RadSite™

Accreditation Reinvented

Advanced Diagnostic Imaging (ADI) Accreditation Program: Standards and Guide

Version 3.3

The tools you need for innovative, cost-effective accreditation.

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Advanced Diagnostic Imaging (ADI) Accreditation Program: Standards and Guide v 3.3

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Disclaimer

All information contained herein is for informational purposes only. Please consult a physician regarding any health matters related to imaging. Statements and findings reported in this publication do not necessarily represent the public policy positions of RadSite**.**

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About RadSite

Since 2005, RadSite has offered comprehensive, affordable, quality-based certification and accreditation programs that evaluate imaging suppliers on established industry standards and emerging best practices. To date, RadSite has certified more than 25,000 imaging facilities operating at least 60,000 imaging systems.

In September 2010, RadSite, LLC, was incorporated as a separate legal entity with its own governance structure. This separation was executed to prepare for independent, unbiased expansion of its quality-based mission, and to become recognized by the U.S. Centers for Medicare and Medicaid Services (CMS) as an accrediting organization pursuant to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), along with other stakeholders including other regulators and payers.. As of January 1, 2012, CMS required that all imaging suppliers who offer CT, MRI, and nuclear medicine imaging exams, and who bill for the technical component under the physician fee schedule, become accredited by a CMS-recognized accrediting agency in order to be eligible for future reimbursement. In 2013, CMS approved RadSite as the fourth Advanced Diagnostic Imaging Accreditation Organization, pursuant to §1834(e)(2) of the Social Security Act ("the Act")[see also 42 USC §1395m(e)(2)]. Today, more than 300 private payers have recognized RadSite for its Advanced Diagnostic Imaging Accreditation Programs, including its specialty designations.

RadSite is run by a volunteer-based committee system, which includes an advisory board, several standards committees, and an accreditation committee. RadSite's corporate charter dictates that the governance structure be made up of a wide range of stakeholders including providers, consumers, payers, regulators, manufacturers, and other interested parties. Annually, RadSite publicly solicits nominations to participate on the committees.

RadSite's offices are located in Annapolis, MD.

RadSite's ADI Accreditation Program

RadSite has earned the reputation of offering an innovative and cost-effective choice for imaging accreditation. RadSite's Advanced Diagnostic Imaging (ADI) Accreditation Programs are made up of five (5) different standards covering:

- Computed Tomography (CT) ADI Accreditation, version 3.3.
- Magnetic Resonance Imaging (MRI) ADI Accreditation, version 3.3.
- Nuclear Medicine (NucMed) ADI Accreditation, version 3.3
  - Planar/Single Photon Emission Computed Tomography (SPECT)
  - Positron Emission Tomography (PET) and PET/CT
- Dental Cone Beam CT ADI Accreditation, version 1.2.
- Medical Cone Beam CT ADI Accreditation, version 1.2.

RadSite distinguishes itself from other accrediting bodies with accreditation services that:

- Use an evidence-based approach to draft and maintain meaningful imaging standards.
- Streamline the accreditation review process by using an online application system.
- Assign each applicant a client service manager to personalize the accreditation process.
- Provide feedback to allow applicants to correct deficiencies.
- Ensure an objective and confidential accreditation review process.
- Offer reasonable pricing with no hidden fees.

ADI Specialty Imaging

RadSite ADI accreditation is required for each qualified ADI imaging system that is owned and or operated by an imaging supplier within a specific location. Applications for integrated imaging suppliers operating as a single Tax ID Number (TIN) can be bundled. But each facility must be accredited individually and all ADI imaging systems at each location must be accredited.

Each applicant must apply for "general" ADI accreditation for each imaging system modality under the applicable ADI accreditation program. In addition, each imaging supplier may apply for and be recognized for specific clinical subspecialties as highlighted in Table 1. Some payers also require one or more clinical specialty module designations.

Note: An applicant may view current accreditation pricing and small and rural supplier discounts online at www.RadSiteQuality.com.

RadSite designates the following ADI clinical specialty modules as follows:

Table 1: RadSite ADI Clinical Specialty Modules		
Computed Tomography	Magnetic Resonance Imaging	Nuclear Medicine
Conventional CT • Angiography • Body • Cardiac • Coronary Calcium Scoring • Maxillofacial • Musculoskeletal • Neurologic	**MRI** • Angiography • Body • Breast • Cardiac • Functional • Musculoskeletal • Neurologic	**Planar, SPECT, or SPECT/CT** • Body ○ Cardiac **PET or PET/CT** ○ Cardiac ○ Inflammation (Infection) ○ Neurologic ○ Oncology

Why RadSite?

RadSite, as a nationally recognized accreditation organization (AO), has many years of experience accrediting imaging suppliers. RadSite is uniquely positioned to work with regulators, private payers, imaging suppliers, patients, and other interested parties because our accrediting organization:

- Is governed by a volunteer committee system comprised of a wide range of stakeholder groups to promote accountability and transparency.
- Uses an evidence-based approach to promote best practices for imaging systems.
- Leverages an experienced leadership team that has brought to market over 25 healthcare accreditation programs during the past 25 years.
- Develops standards that are subject to external peer review, which includes a formal standards' review process, beta testing, and inter-rater reliability assessments.
- Streamlines the application process by using a secure online accreditation portal that can be configured to pre-populate fields for streamlined data entry.
- Offers a competitive pricing structure, with discounts available for multiple imaging systems and rural locations.
- Is approved by CMS and over 300 private payers for reimbursement purposes; and,

- Incorporates third-party feedback in the design and operations of its accreditation processes.

RadSite offers a range of educational programs including complimentary webinars, and it publishes blogs and issue briefs. RadSite also hosts focus groups and other activities to promote safe and efficient imaging practices.

The Application Process

1. Steps Prior to Submitting the Application

- ***Education:***
    - Consider listening to one or more of our complimentary RadSite webinars at https://radsitequality.com/webinars/ or access some of RadSite's other training materials.
    - Download and read the applicable RadSite accreditation standards. Information on each Accreditation Program can be found at www.radsitequality.com.
- ***Pre-Application Preparation****:*
    - Complete the initial questionnaire, which provides RadSite with an overview of the applicant's imaging practice.
    - Review the terms and conditions of the ADI Accreditation Agreement and the Business Associate (BA) Agreement and then execute the agreements.
    - In consultation with a RadSite representative, calculate payment via the instructions in the application materials.
    - A RadSite accreditation coordinator will contact the applicant to verify the scope of the applicant's imaging practice and review the process.
    - Additional documents will be sent to the applicant to complete the application process.

2. Steps of the Application Process

- Fill out the online application.
- Collect additional information as requested via the online accreditation portal based on the ADI Standards.
- Submit clinical, phantom, and test-object images, along with other documents, via RadSite's upload utility.

Here are a couple additional helpful notes:

- If the operations of an applicant's imaging system or imaging facility do not apply to a particular standard, the applicant should record "N/A" for "not applicable."

- Each applicant must take precautions to safeguard any Protected Health Information (PHI) or other confidential information that is sent to RadSite. RadSite does not request PHI during the application process. For example, each applicant can use RadSite's cloud-based utility to anonymize its images when uploading. If they do not utilize this function, applicants should de-identify the images before submission. Applicant's are encouraged to contact their account manager if they need additional information on recommended HIPAA and confidentiality protocols and how to best send information to RadSite.

- Throughout the application process, RadSite customer service representatives are available to assist with any questions. Representatives can be reached at (443) 440-6007 from 8 a.m. to 4 p.m. ET.

3. Steps After Submission of the Application:

a. A RadSite accreditation coordinator will contact the applicant to verify the scope of the applicant's imaging practice and review the process.

b. Additional documents will be sent to the applicant to complete the application process.

4. Information to be Submitted with the Application

***Image Study Submission Requirements*:**

- Each applicant must submit a minimum of three exams for each ADI system under review, and a fourth study if 2% or more of the total caseload of exams are pediatric. See Table 2 for the total number of exams that need to be submitted depending on the number of specialty modules that are part of the application. A complete explanation of the clinical image requirements is provided for each modality in Section VII.

- Each image study must be of an actual patient imaged on the applicable ADI system within six months prior to the submission of the accreditation application.
    - The image studies must include the facility's protocol for that examination and the corresponding clinical report.
    - The goal is to receive a representative sample of the types of exams the imaging supplier completes as part of its general practice, and if applicable, for each specialty module.

- For a general ADI accreditation:
    - Each applicant must submit three image exams for each ADI system under review.
    - If 2% or more of the total caseload of exams are pediatric, one additional image study must be submitted with a patient who is between 0 and 15 years of age.

- For each clinical specialty designation:

- The applicant must submit two image exams in that specialty area. Each study should be a different type of exam within the designated specialty.

- If 2% or more of the total caseload of image exams are pediatric for each applicable specialty area, an additional image exam must be submitted with a patient who is between 0 and 15 years of age.

- For any of the image reviews, RadSite reserves the right to have each applicant submit additional image exams to make sure a representative sample is being scored pursuant to Section VII for Technical Quality. **Table 2** summarizes the image exam submission requirements:

Table 2: Study Submission Requirements (Revised October 2024)		
SPECIALTY AREAS	SUBMISSION REQUIREMENT DETAILS	
General		Total # of Studies
ADI Accreditation with No Specialties	Submit three studies which represent the scanning patterns for the imaging system	3
One Specialty Module	Submit two studies for the specialty module and one additional which represents the scanning patterns for the imaging system	3
Two Specialty Modules	Submit two studies for each specialty module	4
Three Specialty Modules	Submit one study for each specialty module and one additional which represents the scanning patterns for the imaging system	4
Four Specialty Modules	Submit one study for each specialty module	4
Five or more Specialty Modules	Submit one study for each additional specialty module	+1
Note: For Breast and Cardiac specialty modules, two images always need to be submitted and may add to the totals above. . If the machine's caseload is 2% pediatric or more, an additional pediatric study is required.		

Additional details of the different types of image studies that are accepted under each specialty module are detailed in Section VII. Applicants pay an additional fee for two or more clinical specialty designations. See RadSite's pricing policy for additional details.

- ***Physics Report Submission Requirements:***

  The applicant must submit the following for each imaging system with their completed application:

  - The most recent annual medical physicist report for each imaging system.
  - Phantom testing for image quality and dose (for both adults and children if applicable) for each imaging system. A complete explanation of the phantom testing requirements is provided for each modality in Section VII.

5. **Timeline for Submission and Review of Completed Applications**.

- The application must be completed within ninety (90) days (three months) of RadSite's receipt of a cleared payment, whichever is longer.
- Applicants may request one 30-day extension by submitting a written request.
- Once an application is completed in full, RadSite has up to 90 days to complete its review and make its initial determination.
- See Appendix B for a detailed list of timelines.

