

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, acute stroke brain, spine]
- maxillofacial CT [sinus, temporal bone, facial bone, orbits, mandibular]
- body CT [soft tissue neck, chest (non-coronary), low dose CT (LDCT) lung cancer screening, abdomen, pelvis, extremity]
- vascular CTA [neurovascular (including carotids), chest (non-coronary), abdomen, pelvis, peripheral/extremity]

Note: Facilities that only provide whole body CT screening examinations are not eligible to apply for IAC CT accreditation.

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.*

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable.

Facilities are encouraged to <u>contact the IAC</u> for guidance related to utilization of new technology not currently addressed in the IAC Standards.

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

Standards that are highlighted are content changes that were made as part of the August 15, 2023 revision. These Standards become effective immediately. Facilities applying for accreditation after August 15, 2023 must comply with these new highlighted Standards.

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.

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD - Medical Director

1.1A The Medical Director must be a current, state licensed physician (from the state or province in which the facility is located) and certified by the American Board of Medical Specialties (ABMS), the American Board of Podiatric Medicine (ABPM) or the American Board of Podiatric Surgery (ABPS) in a relevant specialty, or board certified in a relevant specialty recognized by the American Osteopathic Association (AOA), the American Podiatric Medical Association (APMA) or the 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 of the American College of Cardiology Foundation (ACCF) / American Heart Association (AHA) / American College of Physicians (ACP) guidelines (See Appendix) for cardiovascular CT with Society of Cardiovascular Computed Tomography (SCCT) letter of verification or a letter of verification from the program director and independent interpretation of at least 50 CT examinations.
- ii. Diplomat of the Certification Board of Cardiovascular Computed Tomography (CBCCT) or Certificate of Advanced Proficiency (CoAP) in Cardiac CT offered through the American College of Radiology (ACR).

1.1.1.2A Formal Training CT

i. 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 or courses relevant to the specialty with a letter of verification from the program director of the CT classes or courses and independent interpretation of at least 50 CT examinations.

1.1.1.3A Established Practice

i. A physician, who has been interpreting CT examinations 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

1.1.1.4A For all training and experience pathways listed above, the CME acquired over the course of their career must include 40 hours of CT relevant CME.

(See Guidelines on Page 13 for further recommendations.)

1.1.2A <u>Medical Director Responsibilities</u>

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 CT examinations performed in the facility;
- 1.1.2.6A the Medical Director, in consultation with the medical physicist and/or qualified expert, may delegate the operation of a cone beam 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 CME 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 must be a nationally registered radiologic technologist with an appropriate, current credential. A current, state-licensed physician (i.e., for the state or province in which the facility is located) can be a Technical Director to operate the specific types of cone beam CT units described in Standard 1.2.2A. The Technical Director must have appropriate training, technical certification (as noted) and documented experience in the field of 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 <u>Technical Director Required Training and Experience</u>

The Technical Director must meet the following criteria of Standard 1.2.1.1A or 1.2.1.2A to

perform CT imaging on any CT unit (i.e., single slice, multi-detector, electron beam and cone beam CT units) for any of the IAC CT testing areas:

- 1.2.1.1A A current American Registry of Radiologic Technologists (ARRT) or Canadian Association of Medical Radiation Technologists (CAMRT) certification in computed tomography imaging (i.e., ARRT(R) (CT)).
- 1.2.1.2A A nationally registered radiologic technologist with a current credential in another medical imaging field to include radiation safety training (i.e., CNMT, ARRT(R), ARRT (R)(MR)).

AND

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

- 1.2.2A A Technical Director that does not meet the training pathways as outlined in Standard 1.2.1.1A or 1.2.1.2A can perform CT imaging on a maxillofacial cone beam CT unit or on an extremity cone beam CT unit that specifically will only perform foot/ankle (e.g., podiatry) CT imaging, per the training pathways listed below:
 - 1.2.2.1A A current, state-licensed physician that has received:
 - i. a minimum of three hours of documented, specific training in radiation safety provided by a medical physicist or qualified expert;

AND

- ii. a minimum of four hours of documented, specific training in the operation of each cone beam CT unit at the facility, provided by the CT unit manufacturer; or by a technical staff member at the facility that has documentation of training provided by the CT unit manufacturer.
- 1.2.2.2A A nationally registered radiologic technologist with a current credential in another medical imaging field to include radiation safety training (i.e., ARRT RT (R)) that has received:
 - i. A minimum of four hours of documented, specific training in the operation of each cone beam CT unit at the facility provided by the CT unit manufacturer; or by a technical staff member at the facility that has documentation of training provided by the CT unit manufacturer.

