undergoing CT imaging.**
- 4.1.2 Radiation dose for CT acquisition should be set at the lowest values that are consistent with satisfactory image quality for the study ordered.**
- 4.1.3 There must be at least one BLS certified staff member on site for all CT exams.**
- 4.1.4 Standard CT examinations must be safe to both patients and technologists. Because CT procedures pose potential risks to the safety of the patient due to radiation exposure, the use of contrast, and in some cases, cardiac medications, the laboratory must have a written procedure in place for handling acute medical emergencies. A CT laboratory providing CT procedures with contrast, exams with drug administration and/or exams with sedation must have the following emergency supplies readily available:**
 - 4.1.4.1 Posting of emergency phone number(s)**
 - 4.1.4.2 [An Automated External Defibrillator \(AED\)](#) or a fully equipped cardiac arrest cart (crash cart)**
 - 4.1.4.3 Equipment for starting and maintaining intravenous access**
 - 4.1.4.4 Oxygen tank or wall mounted oxygen sources with appropriate cannulae and/or masks.**
 - 4.1.4.5 Personnel trained and available to use the above emergency equipment**

- 4.1.5 The laboratory must meet the standards set forth by the Occupational Safety and Health Administration (OSHA) and by The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), where applicable.**
- 4.1.6 The laboratory should comply with the ALARA recommendations of the Radiological Society of North America. The use of higher than recommended radiation doses should be justified. For pediatric patients, protocols must be modified to reduce radiation exposure, where appropriate or possible.**
- 4.1.7 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.**
- 4.1.8 Staff radiation exposure must be monitored, and reviewed by the QA Committee. The results must be communicated to the staff member.**
- 4.1.9 There must be restriction of the public to radiation areas.**
- 4.1.10 All laboratories conducting contrast-enhanced studies should be equipped with remote infusion devices.**
- 4.1.11 Laboratory layout must allow for visual and audio monitoring of the patient.**
- 4.1.12 A policy for documentation of adverse events must be in place.**

STANDARD - Patient Confidentiality

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

SECTION 5

Multiple Sites and Mobile Services

STANDARD – Multiple Sites

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

- 5.1.1 All facilities have the same Medical Director.
- 5.1.2 All facilities have the same Technical Director.
- 5.1.3 All CT examinations are interpreted by medical staff included in the application.
- 5.1.4 All facilities utilize the same medical physicist or qualified expert.
- 5.1.5 All CT examinations are performed by technical staff included in the application.
- 5.1.6 Technical and interpretive quality assessment, as outlined in Part II, Section 7, must be evaluated for all CT testing sites.

STANDARD – Mobile Service

5.2 A mobile service is comprised of one or more units (technologist and equipment) that provide CT testing services at one or more locations if all the following criteria are met:

Comment: Some laboratories provide only mobile services and do not have a primary site laboratory. These mobile service laboratories are required to complete the entire accreditation application.

- 5.2.1 The entire mobile service has the same Medical Director.
- 5.2.2 The entire mobile service has the same Technical Director.
- 5.2.3 All mobile CT examinations are interpreted by medical staff included in the application.
- 5.2.4 All facilities utilize the same medical physicist or qualified expert.
- 5.2.5 All mobile CT examinations are performed by CT technical staff included in the application.
- 5.2.6 CT scanners that are used in a mobile setting must meet the same instrument quality assurance standards as described for fixed scanners in Part II, Section 2.
- 5.2.7 Technical and interpretive quality assessment as outlined in Part II, Section 7 must be evaluated for all CT testing performed by the mobile service.

Bibliography:

- “ACR Practice Guideline for the Use of Intravascular Contrast Media.” In: Practice Guidelines and Technical Standards. *JACR* 2005; 21-25.
- “American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance: a report of the American College of Cardiology Foundation/American Heart Association /American College of Physicians Task Force on Clinical Competence and Training.” Budoff MJ, Cohen MC, Garcia MJ, et al. *JACC* 2005 Jul 19; 46(2): 283-402.
- “Radiation Protection in Humans: Extending the Concept of as Low As Reasonably Achievable (ALARA) from Dose to Biological Damage.” Prasad KN, Cole WC, Haase GM. *Br J Radiol.* 2004 Feb 7; 914: 97-9.
- “Radiation Safety in Cardiology.” Limacher MC, Douglas PS, Germano G, et al.; *JACC* 1998 Mar 15; 31(4): 892-913.
- “Reference Values for Diagnostic Radiology: Application and Impact.” Gray JE, Archer BR, Hobbs BB, Mettler FA, et al. *Radiology*, 2005; 235: 354-358.

Appendix:

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ACCF/AHA Clinical Competence Statement on Cardiac CT and MR

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	