6. **Request for More Information.**

- If the application has been completed and clinical, phantom, and test-object images have been submitted in a timely manner, then RadSite will make its initial accreditation determination typically within 90 days or less from the date of submission.
- An incomplete application is subject to a corrective action period or an accreditation failure.
- If the application is complete, but revisions are required, RadSite will send the applicant a "Request for Information" (RFI) form. The applicant will have 30 days from receipt of RadSite's request to respond.
- If a request for more information is made, RadSite will have up to 90 days from the date of the request to make an accreditation decision.

7. **Audit of Applicants**

Description: RadSite may perform an on-site or virtual audit of in-process applicants to help review, assess and verify that the imaging supplier is meeting RadSite Standards and any related operational/legal requirements and provide additional information to help RadSite's Accreditation Committee render an accreditation determination. RadSite reserves the right to schedule any virtual or site audit as soon as possible without providing any prior notification to the applicant.

Expenses: RadSite will not charge in-process applicants any additional fees for virtual or site audits.

8. The Application Review Process

Each imaging supplier is assigned an application number to facilitate tracking. If more than one imaging facility is owned by an imaging supplier, applications may be bundled to reduce paperwork. Accreditations are issued to each imaging facility by ADI modality. RadSite accreditation reviewers assess the application in its entirety, score the components, and produce a summary report.

As each imaging supplier reviews the RadSite standards and fills out the accreditation application via the RadSite Online Portal, it is important to note that every element of each standard associated with each accreditation program is mandatory based on the ADI modalities and specialty areas that are part of the application. Simply put, there are no optional standards.

The RadSite review team will carefully review each "N/A" response to an accreditation standard on the application and might ask for additional information. RadSite reserves the right to require compliance with the standard in question that it deems applicable to the imaging supplier.

Once the accreditation review is complete, a summary report of each imaging supplier's application is blinded and then forwarded to RadSite's Accreditation Committee for final review and approval.

Accreditations are issued based on successful review of a combination of the administrative and technical components for ADI systems associated with each imaging facility. All imaging systems in each submitted ADI modality must pass all reviews in order for that modality to be accredited.

If one or more imaging systems associated within a modality does not pass, RadSite will send a written explanation of the deficiencies and make recommendations. If after the 60-day corrective action period the non-compliant machine still does not meet the ADI Standards, it must be removed from service before an accreditation decision can be made covering any other similar imaging modalities at the same location.

RadSite will notify each applicant in writing of its decision.

Accreditation determinations include full accreditation or failure. A corrective action period may be issued initially to help an applicant address deficiencies prior to determination of formal accreditation.

Upon issuance of a full accreditation, RadSite will issue each applicant an accreditation certificate(s) under one or more of the following accreditation programs:

- CT ADI Accreditation, version 3.3
- MRI ADI Accreditation, version 3.3
- NucMed ADI Accreditation, version 3.3
- Dental Cone Beam CT ADI Accreditation, version 1.2
- Medical Cone Beam CT ADI Accreditation, version 1.2.

If the applicant has applied for one or more specialty module accreditations and passes, an additional notation will be made on the accreditation certificate(s) and in the online accreditation directory.

9. Accreditation Determinations

- ***Full Accreditation*:**
    - The applicant passes 100% of the standards.
    - Accreditation period is three years from the date of the Accreditation Committee decision.
- ***Corrective Action Period***
    - A corrective action period is an interim step in the accreditation process and does not represent a pass or a failure. This is a situation in which the applicant fails to pass but is close to passing.
    - To qualify for a corrective action period, the applicant must meet at least 90% of the Standards.
    - The applicant will have 60 days from receipt of the corrective action period notice to remedy any deficiencies and resubmit materials to RadSite for re-examination and re-scoring. The notification will specify actions the applicant must take to at least meet standards.
    - No additional fees are assessed for a corrective action period.
- ***Incomplete Application***
    - Applicant did not sufficiently complete the application process within 90 days of RadSite's receipt of the signed ADI Accreditation Agreement and payment.
    - No accreditation status is issued (e.g., accreditation application is withdrawn before submission).
- ***Failure***
    - The applicant fails to meet the criteria to achieve full accreditation.
    - The applicant fails to improve its score sufficiently after a corrective action period.
    - The applicant will receive a written summary report and "Notice of Failure" statement that identifies the reasons for failure.

If the applicant does not receive full accreditation due to a failure or an incomplete application, the applicant cannot apply again for RadSite's ADI Accreditation Program until:

- 90 days after the date of the first adverse decision (i.e., failure or incomplete).

- 180 days after the date of the second adverse decision.

These waiting periods are put into place to ensure that applicants are fully engaged with RadSite during the accreditation review process.

Only imaging suppliers with a full accreditation will receive an accreditation certificate for each imaging facility that passes based on each ADI modality. Imaging suppliers are not accredited through the ADI Accreditation Program if they receive the following accreditation decision:

- Corrective action period;
- Incomplete; or
- Failure.

RadSite sends CMS and other designated payers its current list of accredited organizations on a routine basis. The RadSite online accreditation directory, which designates who is accredited, and the modalities and specialty areas for which they are accredited is also kept up to date. (See Table 1).

Appeals Process

Each applicant has two levels of appeal:

- **Reconsideration (level 1)**

    - The applicant can request a reconsideration of an initial adverse accreditation determination.

    - The applicant's request for reconsideration must be made in writing and submitted within 30 days of the applicant's receipt of the "Notice of Failure" or other adverse determination.

    - The applicant's written request for reconsideration must include an explanation of the basis for the request and any relevant documentation that supports the request for reconsideration of the adverse decision.

    - RadSite will rule on the applicant's requests for reconsideration within 30 days.

- **Appeal (level 2)**

    - If the applicant is not satisfied with the reconsideration decision made by the Accreditation Committee, the applicant may file an appeal.

    - The appeal can be filed with the RadSite Advisory Board within 45 days of the applicant's receipt of the adverse reconsideration decision.

    - RadSite's Advisory Board will rule on the appeal within 45 days.

- The decision of the Advisory Board is the final determination and is not subject to further appeal within the RadSite organization.

Audits and Surveys

During the three-year accreditation interval, all accredited imaging suppliers are subject to random, unscheduled audits as detailed in Table 3.

Table 3: Accredited Supplier Audit Overview	
Audit Frequency	RadSite will perform an unannounced audit of every accredited imaging supplier during the three-year accreditation period to ensure compliance with RadSite Standards. The imaging suppliers to be audited each year are randomly selected.
Types of Audits	RadSite performs 3 types of audits of its accredited suppliers: 1. Desk audits 2. Virtual audits 3. On-site audits
Desktop Audits	A desktop audit consists of review of documents and imaging studies submitted to RadSite from randomly selected accredited imaging suppliers. Additional documentation typically is required to ensure certain elements of the RadSite standards are being implemented by the imaging supplier. **Expenses:** RadSite will cover the labor costs of any additional desktop audits. However, it is the responsibility of the imaging supplier to cover the costs of submitting any additional materials or information requested.
Virtual Audits	A virtual audit consists of a virtual meeting between the RadSite and imaging facility staff via means such as Zoom, GoToMeeting, or WebEx. During the virtual meeting, the RadSite staff will request documents for review and discuss issues with the facility. Virtual audits cannot be completely unannounced because arrangements must be made to set up the required technology. While the virtual audit call needs to be scheduled in advance, no agenda will be provided and documents will not be requested until the time of the meeting. **Expenses:** RadSite will not charge an imaging supplier any additional fees for a virtual audit.

On-site Audits	An on-site audit consists of an unannounced visit to a randomly selected accredited imaging supplier. This means that RadSite will arrive at the selected imaging facility for an on-site audit without providing any prior notification to the imaging supplier. **Expenses:** RadSite will not charge an imaging supplier any additional fees for an on-site audit.
Complaint (For-Cause) Audits of Accredited Imaging Suppliers	**Description:** If a complaint against an accredited imaging supplier is filed with RadSite or referred by a regulator or other third party, and RadSite determines that the complaint merits further investigation, RadSite shall initiate a site audit of such accredited imaging supplier. If RadSite determines a complaint or issue involves a serious patient safety concern (including, but not limited to, situations where the safety concern poses an immediate jeopardy to the accredited imaging supplier's patients or a hazard to the general public), RadSite is obligated to initiate an audit without providing any advance notification to the accredited imaging supplier. **Expenses:** If a complaint (for cause) on-site audit is conducted and the complaint against the accredited imaging supplier is validated, the accredited imaging supplier will pay RadSite fees of $1,000 per diem charge plus reasonable travel costs, but no more than $2,500.
Corrective Action Plan	Depending on the specific deficiencies (if any), that arise during an audit, RadSite reserves the right to: 1. Create and enforce a Corrective Action Plan; and 2. Revoke or suspend the accreditation as it relates to the imaging supplier, a designated ADI service or imaging system. Per the specifications of the Corrective Action Plan, RadSite will monitor the remediation efforts of the accredited imaging supplier. If the deficiencies continue, the RadSite Accreditation Committee may revoke or suspend the accreditation as it relates to the imaging supplier, a designated ADI service or imaging system. Accredited imaging suppliers retain the right to appeal any adverse determination under these circumstances. As appropriate, RadSite will notify CMS and other relevant state or federal agencies regarding the deficiencies and any changes in accreditation status.

Third-Party Notifications	RadSite reserves the right to notify federal, state and local authorities, at any time, if RadSite determines that a malfunctioning imaging system poses a serious patient safety concern (including, but not limited to, situations where the safety concern poses an immediate jeopardy to the accredited imaging supplier's patients or a hazard to the general public).

Notification Requirements

Throughout the accreditation cycle, accredited imaging suppliers must notify RadSite of any substantive changes in its operations, clinical workflows, or any of its imaging systems that could impact with any of the ADI Standards.

Applicants have an obligation to keep their application up to date if any changes are made before an accreditation decision is made that are material to the ADI Standards.

Applicants must notify RadSite:

- Within fourteen (14) days of any business operation "material" change to its business operations that impact the scope of the ADI accreditation, such as revisions or alterations in the company name, address, and ownership or the moving of a facility.

- Within two (2) days of any business operation "adverse change" to its business operations, such as filing for bankruptcy, loss or restriction of business license, no longer providing ADI radiological services, or being sued.

- Within two (2) days of any issues impacting patient safety such as where the safety concern poses an immediate jeopardy to the accredited imaging supplier's patients or a hazard to the general public.

Definitions

Advanced Diagnostic Imaging (ADI) Services includes the technical component of imaging scans and imaging studies provided by using Magnetic Resonance Imaging (MRI), Computed Tomography (CT) including Cone Beam, Nuclear Medicine procedures [including Planar/Single Photon Emission Computed Tomography (SPECT), Positron Emission Tomography (PET), PET/CT], and any other modalities in the future as specified by the Center for Medicare and Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) now or in the future.