1.2.3A <u>Technical Director Responsibilities</u>

- 1.2.3.1A 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.

1.2.4A Continuing Education (CE) Requirements

- 1.2.4.1A 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, as requested.

Comment: If the Technical Director has successfully acquired an appropriate CT credential from national registry (e.g., ARRT CT) within the past three years, the CE requirement will be considered fulfilled.

STANDARD - Medical Staff

1.3A All members of the medical staff must be current, state-licensed physicians (for the state or province in which the facility is located) and certified by the American Board of Medical Specialties (ABMS), the American Board of Podiatric Medicine (ABPM) or the American Board of Podiatric Surgery (ABPS) in a relevant specialty, or board certified in a relevant specialty recognized by the American Osteopathic Association (AOA), the American Podiatric Medical Association (APMA) or the Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Ouebec.

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

- i. Completion of Level 2 or equivalent training meeting of the 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)
- ii. Diplomat of the Certification Board of Cardiovascular Computed Tomography (CBCCT) or Certificate of Advanced Proficiency (CoAP) in Cardiac CT offered through the American College of Radiology (ACR).

1.3.1.2A Formal Training CT

i. 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 or courses relevant to the specialty, a portion of which are in radiation safety, with a letter of verification from program director of the CT classes or courses.

1.3.1.3A Established Practice

i. A physician who has been interpreting CT examinations for at least five years, has acquired a minimum of 150 hours Category I CME, 40 hours of which are CT related (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.

(See Guidelines on Page 13 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 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 <u>Continuing Medical Education (CME) Requirements</u>

- 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.
 - Yearly accumulated CME 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 technical staff members must be current, nationally registered radiologic technologists. A current, state-licensed physician or mid-level medical provider (i.e., for the state or province in which the facility is located) can be a technical staff member to perform the specific types of cone beam CT units listed in Standards 1.4.2.1A, 1.4.2.2A, or 1.4.2.3A. The technical staff members must have appropriate training, technical certifications (as noted), and documented experience in the field of CT imaging.

1.4.1A Technical Staff Required Training and Experience

All members of the technical staff must meet Standard 1.4.1.1A or 1.4.1.2A to perform CT imaging on any CT unit (i.e., single slice, multi-detector, electron beam, and cone beam CT units) for any of the IAC CT testing areas:

- 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., ARRT(R) ARRT(CT)).
- 1.4.1.2A A nationally registered radiologic technologist with a current credential in another medical imaging field to include radiation safety training (i.e., CNMT, ARRT(R), ARRT(R)(MR)).

- 1.4.2A Technical staff members that do not meet the training pathways as outlined in Standard 1.4.1.1A or 1.4.1.2A can perform CT imaging on a maxillofacial cone beam CT unit or on an extremity cone beam CT unit that specifically will only perform foot/ankle (e.g., podiatry) CT imaging per the training pathways of Standard 1.4.2.1A, 1.4.2.2A or 1.4.2.3A:
 - 1.4.2.1A A current, state licensed physician that has received:
 - i. a minimum of three hours of documented, specific training in radiation safety provided by a medical physicist or qualified expert;

