

ICACTL STANDARDS FOR COMPUTED TOMOGRAPHY (CT) LABORATORY OPERATIONS

PART II

CT TESTING

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

SECTION 1 Instrumentation

STANDARD – Instrumentation

- 1.1 All CT imaging devices being used must be appropriate for the organ systems being imaged, and must be FDA approved for the specific imaging task.**
- 1.2 The CT 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.**
- 1.3 The CT systems utilized for diagnostic studies must include, at a minimum, adequate hardware and software to perform and store organ specific procedures.**

1.3.1 Coronary Calcium Scoring

CT scanners that will be used for coronary calcium scoring must meet the following minimum specifications:

1.3.1.1 Electron Beam Computed Tomographic Systems:

1.3.1.1.1 $\leq 100\text{msec}$

OR

1.3.1.2 Multi-slice Rotational CT Systems:

1.3.1.2.1 4 slice system or greater

1.3.1.2.2 **should have ≤ 0.5 sec rotation speed**

1.3.2 Cardiovascular CTA

CT scanners that will be used for cardiovascular computed tomography angiogram (CCTA) must meet the following minimum specifications:

1.3.2.1 Multi-slice Rotational CT Systems:

1.3.2.1.1 64 slice recommended however 16 slice system or greater with ECG gating capabilities and adequate heart rate control is an acceptable alternative

1.3.2.1.2 ≤ 0.5 sec rotation speed

1.3.2.1.3 dual auto injector system

1.3.3 Other Computed Tomography Angiography (CTA)

CT scanners that will be used for CTA (neck, chest, non cardiac, and peripheral vascular, neurovascular CTA and CTP)) must meet the following minimum specifications:

1.3.3.1 Multi-slice Rotational CT Systems:

1.3.3.1.1 4 slice system or greater

1.3.3.1.2 **Should have ≤ 0.5 sec rotation speed**

1.3.3.1.3 auto injector system

1.3.4 Neuroimaging CT (excluding CTA, CTP – see other CTA)

CT scanners that will be used for neuroimaging, excluding CTA, must meet the following minimum specifications:

1.3.4.1 Single, Multi-slice, Helical or Multi-detector Rotational CT Systems:

1.3.4.1.1 **Should have ≤ 0.5 sec rotation speed**

1.3.5 Sinus and Temporal Bone CT

CT scanners that will be used for dedicated sinus and temporal bone imaging must meet the following minimum specifications:

1.3.5.1 Volume or Cone Beam CT System

1.3.5.2 Single, Multi-slice, Helical or Multi-detector Systems:

1.3.5.2.1 Should have \leq 2 sec rotation speed

1.3.6 Whole Body CT (Neck, Chest, Abdomen, Pelvis, Extremities)

CT scanners that will be used for whole body, excluding CTA, must meet the following minimum specifications:

1.3.6.1 Single, Multi-slice, Helical or Multi-detector Systems:

1.3.6.2 Should have \leq 2 sec rotation speed

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

1.4.1 Coronary Calcium Scoring

1.4.1.1 Must be capable of providing a visual representation of coronary calcium exceeding protocol thresholds.

1.4.1.2 Must be capable of quantitating coronary calcium using Agatston, mass and/or volume scoring methodologies.

1.4.1.3 Must be capable of providing user interaction with quantitative program to allow for selecting or de-selecting coronary calcifications based on visual inspection.

1.4.2 Cardiovascular CTA

1.4.2.1 Must be capable of displaying data as Maximum Intensity Projection (MIP), thick or thin slice

1.4.2.2 Must be able to display data as multi-planar reformat

1.4.2.3 Must be able to display data in a curve plane reformat

1.4.2.4 Must be able to present data in a three dimension format with the ability to display data rotated about all three axes

1.4.2.5 Must be able to extract relevant measurements as described in laboratory specific protocol

1.4.2.6 Must be able to load simultaneously multiple phases

1.4.2.7 Must be able to quantitate coronary calcium

1.4.3 Other CTA (Neck, Chest, Abdomen, Pelvis, Non cardiac, neurovascular including CTA and CTP, and Peripheral Vascular)

1.4.3.1 Must be capable of displaying data as Maximum Intensity Projection (MIP), thick or thin slice

1.4.3.2 Must be able to display data as multi-planar reformat data

1.4.3.3 Should be able to present data in a three dimension fashion with the ability to display data rotated about all three axes.