Adverse Determination or Adverse Decision means a denial of ADI accreditation; award of an ADI accreditation status less than what the applicant anticipated; suspension or revocation of ADI accreditation; or requirement of corrective action.

Adverse Event is the occurrence of an undesirable experience associated with radiologic diagnostic testing or treatment. Adverse events span from incidental to serious to seminal. They include items such as consumer's poor experience with office personnel, production of an image of poor quality, failure to forward radiologic images to the referring provider promptly, and inappropriate administration or dosing with contrast dye. The level of seriousness of the adverse event requires action of appropriate dimension and timeliness to remediate the experience and avert its recurrence.

Automatic exposure controls (AEC) are a NEMA XR-29 Standard requirements that automatically adjust the amount of radiation within prescribed bounds as needed to achieve the desired image quality. Studies of AEC procedures have demonstrated dose reductions when used properly.

Business Operation "Material" Change is a change within an applicant or accredited imaging supplier's facility that affects the business operations or work product status that the imaging supplier is obliged to report to RadSite. Examples include revisions or alterations in the company name, address, and ownership or the moving of a facility.

Business Operation "Adverse" Change is a change within an applicant or accredited imaging supplier's facility that affects the business operations or product status that the imaging supplier is obliged to report to RadSite. Examples include filing for bankruptcy, loss or restriction of business license, no longer providing ADI radiological services, or being sued.

Board-Certified or Board Certification is a certification that is granted to a practitioner by the American Board of Medical Specialties, the American Osteopathic Association, or other organizations recognized by RadSite.

Board-Eligible represents a preliminary status for a practitioner before becoming board-certified. Board-eligible typically denotes that the individual has achieved or met certain educational requirements, clinical experiences, and other criteria before full certification.

Centers for Medicare and Medicaid Services (CMS) is the federal agency in charge of overseeing the Advanced Diagnostic Imaging Accreditation Program and promulgating agency regulations for that program.

Chiropractor is a licensed provider focused on noninvasive and integrative medicine based on the diagnosis and manipulative treatment of musculoskeletal disorders often resulting from the misalignment of the spine and joints with a focus on the manual adjustment or manipulation of the spinal vertebrae.

Clinical Director of an imaging facility must be appropriately trained and licensed in a designated specialty area who provides guidance, leadership, oversight, and quality assurance to an imaging supplier's clinical and business operation. The clinical director must meet the applicable professional requirements:

- Dental: Dentist (i.e., DDS or DMD), maxillofacial surgeon, orthodontist, or endodontist.
- Medical: A board-certified physician (i.e., MD, DO, MBBS), chiropractor (DC) or podiatrist (DPM) who provides guidance, leadership, oversight and quality assurance to an imaging supplier's clinical and business operation.

Note: This term shall be used for the following RadSite Cone Beam CT ADI Accreditation Programs:

- Dental Cone Beam CT ADI Accreditation, version 1.2.
- Medical Cone Beam CT ADI Accreditation, version 1.2.

See also definition for medical director.

Clinical Images is a collection of images of a patient obtained during an imaging procedure using an imaging system.

Clinical Image Studies are submitted to RadSite as part of the technical component review under Standard 7.3 and must be accompanied by corresponding patient reports and protocols used during the examination.

Computed Tomography (CT) is a non-invasive test that combines ionizing x-ray technology with the computerized assembly of images to provide cross-sectional images of internal organs, bones, soft tissues, and blood vessels. CT images are more detailed than radiographs and commonly assist in detecting and/or diagnosing disorders such as internal trauma, musculoskeletal disorders, cardiovascular and infectious diseases, appendicitis, and cancer.

Cone Beam Computed Tomography (Cone Beam CT) is a specific type of computed tomography in which the source of ionizing radiation is in the shape of a divergent pyramid or cone and the source and detector rotate around a fulcrum fixed within the center of the region of interest and sequential Planar projection images are acquired in a completed or partial arc. This differs from other types of CT studies that use a fan-shaped x-ray beam in a helical progression to acquire individual slice images of the FOV and then stack the slices to construct a 3D image. When using Cone Beam CT, only one gantry rotation is required.

Corrective Action Period is a designated period of time, typically 30 or 60 days, based upon a written corrective action plan which is sent to the applicant (including imaging supplier's applying for re-accreditation). The corrective action period provides a window of time which an imaging supplier is afforded within the ADI accreditation process to remedy the identified deficiencies and resubmit application materials to RadSite for re-examination and re-scoring.

CT Dose Check is a NEMA XR-29 Standard which incorporates two features—dose notifications and dose alerts—that warn imaging technologists and medical providers when dose exceeds established thresholds.

Dental Specialty is an area of dentistry which has met the Requirements for Recognition of Dental Specialties set by the American Dental Association, or the regulations of the local equivalent.

Dentist is a licensed provider who focuses on the prevention, diagnosis and treatment of diseases, injuries, and malformations of teeth, gums, jaws and mouth. Dentists hold the degree necessary to practice dentistry in their country (e.g., DDS, DMD).

Diffusion Weighted Imaging (DWI) is a specific MRI sequence that uses the diffusion of water molecules to generate contrast in MR images.

Digital Imaging and Communications in Medicine (DICOM) is an industry standard for handling, storing, printing, and transmitting medical imaging information.

DICOM Radiation Dose Structured Report is a NEMA XR-29 Standard that enables recording of post-exam dose information in a standardized electronic format. This information can be included in the patient record, promoting the establishment of diagnostic reference levels as well as facility dose management and quality assurance.

Endodontist is a person recognized by the American Dental Association or local equivalent as having completed dental specialty training in this area and that is board-eligible or board-certified in Endodontics. This specialty addresses the morphology, pathology, and physiology of the dental pulp and periradicular tissues.

Ear, Nose, & Throat (ENT/Otolaryngology/Otorhinolaryngology). This medical specialty performs surgical management of issues related to the head and neck.

Fixed Imaging System is an imaging system that is stationary or permanently fixed to an imaging supplier's location.

Gamma Camera, also called a "scintillation" or "anger" camera, is a nuclear medicine imaging system used to detect gamma radiation emitted from radioisotopes administered to patients. The nuclear medical images are produced to view and analyze tissues and organs of the human body or the subsequent distribution of medically injected, inhaled, or ingested radionuclides.

Imaging Facility is a physical location where an imaging supplier has at least one imaging system; also referred to as a "Site."

Imaging Manager is the individual responsible for supervision of the facility's personnel and imaging systems, including the implementation of policies and procedures which leads to the provision of safe and effective imaging services to patients.

Imaging Practitioner is any individual involved in the acquisition, management, or interpretation of images.

Imaging Safety Officer is a trained medical physicist, imaging technologist, radiologist or healthcare professional assigned to develop, implement, and oversee the medical imaging safety program. See also definition for radiation safety officer.

Imaging Supplier Section 135(a) of MIPPA, §1834(e) of the Social Security Act and the CMS ADI regulations at 42 CFR 414.68 use the term "imaging supplier." Section 1861(d) of the Social Security Act defines the term "supplier" as a "physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title." Section 1834(e)(1)(B) of the Social Security Act defines the term the term "advanced diagnostic imaging services as including "(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography)". See also 42 USC §1395m(e)(2).

Imaging System(s) refers to medical imaging equipment including MRI, CT, nuclear medicine and other modalities, as defined by §1834(e) of the Social Security Act. See also 42 USC §1395m(e)(2).

Imaging Technologist is a trained and licensed healthcare professional who creates medical images of the human body to aid radiologists and other medical providers in diagnosing and treating illness and injury. Formal training ranges from two to four years and may be acquired through college or university degree programs or technical certification programs. Imaging Technologists work in a variety of settings including hospitals, clinics, medical laboratories, nursing homes, and private practice locations.

Immediate Jeopardy represents a situation in which an imaging supplier's noncompliance places the health and safety of a patient in its care at risk for serious injury, serious harm or serious impairment or death.

Interpreting Physician is any Doctor of Medicine or Osteopathy who interprets the imaging study. The professional should be qualified for medical imaging interpretation and patient diagnosis and have an active medical license that carries no restriction relevant to the ADI Accreditation Program in the state(s) where he or she practices.

Interpreting Practitioner (for Cone Beam CT accreditation only) is any Dentist, Doctor of Medicine, Doctor of Osteopathy, Doctor of Chiropractic or Doctor of Podiatric Medicine who interprets the imaging study. The professional should be qualified for medical/dental imaging interpretation and patient diagnosis and have an active medical or dental license, which carries no restriction relevant to the Cone Beam CT Accreditation Program in the state(s) where he or she practices.

License is a permit, official recognition, or the equivalent that authorizes an individual to practice in specific medical or healthcare occupations and is: 1) issued by any state or jurisdiction in the United States, including the U.S. incorporated and unincorporated, organized, and unorganized territories such as Puerto Rico, Guam, the US Virgin Islands, and American Samoa; and 2) required for the performance of job functions.

Magnetic Resonance Imaging (MRI) is a non-invasive or minimally invasive examination that produces images of organs, soft tissues, and bones. An MRI examination is more sensitive to soft tissue differences

than plain x-ray or CT studies and may result in better identification of certain aspects of anatomy and disease.

Maxillofacial Surgeon is a person recognized by the American Dental Association or local equivalent as having completed dental specialty training in this area and that is board-eligible or board-certified in Oral and Maxillofacial Surgery. This specialty diagnoses and surgically treats diseases, injuries and defects involving the hard and soft tissues of the oral and maxillofacial region.

Medical Director is a board-certified physician who provides guidance, leadership, oversight, and quality assurance to an imaging supplier's clinical and business operation. Note: This term shall be used for the following RadSite ADI Accreditation Programs:

- Computed Tomography (CT) ADI Accreditation, version 3.3.
- Magnetic Resonance Imaging (MRI) ADI Accreditation, version 3.3.
- Nuclear Medicine (NucMed) ADI Accreditation, version 3.3.

See also definition for clinical director.

Medical Physics is the application of the scientific principles of advanced mathematics and physics to medicine, including medical imaging and radiotherapy. Medical physics includes quality improvement and analysis of the highly complex signal pattern recognition and acceptable and reasonable dosages or body burdens of radioisotopes involved in imaging modalities such as computed tomography, magnetic resonance imaging, and nuclear medicine.

Medical Physicist is an individual who is competent, trained and licensed to practice independently in one or more of the subfields of medical physics: therapeutic radiological physics, diagnostic radiological physics, medical nuclear physics, or medical health physics. The medical physicist conducts performance evaluations on advanced diagnostic imaging (ADI) systems.

Medical Physicist Report is a document prepared by a Medical Physicist that contains data and observations based on radiation and test-object measurements of a medical imaging system.

Medicare Improvements for Patients and Providers Act (MIPPA), H.R 6331 (110th), is a federal statute that was passed by Congress on July 15, 2008. Section 135(a) of MIPPA established the new accreditation requirement for ADI services. The requirements were codified in section 1834(e) of the Social Security Act. Subsequently, CMS published regulations at 42 CFR 414.68 to implement this accreditation requirement. These regulations detail the program elements associated with this accreditation requirement, such as those contained in the RadSite ADI Accreditation Program.