AND

- ii. a minimum of four hours of documented, specific training in the operation of each cone beam unit at the facility provided by the CT unit manufacturer; or can be provided by a Technical Director or technical staff member at this facility that has documentation of training provided by the CT unit manufacturer.
- 1.4.2.2A A nationally registered radiologic technologist with a current credential in another medical imaging field to include radiation safety training (i.e., ARRT RT (R)) that has received:
 - i. a minimum of four hours of documented, specific training in the operation of each cone beam CT unit at the facility provided by the CT unit manufacturer; or by a technical staff member at the facility that has documentation of training provided by the CT unit manufacturer.
- 1.4.2.3A The mid-level medical providers (i.e., physician assistant (P.A.) or certified registered nurse practitioner (CRNP)) operating cone beam CT scanners that have received:
 - i. current PA or CRNP state license for the state in which the facility is located:
 - ii. a minimum of three hours of documented specific training in radiation safety provided by a medical physicist or qualified expert;
 - iii. a minimum of four hours of documented, specific training in the operation of each cone beam CT unit at the facility provided by the CT unit manufacturer; or by a technical staff member at the facility that has documentation of training provided by the CT unit manufacturer;
 - iv. three months of clinical experience performing volume or cone beam CT examinations under the supervision of a qualified physician;
 - v. a minimum of 50 clinical examinations performed;
 - vi. a letter from the current Medical Director or Technical Director verifying the training, experience, and competency specific to the operation of the volume or cone beam CT scanner.

Comment: This training and experience pathway is not applicable for states that have requirements for all radiographic examinations to be performed by state licensed radiologic technologists.

1.4.3A <u>Technical Staff Responsibilities</u>

Technical staff responsibilities include but are not limited to:

1.4.3.1A reports to the Technical Director; and

1.4.3.2A assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical CT examinations and other tasks assigned.

1.4.4A <u>Continuing Education (CE) Requirements</u>

- 1.4.4.1A 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 CE 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 from a national registry (e.g., ARRT CT) within the past three years, the CE 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 (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Physicists in Medicine (CCPM) in a discipline that includes diagnostic imaging.

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

1.5.1A Medical Physicist or Qualified Expert 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 CE 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 13 for further recommendations.)

Section 1A: Personnel and Supervision Guidelines

1.1.1A <u>Medical Director Required Training and Experience</u>

The majority of the 40 required CME hours should be Category I.

1.3.1A <u>Medical Staff Required Training and Experience</u>

The majority of the 40 required CME hours should be Category I.

1.7A 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.
 - 2.1.2A Patient privacy must be assured with the use of appropriate curtains or doors.
 - 2.1.3A A sink and antiseptic soap must be readily available and used for hand washing in accordance with the infection control policy of the facility.
 - 2.1.4A Direct visualization and audible monitoring of the patient must be available through a leaded glass window, while protecting the personnel from radiation exposure.
 - 2.1.5A 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 below 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. 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.

(See Guidelines on Page 17 for further recommendations.)

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.

(See Guidelines on Page 17 for further recommendations.)

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.

(See Guidelines on Page 17 for further recommendations.)

- 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 within four working days after the date of the performance of the CT examination.
- 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 All final reports must be in an electronic or completely typewritten format. The interpreting physician's signature date of the signature must be in electric format or handwritten when electronic format is not available.
 - 3.3.2A The final report must accurately reflect the content and results of the CT examination. The report must include, but is not limited to:
 - 3.3.2.1A Patient information:
 - i. the patient's name and/or identification (e.g., medical record number);

- ii. the patient's date of birth and/or age;
- iii. the patient's clinical indication that leads to the performance of CT examination.
- 3.3.2.2A An adequate description of the CT examination performed that includes the:
 - i. title (name) of the CT examination;
 - ii. date of the CT examination;
 - iii. imaging protocol (e.g., techniques) used in the CT examination;
 - iv. specific type (brand name) and amount of intravenous contrast administered, if used;
 - v. details of drug and/or medication administration (include the name, dose, administration, and route), if used; and
 - vi. quality of the images if there is sub-optimal image quality.
- 3.3.2.3A The comprehensive findings / overview of the results of the CT examination including pertinent findings.

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

For LDCT Lung Screening exams, the interpretation report must utilize a standardized lung nodule identification, classification and reporting system. Refer to the <u>Low Dose CT Lung Cancer Screening Appendix</u> for details.