1.4.3.4 Must be able to extract relevant measurements as described in the laboratory specific protocol

1.4.4 Neuroimaging, excluding CTA and CTP

1.4.4.1 Must be capable of image processing appropriate to the imaging task

1.4.5 Dedicated Sinus and Temporal CT

1.4.5.1 Must be capable of image processing appropriate to the imaging task

1.4.6 Whole Body CT (Neck, Chest, Abdomen, Pelvis, Extremities, excluding CTA)

1.4.6.1 Must be capable of image processing appropriate to the imaging task

1.5 For all systems:

1.5.1 All data are to be reviewed in a digital, on-screen medium.

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

- 1.5.3 Monitor specifications must be sufficient to prevent any loss of resolution of CT images and to display the thinnest reconstructed images available.**
- 1.5.4 Must have capability to display data in standard contrast settings (Lung field, bone, chest, etc).**
- 1.5.5 Must have capability to adjust brightness and contrast settings manually.**
- 1.5.6 Datasets used for archiving must be DICOM compatible.**
- 1.5.7 Must have the capability to optimize the field of view based on patient size and protocol implemented.**

SECTION 2

Instrument Quality Assurance

STANDARD - Quality Assurance

2.1 There must be a written comprehensive quality assurance program to provide a standard of measurement for system performance and the documentation of any variance thereof. A Quality Assurance Committee should be appointed as an oversight to these procedures.

2.1.1 The Quality Assurance Committee should, at minimum, consist of the Technical Director, Medical Director, service engineer, and/or site-appointed medical physicist. **The use of a site appointed medical physicist or qualified expert is required for an annual survey of the scanner image quality and dose, and for oversight of the quality control (QC) program.**

2.1.2 Quality control (QC) tests, standards, thresholds, timelines and results should be reviewed and discussed on a quarterly basis by the Quality Assurance Committee. **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.**

2.2 The quality assurance program must consist of CT system installation acceptance testing and major upgrade acceptance testing.

- 2.2.1 Acceptance testing must include a comprehensive evaluation of the system components, the QC parameters included in sections 2.3 and 2.4, 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.**
- 2.2.2 The CT site-appointed medical physicist or qualified expert should perform the acceptance testing.**
- 2.2.3 The system parameters must be compared to the manufacturer's system specifications and reviewed by the Quality Assurance Committee.**
- 2.2.4 A written report of the acceptance tests must be maintained at the CT laboratory. The report must be signed and dated by the person performing the tests.**
- 2.2.5 The medical physicist or qualified expert must perform the shielding design to ensure that occupational workers and members of the public are shielded according to NCRP Report 147, state regulation, or other equivalent industry standards. This must be performed prior to installation of each new scanner.**
- 2.2.6 Dose and image quality assessment of representative exams as compared to professional standards must be performed.**

2.3 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 quality assurance testing instructions, recommended testing frequency, a quality control test phantom appropriate for the scanner and acceptable variations in parameter measurements.

- 2.3.1 Daily quality control tests should include, at a minimum:**
 - 2.3.1.1 Mean CT number for water of representative components
 - 2.3.1.2 Mean CT number of other reference material
 - 2.3.1.3 Image Noise
 - 2.3.1.4 Artifact assessment
 - 2.3.1.5 Proper function of audible and visual patient safety equipment

2.3.2 Periodic quality assurance tests should include all from section 2.3.1 and:

2.3.2.1 Spatial resolution for high and low contrast objects

2.3.2.2 Image uniformity

2.3.2.3 Slice thickness

2.3.2.4 Alignment light accuracy

2.3.2.5 Image display and storage devices

2.3.2.6 Air calibration, if required

2.4 Annual system performance measures must be evaluated using an appropriate phantom(s), determined by the medical physicist or qualified expert and should include, where appropriate to the scanner:

2.4.1 Contrast scale

2.4.2 Mean CT number of water and reference materials

2.4.3 Linearity

2.4.4 Internal and external laser light alignment

2.4.5 Gantry tilt (tilt gantry systems only)

2.4.6 Slice localization

2.4.7 Table incrementation accuracy

2.4.8 Slice thickness

2.4.9 Image quality as noted in 2.1.3

2.4.10 Image display and storage devices

2.4.11 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.

2.4.12 Safety analysis including an inspection of audible and visual equipment.

2.5 The Quality Assurance Committee 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).

2.5.1 Preventive maintenance (PM) service is recommended monthly or per the manufacturers' recommendations for each CT scanner at the laboratory.