Mobile Imaging System is an imaging system that is not stationary or permanently fixed to a site and/or that is transported periodically from one location to another.

Modality is referred to as a particular form of imaging such as MRI, CT, SPECT, and PET.

MR Scientist is an individual who is competent, trained and licensed to conduct a performance evaluation of MRI imaging equipment.

National Provider Identifier (NPI) is the unique identifying number assigned to each healthcare provider by the National Plan & Provider Enumeration System (NPPES) from the Centers of Medicare & Medicaid Services (CMS).

Non-Imaging System includes the equipment that supports the rendering of ADI services including, but not limited to, capabilities such as: 1) Picture Archiving and Communications System (PACS) for storage or transfer of images; and 2) Computer-Aided Diagnosis (CAD), which assists the interpreting physician and interpreting provider (Cone Beam CT only) in interpreting the images by marking anatomic structures using highly complex pattern recognition.

Notice of Failure is the official notice that RadSite sends an applicant or accredited imaging supplier who has not met the ADI Standards. The written notification will identify the reasons for failure and the applicant's appeal rights. The document also will detail when and how the imaging supplier can re-apply for ADI accreditation.

Nuclear Medicine includes several types of imaging systems that require the administration of radioisotopes into the body. Once absorbed or contained within the vasculature, ingested, or inhaled, the material enables the structure and function of organs and tissues to be evaluated through the detection of the gamma rays emitted. nuclear medicine imaging modalities include a Planar/SPECT, PET, and PET/CT.

Occupational Safety and Health Administration (OSHA) is a federal agency of the United States that regulates issues related to workplace safety and health. If an OSHA-approved State Plan is applicable in lieu of OSHA, satisfying State Plan requirements shall be considered equivalent to satisfying OSHA requirements for the purposes of this document.

Oral and Maxillofacial Surgery Specialty is the dental specialty addressing the diagnosis, surgical and adjunctive treatment of defects, diseases, and injuries involving the hard and soft tissues of the oral and maxillofacial region, as defined by the American Dental Association or its local equivalent.

Orthodontist is a person recognized by the American Dental Association or local equivalent as having completed dental specialty training in this area and who is board-eligible or board-certified in orthodontics and dentofacial orthodontics.

Orthopedics. This specialty performs the diagnosis, prevention, interception, and correction of deformities, disorders, or injuries of the skeleton, especially the extremities and the spine, and associated structures such as muscles and ligaments.

Patient is an individual who is receiving or has received medical imaging services from an imaging supplier.

Phantom is a device that copies certain specific parameters of a human body part or organ for purposes of evaluating imaging system performance. A phantom is often shaped like a body part to simulate clinical images for visual evaluation and is used to provide a detailed assessment of the capability of any given imaging system by allowing assessment of a predetermined set of measurements or values.

Phantom Images or Test-Object Images are a set of images acquired using either a phantom or a test-object to help assess the performance of an imaging system.

Planar Imaging is a 2D scanning technique used with a Gamma Camera.

Podiatrist is a licensed doctor, specifically a "doctor of podiatric medicine" or DMP, that specializes in the diagnosis and treatment of disorders of the foot, ankle, and lower extremity. Podiatrists hold the degree necessary to practice podiatry in their country (e.g., DPM).

Positron Emission Tomography (PET) is a nuclear medicine imaging modality. The PET examination focuses primarily on the functionality of organs and tissues, assessing the performance of such body processes as glucose metabolism, oxygen absorption, and blood circulation for the purpose of evaluating the heart, brain, and other parts of the body, along with the detection and progress of cancer and other illnesses. A PET scan may be more effective in identifying some diseases in earlier stages than those detected by other forms of diagnostic imaging. PET imaging systems are one of the medical imaging modalities covered by the ADI Accreditation Programs. Regarding a PET/CT scanner, the PET system is combined with a CT system. The CT portion of the PET/CT scanner is used for attenuation correction and anatomic localization but can also be utilized independently.

Practitioner is an individual in a registered or licensed healthcare occupation who is approved to provide medical or personal care to healthcare consumers or patients after gaining informed consent or in a life-saving emergency. Examples of practitioners include physicians, physician assistants, nurse practitioners, nurses, registered radiology technicians, dentists, chiropractors, and podiatrists.

Quality Assurance (QA) Program is the systematic monitoring and evaluation of the key business and clinical workflows of an imaging supplier to maximize the probability that acceptable standards of quality are obtained and that safe ADI services are provided to patients.

Quality Control (QC) Program is a systematic monitoring and evaluation process by which imaging suppliers periodically inspect, test, and review the quality and safety associated with each imaging system. Performance is measured, compared to benchmark levels, and documented through a formal QA Program.

Radiation Safety Officer (RSO) is a trained medical physicist, imaging technologist, radiologist or medical professional, such as a RN or M.D., who is assigned to develop, implement, and oversee the medical imaging safety program. While the title is not restricted to RSO, the trained individual must be performing the responsibilities involved in overseeing the imaging safety program. See also definition for imaging safety officer.

In a non-radiology setting for Cone Beam CT accreditation only, an RSO could be a dental hygienist, dentist (DDS or DMD), maxillofacial surgeon, or any other qualified professional deemed acceptable to RadSite.

Radiologist is a physician specializing in radiology, the branch of medicine that uses imaging for the diagnosis and treatment of disease. A radiologist must have graduated from an accredited medical school, be licensed in the state in which they practice, and have completed additional postgraduate training (internship and residency) typically lasting five years. Many radiologists complete additional subspecialty

training (fellowship) of one to three years. Radiologists may be board-certified or eligible, as certified by the American Board of Radiology or the American Osteopathic Board of Radiology. For Cone Beam CT accreditation only, a radiologist could be a dentist who meets the requirements above and is board-certified or eligible form the American Academy of Oral and Maxillofacial Radiology.

Receipt refers to the receipt of an official notice from RadSite by an applicant or accredited imaging suppliers and is presumed to be five days from the date of the notice being sent from RadSite unless: (1) the fifth day falls on the weekend or a federal holiday in which case the applicant's receipt will be presumed to be on the next business day; or (2) the applicant presents reasonable contrary proof of receipt on a later date.

Reference Adult and Pediatric Protocols are a NEMA XR-29 Standard requirements that include a set of pre-loaded parameters on a CT system that can be selected by the imaging technologist to complete a particular clinical task, such as capturing an image of the abdomen.

Request for More Information is a written document (or email with a confirmed receipt) sent to an applicant during the accreditation process (or accredited imaging supplier during the reaccreditation process) requesting additional details about the imaging supplier's activities, processes or programs to ensure the supplier is meeting ADI Standards. Typically, imaging suppliers will have 30 days to respond to a "Request for More Information".

Sentinel Event is any medical error or event in a healthcare setting that results in serious injury or death to a patient or a hazard to the general public, which is not related to the natural course of the patient's illness.

Single Photon Emission Computed Tomography (SPECT) is a nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional Nuclear Medicine Planar imaging using a Gamma Camera. However, it can provide true three-dimensional image information.

Site is a location at which one or more imaging systems are located. See also "imaging facility."

Specialty Module covers additional imaging specialty areas highlighted in Table 1 and referenced in Section VII for each ADI modality.

Standards indicate a number of mandatory requirements that must be met to become ADI Accredited. 100% of these standards must be satisfied.

Stark Law refers to three laws that address limitations on certain physician referrals, found at §1877 of the Social Security Act and 42 C.F.R. §411.350 through §411.389. The Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) barred self-referrals for clinical laboratory services under the Medicare program, effective January 1, 1992, known as "Stark I." The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid, known as "Stark II." also contained clarifications and modifications to the exceptions in the original law. Minor technical corrections to these provisions were included in the Social Security Amendments of 1994. The Phase III final rule was published on September 5, 2007, at 72 FR 51012, and became effective December 4, 2007.

Supervising Physician is the clinician in charge of a particular imaging facility or department location. They can supervise one or more locations with a primary goal of ensuring that imaging exams are quality-based with a primary focus on patient safety and clinical efficacy. They also can serve as the medical director (sometimes referred to collectively as "supervising physician"). Note: This term shall be used for the following RadSite ADI Accreditation Programs:

- Computed Tomography (CT) ADI Accreditation, version 3.3;
- Magnetic Resonance Imaging (MRI) ADI Accreditation, version 3.3; and
- Nuclear Medicine (NucMed) ADI Accreditation, version 3.3.

See also definition for supervising practitioner.

Supervising Practitioner is the clinician in charge of a particular imaging facility or department location. They can supervise one or more locations with a primary goal of ensuring that imaging exams are quality-based with a primary focus on patient safety and clinical efficacy. They also can serve as the medical director (sometimes referred to collectively as "supervising physician"). Note: This term shall be used for the following RadSite Cone Beam CT ADI Accreditation Programs:

- Dental Cone Beam CT ADI Accreditation, version 1.0; and
- Medical Cone Beam CT ADI Accreditation, version 1.0

(See also supervising physician)

Test-Object is a passive device or geometric shape used to evaluate performance specifications of clinical imaging systems and is usually designed for numerical assessment of spatial resolution, contrast resolution, and other system-specific parameters.

Time Slot-Leasing Arrangement refers to a lease agreement for an imaging system used by non-radiology providers where periods of time are leased by the provider to refer patients for image scans. The phrase as used in the ADI Standards refers to a situation in which the leasing provider may receive a pecuniary benefit from a potential inappropriate financial incentive to refer patients to undergo imaging by one of the leased imaging systems during the rented time. The abuse of time slot-leasing arrangements can occur based on several inappropriate practices, including:

- Referring patients to fill in the time slots without the appropriate medical necessity.

- Billing Medicare or another payer as if the provider "owns" the imaging equipment under the "Group Practice Exemption."

- Any other use of a slot-leasing arrangement that is not in the patient's best interest.

Inappropriate time slot-leasing arrangements can take place both for fixed and mobile imaging systems and should be avoided. Note: These practices are illegal in several states.

Section I: Imaging Supplier Information

Standard 1.1 – Organizational Information

1.1.1 **Background**. The imaging supplier shall provide background information including:

A. Location of imaging supplier's main office or corporate headquarters;

B. Location of all imaging facilities (and for the ADI mobile systems, identify the facilities serviced by each imaging system and list each facility that bills separately for the use of the mobile ADI system);

C. Identification of all imaging systems at each imaging facility;

D. Identification of all imaging systems that are being excluded from the ADI accreditation application; and

E. National Provider Identifier (NPI) numbers and other information for all healthcare providers who are using the imaging systems for ADI services at each location and are billing CMS for those services.