- 3.3.2.4A A summary of the comprehensive findings.
- 3.3.2.5A Physician signature line that contains the typewritten name of the interpreting physician.
- 3.3.2.6A The final report must be reviewed and finalized (signed and dated) manually or electronically by the interpreting physician. Stamped signatures or signatures by non-physician staff are not acceptable.
 - i. If the report is signed manually by the interpreting physician, the date of the signature must also be manually recorded on the report with the signature.
 - ii. If the report is electronically signed and dated by the interpreting physician, the electronic signature and electronic date of signature must be clearly labeled that it is an electronic signature and electronic date of signature.
 - If the facility has a process or reports to be electronically signed, the process for electronic signature by the interpreting physician must be password protected to ensure security of report completion.

(See Guidelines on Page 17 for further recommendations.)

Section 3A: Examination Reports and Records *Guidelines*

- 3.1.2A Critical reconstructed CT data should be readily retrievable for comparison with new examinations.
- 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.
- 3.3.2A In addition to the requirements, it is recommended that the final report include:
 - documentation of dose reduction technique if used (e.g., prospective gating, low energy and/or dose modulation) is recommended in the report;
 - details of any non-standard patient preparation or treatment, if required, should be included in the final report;
 - appropriate recommendation for follow up of incidental findings;
 - the reasons for limited examinations (if performed); and
 - comparison with previous studies (if available).

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 20 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 20 for further recommendations.)

- 4.1.2A There must be at least one Basic Life Support (BLS) (i.e., cardiopulmonary resuscitation (CPR), Advanced Cardiac Life Support (ACLS) or certified staff member on site for all CT examinations
- 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 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 imaging 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 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 technical or medical staff member 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.

(See Guidelines on Page 20 for further recommendations.)

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 below 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 intersocietal.org/helpful-resources/sample-documents-repository.

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 <u>intersocietal.org/legal/policies-procedures</u>.

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 <u>Coronary Calcium Scoring</u> 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 <u>Coronary Computed Tomography Angiography (CTA)</u> 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 <u>Vascular CTA</u> 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 CT scanners that will be used for neurological imaging (brain, acute stroke brain, spine) must meet the following minimum specifications:
 - i. Single or multi-detector CT systems
 Comment: ≤ 0.5 sec rotation speed is recommended.
 - ii. FDA-approved Cone Beam CT (CBCT) unit only for the performance of a brain CT examinations.
- 1.1.2.5B <u>Maxillofacial CT</u> CT scanners that will be used for maxillofacial imaging (sinus, temporal bone, facial bone, orbits, mandible) 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 <u>Body CT</u> CT scanners that will be used for body imaging (soft tissue, neck, chest [non-coronary], abdomen, pelvis, extremities and LDCT lung cancer screening), must meet the following minimum specifications:
 - i. Single, electron beam or multi-detector CT systems Comment: ≤ 2 sec rotation speed is recommended.
 - ii. FDA-approved cone beam CT unit only for performance of extremity examinations.
- 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:

- 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 <u>Vascular CTA</u> (abdomen, pelvis, chest [non-coronary], neurovascular [including carotids] and peripheral vascular):
 - 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 <u>Neurological CT</u> (brain, acute stroke brain, spine):
 - i. must be capable of image processing appropriate to the imaging task.
- 1.1.3.5B <u>Maxillofacial CT</u> (sinus, temporal bone, facial bone, orbits, mandible):
 - i. must be capable of image processing appropriate to the imaging task.
- 1.1.3.6B <u>Body CT</u> (soft tissue neck, chest [non-coronary], abdomen, pelvis, extremities and LDCT lung cancer screening):
 - 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 the capability to display data in standard contrast settings (lung field, bone, chest, etc.);
 - 1.1.4.4B must have the 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 28 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 on Pages 43-45).
 - 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 radiation shielding design prior to the installation of each new CT unit to ensure that occupational workers and members of the public are shielded according to NCRP Report 147, state regulation, or other equivalent industry standards.