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

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

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

2.7 All QC and QA results must be documented.

2.7.1 **Quality assurance documentation (policies, reports, records, etc.) must be maintained at the CT laboratory and made available to all personnel.**

SECTION 3

Indications, Ordering Process, Scheduling and Patient Preparation

STANDARD - Indications

3.1 CT testing is performed for appropriate indications.

3.1.1 **Verification of the indication: A process must be in place in the laboratory 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.**

STANDARD - Ordering Process and Scheduling

3.2 CT testing is appropriately ordered and scheduled.

- 3.2.1 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.**
- 3.2.2 Sufficient time for patient assessment, preparation and testing must be allotted for each study according to the procedure type.**

STANDARD - Patient Identification and Preparation*

3.3 Patient Identification - For all clinical procedures there must be a process that assures accurate patient identification prior to initiating the procedure. It is preferable that this be done using at least two pieces information that are provided by the patient and compared with existing documents.

- 3.3.1 Pregnancy screening – For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and should contain the signature/initials of the patient and/or technologist verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant.**
- 3.3.2 If a diagnostic CT examination is needed for a patient who is pregnant, knowledgeable staff (e.g. medical director, or other designee) must discuss the potential risk to the fetus and document the general content of the discussion.**
- 3.3.3 If determined that the study will not be performed, then the patient must receive options for alternative care.**

- 3.4 There must be a policy in place for determining and administering any necessary pre test preparations including:**
- 3.4.1 Education/instructions such as dietary or medication restrictions, examination specific preparation or other relevant information.**
 - 3.4.2 Sufficient time must be allowed for adequate patient preparation.**
 - 3.4.3 There must be a policy in place for performing CT examinations in patients with documented or possible sensitivity to contrast.**
 - 3.4.4 There must be a policy in place that addresses patients with increased risk of renal toxicity.**
 - 3.4.4.1 If contrast is used serum creatinine and BUN should be obtained if clinically indicated and results reviewed prior to the CT examination.**
 - 3.4.5 There must be a policy in place that addresses medication and contrast administration that includes:**
 - 3.4.5.1 IV access including location of insertion site and size of catheter**
 - 3.4.5.2 Medications, including contrast, used in the procedure (i.e. beta blockers, conscious sedation)**
 - 3.4.5.3 Dosage, timing, route of administration**
 - 3.4.5.4 Patient instruction**
 - 3.4.5.5 Patient monitoring**
 - 3.4.5.6 Any precautions or restrictions needed**
 - 3.4.5.7 Treatment of adverse reactions**
 - 3.4.5.8 Consent form (if required)**
 - 3.4.6 Any other types of necessary pre test preparation must be assessed prior to the start of the examination.**

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

***See Appendix for Emergent CT Studies for Patients Presenting With Acute Stroke Symptoms**

SECTION 4

Elements and Components of CT Examination Performance

STANDARD - Elements of CT Examination Performance

4.1 Examination performance must include proper technique.

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

4.1.1 Elements of examination performance include **as appropriate, but are not limited to:**

4.1.1.1 Proper patient positioning

4.1.1.2 Optimization of image acquisition parameters

4.1.1.3 Appropriate protocol selection based on:

4.1.1.3.1 Clinical diagnosis

4.1.1.3.2 Patient age

4.1.1.3.3 Body habitus/weight

4.1.1.3.4 Surgical history

4.1.1.3.5 Patient clinical presentation

4.1.1.3.6 Contraindications

4.1.1.3.7 Utilization of appropriate protocol.

4.1.2 The laboratory 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:**

4.1.2.1 The indication for the study

4.1.2.2 Anatomical region(s) to be imaged

4.1.2.3 Utilization of the correct scanner for the indication

- 4.1.2.4 Clear criteria for deviating from protocols**
- 4.1.2.5 Adherence to established practice guidelines. There may be allowance for exceptions if validated.**
- 4.1.2.6 All orientations/views that will be displayed**
- 4.1.2.7 Scanner settings or acquisition parameters to include:**
 - 4.1.2.7.1 Acquisition mode**
 - 4.1.2.7.2 Patient orientation**
 - 4.1.2.7.3 KV**
 - 4.1.2.7.4 mA/mAs**
 - 4.1.2.7.5 Dose modulation, if used**
 - 4.1.2.7.6 Collimation**
 - 4.1.2.7.7 Rotation time**
 - 4.1.2.7.8 Slice thickness**
 - 4.1.2.7.9 Increment**
 - 4.1.2.7.10 Table speed/pitch**
 - 4.1.2.7.11 FOV**
 - 4.1.2.7.12 Gantry angle, if used**
- 4.1.2.8 Filming instructions to include window level and contrast settings, views, format, magnification**
- 4.1.2.9 Reconstruction algorithm and filter**
- 4.1.2.10 Reconstruction interval**
- 4.1.2.11 Phase(s) of cardiac cycle reconstructed**
- 4.1.2.12 Indication for IV contrast to include: type of contrast, amount, injection rate and scan delay protocol**