1.1.2 **Scope of Services.** The imaging supplier shall also provide additional background information regarding the imaging supplier's scope of services in regard to:

A. The clinical setting of each imaging facility, including:

i. Identification of key clinical personnel;

ii. A physician or practitioner's specialty areas;

iii. Freestanding radiology facilities;

iv. Other practitioners that provide ADI service who are paid under the fee schedule established under section 1848(b) of the Social Security Act.

B. Patient and general populations served; and

C. Any additional imaging services that are not within the scope of ADI services, such as:

i. x-rays;

ii. fluoroscopy;

iii. ultrasounds;

iv. mammograms

Further Explanation

The intent of this standard is to obtain the information necessary to evaluate the merits of the imaging supplier and its imaging systems for purposes of ADI accreditation. The application for ADI accreditation requests specific information regarding the imaging supplier's business name, contact information, NPI numbers, , types of ADI modalities provided, portability of imaging systems (i.e. - stationary versus mobile equipment), and ADI services rendered), and other information relevant to the ADI Standards.

Document Submission

The applicants and accredited suppliers undergoing reaccreditation audits shall provide information through the RadSite Online Portal which documents each facility location. Imaging suppliers who are using a mobile imaging system must submit a list identifying the facilities serviced by each mobile ADI imaging system and list each supplier that bills separately for this service as required by Standard 1.5 and other applicable RadSite requirements. Each applicant must carefully and thoroughly document how each billing supplier is using mobile ADI imaging systems to ensure that each location is in full compliance with the RadSite Standards and federal, state and local ordinances/regulations.

Standard 1.2 – Imaging Supplier Specialty

1.2.1 **Scope of Practice**. If the imaging supplier specializes in providing certain types of imaging services, the imaging supplier shall:

A. Provide documentation demonstrating that its staff, physicians and non-physician practitioners follow evidence-based medical guidelines in the appropriate diagnostic uses of these services;

B. Describe the necessary expertise in administering these services and interpreting the images produced or have contracted with a third-party with the necessary expertise to do so; and

C. Ensure their scope of practice and imaging practices are permissible under federal, state and local regulations.

1.2.2 **Qualifications.** The imaging supplier shall comply with the experience and education requirements set forth in Section III and the exam submission requirements set forth in Section VII.

Further Explanation

The intent of this standard is to ensure that each imaging supplier seeking accreditation possesses the necessary professional experience and staff necessary to support the appropriate and safe use of its imaging systems. The application asks for the identification of the medical specialties that are or will be utilizing the imaging supplier for imaging studies as highlighted in Table 1. The accreditation applicant at its option, can choose to become accredited for one or more specialty modules, but as part of the application process, still need to identify the specialty areas.

Standard 1.3 – Imaging Facility Requirements

1.3.1 Each imaging supplier's imaging facility shall ensure that it:

A. Meets local zoning laws and ordinances;

B. Complies with federal, state and local requirements regarding radiation and occupational safety protocols;

C. Offers appropriate and safe access and privacy for patients;

D. Uses separate areas with restricted access for the interpretation of imaging studies in order to ensure patient confidentiality;

E. Maintains the secure storage and transfer of patient records;

F. Properly stores radioactive materials and other medical supplies in an area with restricted access; and

G. If applicable, meets Nuclear Regulatory Commission (NRC) and/or state licensing requirements regarding safe materials handling.

1.3.2 Additional Requirements for Nuclear Medicine. If the imaging supplier is authorized to perform nuclear medicine imaging, the applicable facility's management shall be:

A. Trained in the procedures of nuclear medicine; and

B. An authorized user of radioisotopes according to the regulations of the Nuclear Regulatory Commission (NRC).

Further Explanation

The intent of this standard is to ensure each imaging supplier's imaging facility is following federal, state and local regulations/ordinances and licensing requirements. The application requests the imaging supplier to provide supporting information as detailed in the accreditation application related to each site.

Standard 1.4 – Non-Imaging System Requirements

1.4.1 The imaging supplier's non-imaging systems shall:

A. Meet manufacturer's safety recommendations and procedures;

B. Meet all federal, state and local regulations;

C. Meet or exceed all non-safety manufacturer recommendations;

D. Conduct regular inspections which are scheduled and performed at least annually or per the manufacturer's specifications, whichever is shorter;

E. Keep service and maintenance records up to date; and

F. Perform periodic quality control testing.

Further Explanation

The intent of this standard is to ensure each non-imaging system at each location is installed, operated, and maintained in accordance with manufacturer requirements and federal, state and local regulations. In addition, the applicant or accredited imaging supplier needs to ensure that both its imaging and non-imaging systems are included in their quality assurance program.

Standard 1.5 – Mobile Imaging Requirements

1.5.1 **General Requirements**. The imaging supplier shall provide information on all mobile imaging systems that demonstrates the proper installation, use and maintenance according to manufacturer recommendations, as well as, compliance with all federal, state and local requirements.

1.5.2 **Leasing**. If the imaging supplier leases the mobile imaging system(s), the imaging supplier shall have a written agreement with the owner of the mobile imaging system(s) that:

A. Sets the terms for use of the mobile imaging system(s) by the provider (Leasee);

B. Ensures continuity of services;

C. Permits all applicable standards and regulatory requirements to be met; and

D. Allows the imaging supplier to audit all aspects of the mobile imaging system operations in an appropriate and timely manner.

1.5.3 **Safety Protocols**. The imaging supplier shall follow the same safety procedures when using mobile imaging systems as it does with stationary imaging systems, as well as additional pertinent requirements associated with the mobile imaging system's relocation abilities and frequencies. This includes but is not limited to these items:

A. Implementing quality control procedures at each new location to set up and run operations, including procedures to address safe power hook up, machine recalibration and temperature monitoring;

B. Using properly licensed and professional staff necessary to support proper use, as defined below in Sections III and IV;

C. Ensuring appropriate cleaning of the mobile imaging system including an infection control program;

D. Implementing patient safety policies and procedures for handling medical emergencies and urgencies along with necessary basic and advanced first aide equipment including immediate access to a crash/code cart, along with a direct communication link to handle resuscitations and other life-sustaining measures; and

E. Ensuring proper, sufficient, and safe back-up power supply.

Further Explanation

This standard only applies to ADI mobile imaging systems. If the imaging supplier does not own, contract or use a mobile imaging system, this standard shall be marked "N/A" in the RadSite Online Portal.

The intent of this standard is to ensure all imaging suppliers who use a mobile ADI imaging system meets the same standards and regulatory requirements as the imaging systems that are stationary or at fixed locations. Special attention needs to be taken as mobile imaging systems can be used by one or more providers or suppliers and moves from one facility or location to the next. Each imaging supplier must follow the same quality control checks for both fixed imaging systems and mobile imaging systems pursuant to the standards in Section VII. For example, imaging suppliers using mobile ADI imaging systems must implement patient safety policies and procedures, including but not limited to the proper: 1) shielding of the patient; 2) use of qualified imaging technologists; 3) access to back-up power supply; 4) maintenance of temperature levels in the mobile imaging system space; 5) procedures to ensure patient privacy; and 6) procedures to maintain the confidentiality of patient records (including images).
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Section II: Imaging Systems

Standard 2.1 – Imaging System Requirements

2.1.1 For each ADI imaging system, the imaging supplier shall:

A. Provide information which demonstrates the proper installation, calibration, use, maintenance and troubleshooting in accordance to manufacturer recommendations and in compliance with all federal, state and local requirements;

B. Demonstrate that the imaging supplier meets the applicable manufacturer's recommendations for quality control testing as further defined in Section VII; and

C. Conduct regular inspections which are scheduled and performed at least annually or per the manufacturer's specifications, whichever is shorter.

Standard 2.2 – CT Imaging System Requirements

2.2.1 **General System Requirements.** For CT imaging systems, the imaging supplier shall monitor the following quality and performance control factors pursuant to Section VII:

A. Quality control program (e.g., routine calibrations and service);

B. Reconstructed slice thickness;

C. High contrast (spatial) resolution;

D. Low contrast resolution;

E. Noise level;

F. Artifact-free status; and

G. CT number accuracy and linearity.

2.2.2 **Strength Thresholds**. The imaging supplier shall maintain regular CT imaging systems pursuant to the following minimum thresholds:

A. General CT imaging systems shall have a minimum of 4 slices;

B. Imaging systems used for Angiography CT and Coronary Calcium scoring shall have a minimum of 16 slices/channels (Angiography CT imaging studies cover carotid, pulmonary, renal, peripheral and intracranial studies); and

C. Imaging systems used for Coronary CT Angiography (CCTA) imaging shall have a minimum of 64 slices/channels.

2.2.3 **Cardiac Imaging.** Imaging suppliers shall use dual injectors for the contrast administration related to CT cardiac imaging.

Standard 2.3 – MRI Imaging System Requirements

2.3.1 **General System Requirements.** For MRI imaging systems, the imaging supplier shall monitor the following quality and performance control factors pursuant to Section VII:

A. Quality control program (e.g., routine calibrations and service);

B. Maximum level for static magnetic field strength (Bo);

C. Gradient magnetic field strength (dB/dt);

D. Radio frequency power deposition (specific absorption rate);

E. Auditory noise levels;

F. Center frequency;

G. Table positioning;

H. Setup and scanning;

I. Geometric accuracy;

J. High-contrast resolution;

K. Low-contrast resolution;

L. Artifact analysis;

M. Slice position accuracy; and

N. Slice thickness accuracy.

2.3.2 **Strength Thresholds**. The imaging supplier shall ensure the appropriate usage of their MRI imaging systems pursuant to the following guidelines and minimum strength requirements:

A. All units must be capable of performing diffusion weighted imaging (DWI); and

B. MRI Tesla strength requirements are:

i. Units with a field strength of < 0.3 Tesla are not permitted,

ii. Units with a field strength of ≥ 0.3 Tesla can perform examinations of the brain, spine, and extremities,

iii. Units with a field strength of ≥ 1.0 Tesla can perform all examinations (other than Breast and Cardiac MRI), and

iv. Units with a field strength of ≥ 1.5 Tesla with a slew rate of at least 70mT/meter/sec can perform all examinations including breast and cardiac imaging.

2.3.3 **Breast Imaging**. The imaging supplier must meet the additional requirements for breast MRI imaging:

A. Use bilateral breast coils for breast tissue examinations;

B. Be capable of simultaneous, bilateral imaging;

C. Produce images with slice thicknesses ≤3mm and in-Planar pixel resolution ≤ 1mm;

D. Utilize fat suppression or image subtraction processing on all contrast enhanced sequences;

E. For any MRI Breast imaging, facilities must use the Breast Imaging Reporting and Data System (BI-RADS) final assessment codes and terminology for reporting and tracking outcomes;

F. Have the capacity to perform or make a referral for other breast diagnostic imaging services such as mammography, breast ultrasound and MRI guided intervention (Note: these imaging suppliers must offer those secondary services or document a referral arrangement with a facility that can provide these services).