- 1.2.4B A Radiation Protection Survey must be performed by a medical physicist or qualified expert after the CT unit was installed. A Radiation Protection Survey must also be performed by a medical physicist or qualified expert if the CT unit is relocated within the CT room or to a different room, or if the actual workload changes by more than a factor of two from the workload that was used for the Radiation Protection Survey. The Radiation Protection Survey must include:
 - 1.2.4.1B 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 outline of) the CT unit room;
 - 1.2.4.2B determination of weekly workload (mAs per scan x # patients per week) or some other acceptable methodology;
 - 1.2.4.3B occupancy factors specified for surrounding areas;
 - 1.2.4.4B calculation of weekly exposure to persons inside and outside of the room, corrected for occupation factor.
- 1.2.5B Dose and image quality review of representative exams as compared to professional standards must be performed.

(See Guidelines on Page 28 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. The routine operator QC tests may be performed as specified by the CT manufacturer (e.g., daily, weekly, or monthly). If no test frequencies are specified by the CT manufacturer, the medical physicist or qualified expert should specify which QC tests must be performed at least once a month to confirm the CT unit image quality.
 - 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 on Pages 43-45).
 - 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 incrimination 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

- 1.5B 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.

safety analysis including an inspection of audible and visual equipment.

(See Guidelines on Page 28 for further recommendations.)

STANDARD – Quality Control Documentation

1.4.2.11B

- 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 28 for further recommendations.)

Section 1B: Instrumentation and Equipment *Guidelines*

- 1.1.4B If images are transmitted to another location for interpretation, the original resolution should be maintained.
- 1.2B The CT site-appointed medical physicist or qualified expert should perform the acceptance testing.
- 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 31 for further recommendations.)

STANDARD – Indications, Ordering Process and Scheduling

2.2B CT testing is performed for appropriate indications.

Note: Facilities that only provide whole body CT screening examinations are not eligible to apply for IAC CT accreditation.

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.

Comments: For patients presenting with acute stroke symptoms refer to the <u>Acute Stroke Appendix</u>. In addition to compliance with all Standards requirements, all patients referred for LDCT screening examinations must meet the CMS "Beneficiary Eligibility Criteria." Refer to the <u>Low Dose CT Lung Cancer Screening Appendix</u> for details.

- 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.

Comment: In addition to compliance with all Standards requirements, all patient orders (requests) for LDCT lung screening exams must state lung cancer screening with LDCT and meet the CMS requirements for LDCT lung cancer screening examinations. Refer to the *Low Dose CT Lung Cancer Screening Appendix* for details.

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;
 - xiii. representative exposure or dose as recorded by the CT system.

Section 2B: Protocols Guidelines

2.18 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 The facility must have a written QI program for all imaging procedures. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:
 - 1.1.1C test appropriateness;
 - 1.1.2C technical quality and safety of the imaging;
 - 1.1.3C interpretive quality review;
 - 1.1.4C report completeness and timeliness; and
 - 1.1.5C radiation safety.

(See Guidelines below for further recommendations.)

1.2C The Medical Director, staff and/or an appointed QI Committee must provide oversight to the QI program including but not limited to review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.

(See Guidelines below for further recommendations.)

1.3C 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.

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 Facilities are required to have a process in place to evaluate the QI measures outlined in 2.1.1C through 2.1.5C.
 - 2.1.1C <u>Test Appropriateness</u>: The facility must evaluate the appropriateness of the test performed based on criteria published and/or endorsed by professional medical organizations (if available) and categorize as:
 - 2.1.1.1C appropriate/usually appropriate;
 - 2.1.1.2C may be appropriate; or
 - 2.1.1.3C rarely appropriate/usually not appropriate.

(See Guidelines on Page 34 for further recommendations.)

- 2.1.2C <u>Technical Quality Review</u>: The facility must evaluate the technical quality of the images and the safety of the procedure. The review of the clinical image quality must include but is not limited to the evaluation of:
 - 2.1.2.1C review of the clinical images for clarity of the images and/or evaluation for suboptimal images or artifact;
 - 2.1.2.2C completeness of the study;
 - 2.1.2.3C adherence to the facility imaging acquisition protocols; and
 - 2.1.2.4C patient and facility safety (see Section 4A: Facility Safety).

(See Guidelines on Page 34 for further recommendations.)