4.1.2.13 Other medications used including dose and route of administration

4.1.2.14 Instruction on data archiving and transmission of images including what files are to be stored/transmitted.

4.1.3 Separate pediatric protocols must be established based on patient age or weight.

4.1.4 All protocols must 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 should be modified to reduce radiation exposure where appropriate or possible.

SECTION 5

Examination Interpretation

5.1 CT examination reporting must be standardized in the laboratory. All physicians interpreting CT examinations in the laboratory must agree on a standardized report format.

5.1.1 The final report must accurately reflect the content and results of the study. The report must include, but may not be limited to:

5.1.1.1 The date of the examination.

5.1.1.2 The clinical indications leading to the performance of the examination.

5.1.1.3 An adequate description of the test performed including:

5.1.1.3.1 the name of the examination

5.1.1.3.2 the protocol used in the examination

5.1.1.3.3 the quality of the study

5.1.1.3.4 details of any pertinent patient preparation

5.1.1.3.5 drug administration

5.1.1.3.6 Contrast, if used, to include amount, type, and route of administration

- 5.1.1.4 An overview of the results of the examination including pertinent findings. Where appropriate, this must include localization and quantification of abnormal findings.**
- 5.1.1.5 Appropriate recommendation for follow up of incidental findings.**
- 5.1.1.6 The reasons for limited examinations.**
- 5.1.1.7 A summary of the test findings.**
- 5.1.1.8 Comparison with previous studies if available**
- 5.1.1.9 Reports must be typewritten**
- 5.1.1.10 Physician signature line (the printed name of the interpreting physician) and be manually or electronically signed by the interpreting physician and include the date of signature and/or verification.**

SECTION 6

Procedure Volumes

STANDARD - Procedure Volumes

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

A laboratory 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 laboratory. Lower volumes than those recommended here, however, should not dissuade a laboratory that is otherwise compliant with the *ICACTL Standards* from applying for accreditation.

SECTION 7

Technical and Interpretive Quality Assessment (QA)

Quality assessment procedures must be designed to provide a standard of measurement laboratory performance and the documentation of any variance.

STANDARD – Technical Quality Assessment

7.1 Under the supervision of the Technical Director and the Medical Director, and with the guidance of the Medical Physicist or qualified expert, the laboratory must have a defined quality assessment program that evaluates the ongoing technical quality and radiation dose information including Computed Tomography Dose Index (CTDI) or Dose Length Product (DLP), of the CT procedures performed in the laboratory.

7.2 This program should have predefined indicators of quality and predefined thresholds that indicate the need for corrective action. The laboratory should maintain reports of quality assessment evaluations and corrective actions taken.

7.2.1 Indicators may include, but not be limited to:

7.2.1.1 adverse effects

7.2.1.2 poor quality of examinations

7.2.1.3 poor reproducibility of computer processing

7.2.1.4 radiation dose review and assessment

7.2.1.5 thresholds are determined for each indicator

7.2.1.6 Corrective actions should be taken to improve the operation of the laboratory.

STANDARD – Interpretive Quality Assessment

7.3 Under the supervision of the Medical Director, the laboratory must have a defined quality assessment program that evaluates the ongoing quality of the interpretation of the CT examinations.

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

7.4.1 Peer Review

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

7.4.2 Correlation and Confirmation of Results

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

7.5 QA review

The results of the QA must be disseminated to the medical and technical staff on a regular basis and at a minimum of two times per year.

7.6 Quality Assurance Record Keeping

Records must be maintained of the quality assurance process. These records should include, but not be limited to, peer review, correlation data and information gained from the areas outlined in Section 5. The records must include a description of how the information is used to improve quality in the CT laboratory.

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* APPENDIX

Emergent CT Studies For Patients Presenting With Acute Stroke Symptoms.

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

-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.

-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.

-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 neuroimaging criteria for inclusion or exclusion of acute stroke therapies based on available published neuroimaging guidelines.

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

-When the CT interpreter and the treating physician are different individuals who both render written opinions regarding neuroimaging criteria for inclusion or exclusion of acute stroke therapies, the CT laboratory must track this information as a part of quality assurance.

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

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

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

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