2.3.4 **Cardiac Imaging**. The imaging supplier must meet the additional requirements for cardiac MRI imaging:

A. Be capable of electrocardiographic (ECG) gating, including prospective, retrospective and triggered retrogating, and new units must have vectorcardiographic gating;

B. Use an MRI-compatible power injector; and

C. Use FDA-approved processing software for calculation of ejection fraction and multi-Planar imaging

Standard 2.4 – Nuclear Medicine Imaging System Requirements

2.4.1 **General System Requirements.** For nuclear imaging systems, the imaging supplier shall monitor the following quality and performance control factors pursuant to Section VII:

A. For Nuclear Medicine – Gamma Camera with Planar imaging (if applicable):

i. Quality control program (e.g., routine calibrations and service),

ii. Intrinsic resolution,

iii. Extrinsic resolution,

iv. Count rate linearity, and

v. System or intrinsic uniformity;

B. For Nuclear Medicine – Gamma Camera with SPECT imaging (if applicable):

i. All factors set forth in 2.4.1 above,

ii. Image reconstruction algorithms,

iii. System safety interlocks,

iv. Spatial resolution,

v. Uniformity,

vi. SPECT tomographic uniformity, contrast, and spatial resolution,

vii. SPECT center-of-rotation for multi-detector registration calibration, and

viii. SPECT high-flood counts for uniformity correction;

C. For Nuclear Medicine – PET imaging systems (if applicable):

i. Quality control program (e.g., routine calibrations and service) covering:

a) Coincidence timing window,
b) Photon attenuation correction,
c) Dead time,
d) Random or scatter coincidence,
e) Noise equivalent count rate, and
f) Sensitivity,

ii. SUV measurement,

iii. Spatial resolution,

iv. Uniformity, and

v. CT scanner 16 slices or higher;

D. For Nuclear Medicine equipment -- collimator requirements include a:

i. Low energy collimator (e.g., for technetium scans),

ii. Low energy, high resolution (LEHR) collimator,

iii. Medium energy collimator (e.g., for indium or gallium scans), and

iv. High energy collimator (e.g., for Iodine 131 scans).

2.4.2 **Cardiac Imaging**. For cardiac nuclear imaging equipment, the imaging supplier must use:

A. Quantitative analysis software;

B. Cardiac gating;

C. EF (Ejection Fraction) Calculation software; and

D. Motion correction, back filter projection reconstruction, or line spread function software.

Standard 2.5 – Regulatory Requirements and Testing Protocols

2.5.1 **General Requirements.** The imaging supplier must ensure and demonstrate that all ADI imaging systems:

A. Meet all federal, state and local requirements as required by law; and

B. Implement a routine maintenance and operation plan that includes:

i. Regularly scheduled annual inspections,

ii. Appropriate cleaning and disinfecting of medical and imaging equipment after each patient,

iii. Preventive maintenance in accordance with the manufacturer's recommendations or at least every 3 months (whichever is shorter),

iv. Maintaining a record of all service performed on each ADI imaging system and its components

v. Safe power hook-up,

vi. Machine recalibration, and

vii. Temperature monitoring.

2.5.2 **NEMA XR-29 Standard Requirements**. All imaging suppliers operating CT imaging systems must identify whether each CT system they own or operate comply with the NEMA XR-29 Standards covering the four (4) attributes:

A. Implementation of a DICOM Radiation Dose Structured Report, which enables recording of post-exam dose information in a standardized electronic format. This information can be included in the patient record, promoting the establishment of diagnostic reference levels as well as facility dose management and quality assurance.

B. Application of a CT Dose Check, which incorporates two features i.e., dose notifications and dose alerts, that warn imaging technologists and medical providers when dose exceeds established thresholds.

C. Use of Automatic exposure controls (AEC), which automatically adjust the amount of radiation within prescribed bounds as needed to achieve the desired image quality. Studies of AEC procedures have demonstrated dose reductions when used properly.

D. Reliance to evidence-based adult and pediatric protocols, which shall include a set of pre-loaded parameters on a CT system that can be selected by the imaging technologist to complete a particular clinical task, such as capturing an image of the abdomen.

Document Submission

The applicant or accredited imaging supplier undergoing a reaccreditation audit shall submit the following documentation:

1) A policy describing each facility's imaging system maintenance program.

2) A written narrative explaining the imaging supplier's existing approach to its quality control program. The purpose of this requirement is to ensure that imaging suppliers provide safe and appropriate ADI services to their patients.

3) A manufacturer's certificate of NEMA XR-29 compliance for each CT system they own or operate.

For additional information regarding imaging system material submission and scoring, see Section VII.

Further Explanation

The intent of this standard is to ensure imaging systems at each location are installed, operated, and maintained according to the requirements of the manufacturer as well as from federal, state and local

government agencies. RadSite requests imaging suppliers to provide specific information related to each ADI imaging system at each site, including:

- Manufacturer name.
- Date of manufacture.
- Model and serial number.
- Distinguishing features.
- Performance capabilities.
- Location of the imaging system.
- Estimated annual volume of image studies performed by each imaging system.
- The medical physicist report.

The applicant or accredited imaging supplier undergoing reaccreditation audit must implement patient safety policies and procedures including, but not limited to, properly shielding the patient, using qualified imaging technologists, having a back-up power supply, keeping the temperature at proper levels in the imaging system space, and ensuring patient privacy.

Section III: Professional Qualifications

This section identifies the minimum professional qualifications for several key imaging professionals. A professional working for the imaging supplier can hold more than one position, but normal conflict of interest policies will apply. For example, the imaging manager cannot also serve as the medical physicist when evaluating the performance of the imaging systems the imaging manager oversees. RadSite is promoting continuity in the training, education and experience requirements between different professionals.

Standard 3.1 – General Staffing Requirements

3.1.1 The imaging supplier shall:

A. Maintain an employee manual that is reviewed and updated at least annually and distributed to staff;

B. Implement a grievance process for employees;

C. Maintain written job descriptions for all staff members involved in the delivery of the technical component of ADI services, which, at a minimum, provides the following information:

i. Job title,

ii. Description of job responsibilities,

iii. Minimum qualifications for education, training and professional experience,

iv. Appropriate licensure or certification requirements, and

v. Identification of supervisor or otherwise reference reporting responsibilities; and

D. Maintain personnel files for each employee and all applicable credentialing information for professional staff, with said files being kept in a secured location with restricted access to the appropriate management staff only.

Further Explanation

The intent of this standard is to ensure that the imaging supplier has a human resource (HR) program along with applicable personnel policies and procedures. The imaging supplier must have written job descriptions for all key positions in the organization, which are reviewed annually and updated as needed. The ADI accreditation application requests the imaging supplier to attest that it has personnel files for all employees who engage in providing ADI services and that these personnel files contain the relevant information for each employee. If an on-site audit is performed, the personnel files related to different positions will be selected at random and reviewed for compliance.

Standard 3.2 – Credentialing of Professional Licensure and Qualifications

3.2.1 **General Requirements**. The imaging supplier shall ensure that all imaging practitioners are qualified to carry out their respective job functions by verifying the current credentials of all imaging practitioners through primary and secondary source verification upon hire, including current license(s) or credentials and history of licensure in all jurisdictions in which the practitioners have credentials in addition to the other requirements detailed in this Standard.

3.2.2. **Credentialing Elements**. The imaging supplier's credentialing verification program shall include the following elements:

A. ***General.*** History of education, professional training, licensure, certifications, board certification status, and history of professional complaints, disciplinary actions, sanctions, and license suspensions;

B. ***Primary Source*.** Primary verification of credentials from granting institutions covering state licensing boards, specialty certification boards (if applicable), and the highest level of education; and

C. ***Secondary Source*.** Secondary verification of:

i. Credentials from societies, professional organizations, or trade organizations,

ii. Work history for a minimum of the last five years (or since last credentialed by the organization),

iii. Review of professional liability claims,

iv. Review of grievances history,

v. Review of history of disciplinary actions, sanctions, admonishments, and penalties imposed by any agencies such as, but not limited to, hospitals, licensing boards, and government entities,

vi. Valid and current Drug Enforcement Agency (DEA) certificate or state-controlled substance certificate, if applicable,

vii. Proof of professional liability insurance, ability to self-insure, or other coverage as required by the state, if applicable, and

viii. Current hospital affiliations or privileges, if applicable.

3.2.3 **Ongoing and Re-Credentialing Requirements**. The imaging supplier shall include in its credentialing program:

A. Review of the licenses and credentials of all imaging practitioners at least once every three years, or more often as appropriate;

B. Implementation of corrective actions in response to adverse changes in certification, licensure or status;

C. Notification of the applicable authorities of any material changes in licensure or certification status of all imaging personnel within 30 days of such changes; and

D. Notification to RadSite of any material changes in licensure or certification status of the medical director or supervising physician within 30 days of such changes.

Further Explanation

The intent of this standard is to ensure that imaging suppliers only hire or contract with qualified registered or licensed practitioners, and that current credentials and qualifications are regularly verified through an enforced credentialing policy. Each imaging supplier must credential physician and non-physician practitioners through a formal program which is supported by a documented policy or written narrative describing the imaging supplier's approach to credentialing its staff. If there is a deficiency in the practitioner's qualifications, the imaging supplier must take appropriate action which could include a suspension or revocation of his or her privileges to work at the imaging facility or to see patients.

Document Submission

The applicant or accredited imaging supplier undergoing a reaccreditation audit shall submit policies and procedures supporting its credentialing program, addressing the elements listed above in Standard 3.2.

If the imaging supplier uses a credentialing verification organization (CVO) or another third party, then the agreement(s) between the imaging supplier and the delegated credentialing organization(s) must be uploaded into the RadSite Online Portal. RadSite needs to confirm that any delegated credentialing activity to a third party still meets these standards.

Standard 3.3 – Medical Director Qualifications

3.3.1 **General Requirements**. The imaging supplier shall employ or contract with one or more medical directors who:

A. Are responsible for the clinical oversight of the imaging supplier, its imaging facilities, and its ADI services;

B. Have a current, unrestricted license to practice medicine within the state in which the imaging facility is located.,

i. If working at imaging facilities in multiple states, the medical director is required to have multiple current, unrestricted licenses in each of those jurisdictions.

ii. If the license of the medical director is restricted, the imaging supplier must have a process to ensure job functions do not violate the restrictions imposed by the applicable state board(s)];

C. Meet one of the following requirements:

i. Board-certified in radiology by a recognized specialty group in radiology (e.g., American Board of Radiology and American Osteopathic Board of Radiology);

ii. Board-certified in a related specialty with documentation of supervised training in the interpretation and reporting of imaging examinations; or

iii. Completed a recognized training program in the interpretation and reporting of imaging examinations when using a third-party radiologist to interpret or complete overreads of the ADI studies.