2.1.3C <u>Interpretive Quality Review</u>: The facility must evaluate the quality and accuracy of the interpretation based on the acquired images.

(See Guidelines on Page 34 for further recommendations.)

- 2.1.4C <u>Final Report Completeness and Timeliness</u>: The facility must evaluate the final report for completeness and timeliness as required in the Standards.
- 2.1.5C Radiation Safety:
 - 2.1.5.1C The facility must evaluate patient radiation dose to include:
 - i. documentation of dosimetry data ranges (DLP; CTDI vol or dose (mGy) per sequence or cumulative per examination) for protocols used in the facility based on patient age and habits;
 - ii. comparison of the patient radiation dose for each imaging protocol as determined by a medical physicist or qualified expert; and
 - iii. tracking of repeat CT examinations.
 - 2.1.5.2C Each facility must document the available dose reduction techniques and clinical indications/contraindications for their use.
 - 2.1.5.3C The facility must review the results of staff occupational radiation exposure monitoring according to state regulations.

Section 2C: Quality Improvement Measures *Guidelines*

2.1.1C <u>Test Appropriateness</u>:

- A mechanism should be in place for education of referring physicians to improve the appropriateness of testing.
- A program for education and reporting should be developed and may include but is not limited to:
 - o patterns of adherence to Appropriate Use Criteria (AUC);
 - o baseline rates of adherence;
 - goals of improvement of adherence to AUC;
 - o measurement of improvement rate; and
 - o confidential comparison reports on patterns of adherence in aggregate by ordering physician, ordering practice and interpreting practice.

2.1.2C <u>Technical Quality Review</u>:

- Peer review may also be used to compare reproducibility.
- Physicians and technologists should be involved in the peer review process in order to achieve standardized protocols.
- Results of the 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.
- Thresholds should be determined for each indicator (e.g., a threshold for the percentage of scans that should be free from motion artifact=90%).

2.1.3C Interpretive Quality Review:

- Peer review may be used to compare reproducibility of interpretation with previous interpretation or with interpretation of the same study by other interpreting physicians.
- Physicians should be involved in the peer review process in order to achieve standardized 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.
- Clinical correlation and confirmation of results: For patients who have undergone CT examinations and surgical intervention or treatment, the results of the CT examination and other procedures may be compared. A process for reviewing variations between CT examination results and results of other procedures may be in place.

Section 3C: Quality Improvement Meetings

STANDARD - QI Meetings

- 3.1C The facility must have a minimum of two QI meetings per year.
 - 3.1.1C The content of at least one meeting per year must include the review of the results of the QI analyses.
 - 3.1.2C All staff must participate in at least one meeting per year.

Section 4C: Quality Improvement Documentation

STANDARD - QI Documentation

- 4.1C QI Documentation and Record Retention
 - 4.1.1C The facility QI documentation must include, but not be limited to:
 - 4.1.1.1C the data for all of the QI measures above;
 - 4.1.1.2C a description of how the QI information is used to improve CT quality; and
 - 4.1.1.3C minutes from the QI meetings.
 - i. Participant list (may include remote participation and/or review of minutes).
 - 4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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Appendix

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
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	Level 2- or 3-trained physician
Maintenance of competence	Contrast CCT examinations per year be performed and interpreted: Level 2: 50 Level 3: 100	

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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.

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.
- 9. The radiation dose for CT perfusion protocols should be evaluated to institute the lowest dose possible that still maintains appropriate diagnostic clinical imaging resolution.
- 10. References to articles related to therapeutic procedures (e.g., administration of t-PA) are included in the *Acute Stroke Bibliography*.
- ** The above guidelines are applicable to any CT study used to guide emergent treatment decisions.

Acute Stroke Bibliography

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 - Routine Pediatric Head CT www.aapm.org/pubs/CTProtocols/documents/PediatricRoutineHeadCT.pdf; and
 - Routine Adult Brain Perfusion www.aapm.org/pubs/CTProtocols/documents/AdultBrainPerfusionCT.pdf.

Low Dose CT Lung Cancer Screening Appendix

Requirements for CT Studies for Patients Presenting for Low Dose CT Lung Cancer Screening Examinations generated by CMS and listed on the CMS website: www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

Beneficiary eligibility criteria includes the items listed below:

- 1. All patients must be:
 - a. Between 50 and 77 years of age;
 - b. Asymptomatic (no signs or symptoms of lung disease);
 - c. Tobacco smoking history of at least 20 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
 - d. Current smoker or one who has quit smoking within the last 15 years.
- 2. All patients must have an order for Lung Cancer screening with LDCT.
- 3. The radiologist interpreting the LDCT lung cancer screening must have current certification with the American Board of Radiology or equivalent organization.
- 4. The interpretation report must utilize a standardized lung nodule identification, classification, and reporting system.

Low Dose CT Lung Cancer Screening Bibliography

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Medical Physicist or Qualified Expert Guidance Document

IAC CT Standard Requirements for the Medical Physicist or Qualified Expert:

Per the IAC Standards and Guidelines for CT Accreditation, Section 1.5.1A:

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 stateapproved to measure dose and evaluate image quality at CT scanning facilities, these credentials are acceptable to be submitted.

Radiation Safety Training Session Provided by a Medical Physicist or Qualified Expert:

If a medical physicist or qualified expert provides radiation safety training for facility staff members:

Documentation must confirm a minimum of 3 hours continuing medical education (CME)/continuing education (CE) related to radiation safety, record the course title, and record the Commission on Accreditation of Medical Physicist Education Programs (CAMPEP) topic description or course topic outline should include radiation safety or radiation dose.

Any course specifically intended for medical physicists will typically be acceptable.

IAC CT Guidance for Surveys of Image Quality, Radiation Dose, and Radiation Protection (i.e., Shielding Verification):

IMAGE QUALITY SURVEYS:

- 1. Image quality assessments must include the parameters specific to the CT scanner (conventional or cone beam.)
- 2. The report must contain the actual results of the assessments with comparisons of the results to the manufacturer specifications and indicate "Pass" or "Fail" for the results of each item.
- 3. Record in the report a description of the specific quality control (QC) phantom utilized.
- 4. Submit the phantom images performed with the results to verify the image quality results.

RADIATION DOSE SURVEYS:

- 1. CT dosimetry reports for all scanners, including single slice CT, electron beam CT (EBCT), multi-detector CT (MDCT) and cone-beam CT (CBCT) scanners must include:
 - a. The manufacturer, serial number, and most recent calibration date of the dose measurement instrument used. (*Instruments should be calibrated at intervals not exceeding 24 months.*)
 - b. Radiation measurements, (with the appropriate units of measure indicated), and calculations of dose, dose index (CTDI_{vol}), Dose-Length Product (DLP), kerma-air-product (KAP)¹, the air kerma at the focus-to-detector distance K_a(FDD)¹ (or other appropriate dosimetry metric). Analysis of dose (for representative clinical protocols) must include comparison with some applicable reference values or manufacturer's specification, using the same units as the reference standard or specification. The report must be clear about whether the results are acceptable and identify suggested corrective actions for improvement if the results are not acceptable.
 - c. The report must identify the phantom used (if any).
- 2. For MDCT scanners, dosimetry measurements and analysis should be performed for the most commonly used clinical protocols at the facility. At a minimum these should include, if they are used at the facility, adult head, adult abdomen, pediatric head, pediatric abdomen and low-dose lung screening. Dosimetry should be reported

in units of $CTDI_{vol}$, point dose at the central ray, or Dose Length Product (DLP) for typical clinical protocols. Effective Dose is intended for populations (not individuals) and introduces additional variables (including estimated radiosensitivity of each organ) unrelated to the actual dose but reporting and comparisons using Effective Dose may be acceptable. The clinical protocol factors must be shown for each protocol addressed in the report.