D. Meet the following requirements:

i. Meet the baseline education and experience requirements of an interpreting physician or practitioner for the applicable specialty areas of the imaging supplier practice,

ii. Possess continuing experience as documented from interpretation and reporting of examinations, and

iii. Maintain continuing education as required by medical licensing and board certification.

3.3.2 **Continuing Education**. The medical director shall complete at least 90 hours in Category 1 CMEs during the past 3 years which shall include 10 CMEs for each specialty module.

Further Explanation

The intent of this standard is to ensure that an appropriately trained, licensed, and experienced physician is overseeing all clinical and quality assurance aspects of the imaging supplier's ADI services. The ADI application requests information regarding the standards for the roles and responsibilities of the medical director(s) and if applicable the supervising physician(s)(s), which includes information related to specialty type(s), licensing, residency training, board eligibilities and certifications, and other identifying information such as the National Provider Identification (NPI).

In general, a medical director oversees the entire imaging supplier's operations; and a supervising physician is in charge of a particular facility location. In many instances, both positions can be served by the same qualified professional. In larger organizations, it is more likely that different professionals fill these functions.

A medical director's professional qualifications often are subject to multiple requirements from various licensing boards, specialty societies, regulatory agencies and accreditation organizations. As a general principle, if an imaging professional is subject to one or more overlapping requirements based on their scope of practice and specialty areas, the highest job requirement will apply to that individual.

Applicants are asked on the RadSite Online Portal about which professionals fill the specific roles in each organization as highlighted in Section III.

Note: Contact RadSite for any new organizations that provide certifications or CME/CE/CDE instruction that are not referenced in the Standards to determine if they will be recognized by RadSite for meeting this or any other standard.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit:

- Medical director credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.3.

- Documentation of completion of the required continuing education studies by the medical director.

Standard 3.4 – Interpreting Physician Qualifications

3.4.1 **Basic Qualifications.** Only physicians with an MD or DO are qualified to interpret ADI images. Therefore, the imaging supplier shall employ or contract with qualified interpreting physicians that meet the following criteria:

A. ***Licensure.*** A current, unrestricted license(s) to practice medicine within the state in which the imaging facility is located.

i. If working at imaging facilities in multiple states and/or if required by federal, state, or local regulations or by other practice requirements, the interpreting physician is required to have multiple current, unrestricted licenses in each state in which the imaging facilities in which he or she works are located.

ii. If the license of the interpreting physician is restricted, the imaging supplier must have a process to ensure that job functions do not violate the restrictions imposed by the applicable state board(s);

B. ***Board Certification***. Board certification or eligibility from a recognized specialty group in radiology (including the American Board of Radiology and American Osteopathic Board of Radiology); or board certification or eligibility in another specialty including the Society of Cardiovascular Computed Tomography and the American Board of Nuclear Medicine with documentation of supervised training in the interpretation and reporting of examinations;

C. ***Residency.*** Completion of an accredited ACGME residency program for the applicable modalities; and

D. ***Training/Experience.*** The interpreting physician shall meet the following requirements:

i. Baseline Education Requirement:

a) Completing 150 Category I CME hours or the equivalent for CT and MRI imaging and 35 Category I CME hours or the equivalent for NM, which track the physician's imaging practice patterns,

b) In terms of IV contrast and conscious sedation of a patient, the interpreting physician must be properly trained and meet all state regulatory requirements, and

ii. Baseline Experience Requirements:

a) Being previously supervised by a qualified physician or medical director who meets the experience and training requirements set forth in Standard 3.3,

b) Interpretation of 100 supervised exams for each applicable ADI modality within a 24-month period (where the candidate is physically present and involved in the acquisition of at least 35% of the exam studies), and

c) Interpretation of 150 supervised exams within a 24-month period for each specialty module selected for additional certification (where the candidate is physically present and involved in the acquisition of at least 35% of the exam studies); and

iii. Continuing Education Requirements:

a) Fulfilling education requirements as required by medical licensing and board certification/eligibility requirements,

b) Completing 90 CME hours every 36 months for CT and MR imaging and 21 CME hours every 36 months for NM imaging, and

c) Completing 20 CME hours every 36 months for each specialty module selected for additional certification; and

iv. Continuing Experience Requirements:

a) Continuing experience as documented from interpretation and reporting of examinations which shall include the interpretation of at least:

1) 250 (radiologists)/500 (non-radiology physicians) applicable CT and MR exams within the past 36 months, and

2) 125 applicable NM exams within the past 36 months, and

b) Interpretation of at least 60 specialty exams every 36 months for each specialty module selected for additional certification.

3.4.2 **Additional Requirements for Interpreting Physicians.** In addition to the Standard 3.4.1 requirements, the imaging supplier shall employ or contract with qualified interpreting physicians who meet the following criteria for specialty imaging (when they are not board-certified radiologists):

A. ***Breast MR -- Training/Experience***. Additional requirements shall include:

i. ACGME approved residency,

ii. 200 CMEs in breast MRI, and

iii. Interpretation of 300 supervised Breast MR exams within the past 36 months.

B. ***Cardiac CT -- Training/Experience***. Additional requirements shall include:

i. 3-month residency or fellowship in Cardiac CT,

ii. ABIM with cardiovascular certification,

iii. COCATS Level 2 or higher training,

iv. 30 CMEs in CT or Cardiac CT, and

v. Interpretation of 150 supervised Cardiac CT exams and being physically present during acquisition of 50 or more exams.

C. ***Cardiac MR -- Training/Experience.*** Additional requirements shall include:

i. 3-month residency or fellowship Cardiac MR,

ii. ABIM with cardiovascular certification,

iii. COCATS Level 2 or higher,

iv. 30 CMEs in MR or Cardiac MR, and

v. Interpretation of 150 supervised Cardiac MR exams and being physically present during acquisition of 50 or more exams.

D. ***Cardiac NM/PET -- Training/Experience.*** Additional requirements shall include:

i. Board certified or board eligible by ABIM, AOBIM **AND** certified by the Certification Board of Nuclear Cardiology or COCATS Level 2 or higher in nuclear cardiology and PET,

ii. 20 CMEs in NM/PET initially and every 36 months,

iii. 30 supervised specialty exams every 36 months for cardiac NM/PET, and

iv. Interpretation of 150 supervised Cardiac NM/PET exams and being physically present during acquisition of 50 or more exams.

3.4.3 CT Colonography Imaging. In addition to Standard 3.4.1, the imaging supplier shall employ or contract with qualified interpreting physicians for CT colonography imaging that meet the following criteria:

A. Completing a CME training course to include a minimum of 75 proven cases;

B. Interpretation of 50 supervised exams (and where the candidate is physically present and involved in the acquisition of at least 35% of the exam studies) prior to performing independent interpretation;

C. Interpreting or co-interpreting a minimum of 50 cases per year (Note: If a physician cannot document 50 cases per year, then they will be required to document evidence of at least 15 hours of CME training in virtual colonoscopy every three years); and

D. Participating in an annual medical audit by the imaging supplier of all CT colonography cases read by the interpreting physician, which is documented.

<table>
<tr><th colspan="6">Table 4: Interpreting Physician Requirements</th></tr>
<tr><th></th><th colspan="3">Baseline Experience Requirements</th><th colspan="2">Continuing Experience Requirements</th></tr>
<tr><th>Subject Area</th><th># of Studies</th><th>CME Hours</th><th>Certifications</th><th># of Studies /months</th><th>CME Hours /months</th></tr>
<tr><td colspan="6">General ADI Modality Requirements</td></tr>
<tr><td>General CT & MR</td><td rowspan="2">100 supervised cases within 24-months (being physically present for 35%) for each applicable ADI modality</td><td>150 Category I CMEs or the equivalent tracking practice patterns</td><td>Physicians Board eligible</td><td>Radiologists = 250/36
Non-Radiologists = 500/36</td><td>90/36 Category I CME tracking practice patterns</td></tr>
<tr><td>General NM</td><td>35 Category I CMEs or the equivalent tracking practice patterns</td><td>Physicians Board eligible</td><td>125/36</td><td>21/36 Category I CME tracking practice patterns</td></tr>
<tr><td colspan="6">Additional Requirements for Non-Radiologist Interpreting Physicians</td></tr>
<tr><td>Breast MR</td><td rowspan="3">150 supervised cases within 24-months (being physically present for 35%) for each specialty module selected for additional certification</td><td>200 CMEs in Breast MR</td><td>ACGME approved residency</td><td>300/36 supervised cases</td><td rowspan="3">20/36 CMEs for each specialty module selected for additional certification</td></tr>
<tr><td>Cardiac MR</td><td>30 CMEs in MR or Cardiac MR</td><td>3-month residency Cardiac MR
• ABIM with cardiovascular cert
• COCATS Level 2 or higher</td><td rowspan="2">60/36 per each specialty module selected for additional certification</td></tr>
<tr><td>Cardiac CT</td><td>30 CMEs in CT or Cardiac CT</td><td>• 3-month residency Cardiac CT
• ABIM with cardiovascular cert</td></tr>
</table>

			• COCATS Level 2 or higher		
Cardiac NM/PET		30 CMEs in NM/PET	• ABIM/AOBIM and CBNC certification **OR** COCATS Level 2 or higher in nuclear cardiology and PET	30/36 NM/PET supervised cases	20/36 CMEs in cardiac NM/PET
Note: Table 4 is not exhaustive. Read Standards for additional details.					

Further Explanation

The intent of this standard is to ensure appropriately trained, licensed, and experienced interpreting physicians (for CT, MRI and nuclear medicine exams) are analyzing and reporting results of examinations.

The ADI application (for CT, MRI and nuclear medicine imaging systems) requests information about whether the imaging supplier directly employs the physician/radiologist(s) interpreting the clinical images or contracts with a third-party radiologist or radiology group through a consulting firm or other contractual situation. Information regarding each practitioner's specialty type(s), licensing, residency training, board eligibilities and certifications, and other identifying information such as National Provider Identifier (NPI) also is requested.

As a general principle, if an imaging professional is subject to one or more overlapping requirements based on their scope of practice and specialty areas, the highest job requirement will apply to that individual. If an imaging professional is subject to more than one requirement that is not overlapping based on their scope of practice and specialty areas, all of the requirements will apply to that individual.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the interpreting physician's credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.4.

Standard 3.5 – Imaging Technologist Qualifications

3.5.1 **General Requirement**. The imaging supplier shall employ or contract with one or more imaging technologists to operate the imaging systems for ADI services and to obtain medical images of optimal diagnostic quality. In addition, the imaging supplier shall identify a lead technologist for each ADI modality performed.