- a. CTDI is not rigorously defined for MDCT scanner with z-axis collimation greatly exceeding 10 mm. While imperfect, CTDI is the most ubiquitous metric, for which several reference standards currently exist. To estimate CTDI for CBCT systems, if possible 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 and small field collimation available on some dental CBCT scanners often meet this criterion. As new techniques for CT dosimetry are published, more rigorous methods should be used. If the full length of the pencil chamber is exposed, use 100 mm for N*T in the CTDI calculation.
- 3. For CBCT scanners, dosimetry should include analysis of each clinical protocol commonly used at the facility. At a minimum, adult and pediatric (as applicable) protocols should be evaluated, up to a maximum of 6 protocols. Additional dosimetry may be performed but is not required for accreditation.

RADIATION PROTECTION SURVEYS (e.g., radiation shielding verification):

- 1. Radiation Protection Surveys (RPS) must be performed after installation of a new CT scanner or after major changes in CT scan room configuration, equipment location, or usage of areas adjacent to the CT scanner. Otherwise, the RPS is not required to be performed annually.
- 2. IAC CT requires that a post-installation RPS be submitted to demonstrate that the safety of the installation and the surrounding areas have been assessed. Therefore, it may be necessary to locate the original acceptance test report of the CT scanner to find the RPS. For reaccreditation, the application process allows for the applicant to indicate that no CT equipment or room configuration changes have been made and resubmission of the RPS will not be needed.
- 3. A complete RPS must include:
 - a. The manufacturer, serial number, and most recent calibration date of the survey instrument used. (*Instrument should be calibrated at intervals not to exceed 24 months.*);
 - b. A sketch (design) showing the layout of the equipment in the room, and identifying the surrounding areas (e.g., toilet, corridor, outside wall, exam room, office, etc.) and the shielded control area;
 - c. Measurements of radiation exposure (or exposure rate) obtained with an appropriately sensitive radiation measurement system;
 - d. 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 (for controlled and non-controlled areas).

Medical Physicist or Qualified Expert Assessment Requirements

			1
1.		reports must be signed and dated by the medical physicist or qualified expert.	
2.	sys	e reports must indicate if it is of an acceptance test (performed at the time if installation or tem upgrade) or an annual survey.	
3.		e reports must document specific recommendations, corrective actions needed, or issues to be ressed to the facility, if applicable.	
4.	Rac	liation Dose report must include:	Standard 1.4B
	a.	Radiation Dose reported for typical clinical protocols; and	
	b.	Comparison of measured dosimetry with some reference standard (using the same dose units) and indicate <i>Pass</i> or <i>Fail</i>	
5.		age quality report must record the actual results of the assessments, manufacturer cifications for comparison, and indicate <i>Pass</i> or <i>Fail</i> for the following parameters:	Standard 1.4B
	a.	Contrast scale;	
	b.	Mean CT number of water and reference materials;	
	c.	CT number linearity;	
	d.	Laser light alignment (if applicable to the CT scanner);	
	e.	Gantry tilt (for conventional CT scanner);	
	f.	Slice localization accuracy (if applicable to the CT scanner);	
	g.	Table incrementation accuracy (for conventional CT scanner);	
	h.	Slice thickness accuracy;	
	i.	Image quality performance that includes:	
		i. Image noise;	
		ii. Artifact assessment;	
		iii. Spatial resolution for high and low contrast objects;	
		iv. Low contrast performance (if applicable to the CT scanner);	
		v. CT number uniformity;	
		vi. Air calibration (if required).	
	j.	Quality of image display (luminance level, luminance uniformity, GSDF performance), and storage devices; and	
	k.	Safety analysis including an inspection of audible exposure indications and visual assessment of safety devices.	
5.		Radiation Protection Survey (RPS) performed after the CT scanner has been installed (or er structural changes to the CT scan room) must include:	Standard 1.2B
	a.	CT scanner room design showing equipment location in the room and type of occupancy for adjacent areas (i.e., office, toilet, outside, corridor, etc.) and the shielded control area/operator position;	
	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 acceptable methodology;	
	d.	Occupancy factors specified for surrounding areas;	
	e.	Calculation of weekly exposure to persons inside and outside the room, corrected for occupancy factor; and	
	f.	Final assessment of results as "Acceptable," "ALARA," within restricted vs. unrestricted guidelines.	