3.5.2 **Basic Qualifications.** Each imaging technologist(s) shall:

A. Be trained for in each of the modalities performed;

B. Hold unrestricted state licensure, as required, for each of the modalities performed;

C. Have current, unrestricted registration or certification from the American Registry of Radiologic Technologists (ARRT), American Registry of Magnetic Resonance Imaging Technologists (ARMRIT), Nuclear Medicine Technology Certification Board (NMTCB) or from another recognized certification agency for each ADI modality performed;

D. Have an associate or bachelor's degree in radiologic science whenever required, with the requisite job experience; and

E. Complete ongoing continuing education as required by the license, certification, and medical director's directives.

3.5.3 **Lead Technologist Qualifications**. The lead imaging technologist designated for each applicable ADI modality shall have the following registrations or certifications:

A. CT -- ARRT for CT,

B. MRI -- ARRT for MR or ARMRIT,

C. Nuclear Medicine

1) PET or PET/CT - ARRT for PET or NMTCB for PET,

2) Planar/SPECT -- ARRT for NM or NMTCB for NM

3.5.4 **Training/Experience.** The imaging technologist shall meet the following requirements:

A. *Baseline Education Requirements:*

i. Education. Completion of at least 20 CE hours or the equivalent in the applicable specialty areas;

ii. Training Topics. Completed adequate training covering the applicable ADI technology and imagery shall cover:

a) Image acquisition and image processing,

b) Basic principles of the applicable ADI technology and functionality,

c) Review of different imaging techniques,

d) Care for patients undergoing an exam,

e) Image quality analysis,

f) Implementation of a quality control program,

g) Knowledge of selection criteria for the applicable ADI exams, and

h) Administration of contrast media and signs and symptoms of contrast reactions; and

iii. Additional Course Work. Have completed a course in radiobiology (the branch of biology concerned with the effects of ionizing radiation on organisms) as a part of prior training, or separate from prior training, and shall supply documentation that the course has been completed;

B. *Baseline Experience Requirements:* Performed a minimum of 100 ADI scans within 24-months under the supervision of a person qualified to be a medical director or supervising physician and if a recent graduate, are working directly under the supervision of an experienced imaging technologist.

C. *Continuing Education Requirements:*

i. Continuing Education. Complete 30 CE hours every three years covering imaging safety and the following topics (as applicable to the ADI system):

a) Radiation physics,

b) Radiation dose estimates and risks associated with radiation,

c) Protection for staff and patients,

d) Principles of radiation dose optimization,

e) Principles of MRI magnetic field safety,

f) Imaging system equipment and apparatus,

g) Patient specific risk factors, and

h) Imaging safety reporting requirements (including local, state and national mandates);

ii. Vendor Training. Be familiar with (and implement) vendor-specific imaging system protocols; and

iii. Ongoing Mentoring. Ongoing supervision/mentoring by the medical director or supervising physician and other imaging technologists in order to demonstrate clinical and technical proficiency.

D. *Continuing Experience Requirements:* Perform a minimum of 50 ADI exams annually.

Table 5: Imaging Technologist Requirements					
	Baseline Experience Requirements			Continuing Experience Requirements	
Imaging Technologist	**# of Studies**	**CE Hours**	**Certifications**	**# of Studies /months**	**CE Hours /months**
Medical Imaging Technologist - **-General**	100 exams within 24-months under supervision of medical director	20 CEs or the equivalent per specialty area	• Trained in the applicable ADI modalities; • Hold current, unrestricted state licensure in each of the modalities performed; **AND** • Hold current, unrestricted registration(s) or certification from: ARRT, ARMRIT, NMTCB or another recognized certification agency • See additional requirements for cardiac imaging in Standard 3.4.5	50/12 (or 150/36)	30/36 patient safety focus
Medical Imaging Technologist **–Lead Technologist**	See above	See above	See above AND (one of the following): • CT -- ARRT for CT, • MRI -- ARRT for MR or ARMRIT, • PET or PET/CT - ARRT for PET or NMTCB for PET • Planar/SPECT -- ARRT for NM or NMTCB for NM	See above	See above

3.5.5 **Cardiac Imaging**. For the imaging technologist performing within a site offering CT Cardiac and Coronary CT Angiography (CCTA), the additional following requirements must be met, and documented:

A. Documentation of training specifically in Cardiac CT;

B. The senior cardiac imaging technologist must document the performance of daily calibration of scanners to be used for Cardiac CT;

C. Certification in Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), or Advanced Radiology Life Support (ARLS);

D. Completion of training in the use of a powered dual-head contrast injector.

Further Explanation

The intent of this standard is to ensure an appropriately trained, licensed, and experienced imaging technologist is utilized for obtaining medical images from patients. It is important to note that all of the applicable baseline qualifications, baseline education/experience requirements and on-going education/experience requirements must be met by each technologist. Additional sub-elements of this Standard also must be met for lead technologists and technologists overseeing designated specialty imaging.

The ADI application also requests information regarding whether or not the imaging technologist is qualified to produce diagnostic imaging or participate in procedures involving nuclear medicine if applicable to the imaging supplier's scope of imaging services.

Imaging technologists certifications recognized by RadSite include but are not limited to:

- American Registry of Magnetic Resonance Imaging Technologists (ARMRIT).
- American Registry of Radiologic Technologists (ARRT).
- Nuclear Medicine Technology Certification Board (NMTCB).
- Registered Cardiovascular Technologist (RCVT).
- Registered Vascular Specialist (RVS).
- Registered Vascular Technologist (RVT).

If an individual has another applicable certification currently not recognized by RadSite, please contact RadSite to request an evaluation of the certification program. The RadSite Standards Committee will consider additional certifications that meet or exceed commonly accepted professional requirements.

All imaging technologist names, ADI modality expertise, and registration information must be entered into the RadSite Online Portal. In addition, a description of their licenses and certification information must be entered as well. In addition to listing all of the imaging technologists, the imaging supplier must designate a lead imaging technologist for each ADI modality type that the imaging supplier uses. For the imaging technologist leads, their licensure and certifications shall be uploaded into the RadSite Online Portal.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the imaging technologist credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.5.

Standard 3.6 – Imaging Manager Qualifications

3.6.1 **General Requirement.** The imaging supplier shall employ or contract with one or more imaging managers at each imaging facility, who among other responsibilities help oversee the operations and safety policies and procedures associated with the imaging supplier.

3.6.2 **Qualifications.** Specifically, each imaging manager shall:

A. Have one of the following levels of education, professional certification, and/or experience:

i. American Registry of Radiologic Technologists (ARRT), an ARRT sub-certification, American Registry of Magnetic Resonance Imaging Technologists (ARMRIT), Nuclear Medicine Technology Certification Board (NMTCB) certification, or registered nurse license with relevant specialty certification, or sufficient requisite certification based on the jurisdiction where the imaging supplier is located,

ii. Certified Radiology Administrator (CRA), or

iii. At least two years of documented experience as an imaging manager; and

B. Complete continuing education as required by licensing and certification or medical director (and if applicable the supervising physician's) directives.

Further Explanation

The intent of this standard is to ensure properly qualified individuals help oversee the operation and safety policies and procedures supporting each imaging facility.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the imaging manager credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.6.

Standard 3.7 – Medical Physicist (MR Scientist) Qualifications

3.7.1 **General Requirement**. The imaging supplier shall utilize one or more medical physicists (or MR scientist for MRI units) to:

A. Evaluate the technical quality and appropriate functional capacities of each imaging system; and

B. Produce medical physicist reports for each imaging system.

3.7.2 **Qualifications**. The imaging supplier shall contract or employ medical physicists or MR scientists who have:

A. A master's degree or higher in physics, physical science, or a closely related field;

B. An active license to provide services as a medical physicist or MR scientist in the states where licensure is applicable; and

C. The following additional experience:

i. A medical physicist shall have board certification or eligibility from the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP), the American Board of Health Physics (ABHP), or the American Board of Science in Nuclear Medicine (ABSNM) to practice independently in one or more of the subfields of medical physics.

ii. A MR scientist shall have 3 years of documented experience in a clinical MRI environment.

Further Explanation

The intent of this standard is to ensure medical physicists or MR scientists are properly qualified to produce physicist reports for the appropriate imaging systems. Applicants also must demonstrate that the imaging supplier is meeting any federal and state regulations governing the role and qualifications of medical physicists. Benchmarks include education, training and certification levels.

Standard 3.8 – Imaging Safety Officer Qualifications

3.8.1 The imaging supplier shall contract or employ an imaging safety officer [which includes a radiation safety officer (RSO) or a MR safety officer (MRSO)] who:

A. Is certified by a specialty organization recognized by RadSite or the Nuclear Regulatory Commission;

B. Meets any additional federal, state or local safety requirements for each applicable advanced diagnostic system in use by the imaging supplier; and

C. Has satisfactorily completed training in patient safety, radiation/MRI safety, regulatory issues related to radiation, and emergency procedures for the imaging systems in use in the imaging facility.

Further Explanation

The intent of this standard is to ensure properly qualified individuals help implement the patient and radiation/MR safety program in the imaging facility. The imaging safety officer is responsible for protecting patients based on the type of imaging systems used. For example, safety protocols for CT systems would cover ionizing radiation and MRI systems would cover magnetic field strength.

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Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the imaging safety officer's credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.8.

Section IV: Professional Oversight

Standard 4.1 – Medical Director Responsibilities

4.1.1 The medical (and if applicable the supervising physician) shall carry out the following functions:

A. Supervise and participate in the development and implementation of written policies and procedures regarding the work performed by the imaging supplier, and the operation of any applicable imaging systems;

B. Implement guidelines for safety of patients, including pediatric, and pregnant patients as well as medically compromised patients;

C. Ensure that only qualified practitioners are hired;

D. Ensure compliance with policies and procedures regarding (if applicable):

i. The appropriate and safe use of pharmacological agents for sedation, allergy or reaction suppression, contrast enhancement, and other applications, and

ii. The appropriate physician oversight as required by standards of practice and regulations regarding dispensing or administering such pharmacological agents;

E. Consult with and supervise senior managers who are affiliated with the imaging supplier;

F. Follow-up with medical physicist or medical physicist report recommendations;

G. Supervise the imaging supplier's risk management program to ensure optimal patient health and safety; and

H. Ensure that the facility is complying with the RadSite accreditation standards by doing the following:

i. Notifying RadSite within 14 days of any material or adverse change to its business operations that may directly impact the scope of the ADI accreditation,

ii. Providing immediate notification to RadSite of any outcomes of patient injury, untoward event, or death due to malfunction or improper use of radiology equipment, or due to lack of compliance with policies and procedures,

iii. Notifying RadSite promptly of complaints of any kind that are received about the ADI services provided, and

iv. Addressing any substantive deficiencies related to the RadSite Standards.

Further Explanation

The intent of this standard is to detail the role and responsibilities of the medical director (and supervising physician) and to ensure the integrity of the imaging supplier's clinical practice and operations. It is important that each imaging supplier, along with its imaging facilities, have strong clinical leadership to promote a quality-based operation and protect patients. The director (and if applicable the supervising physician) should be engaged in a meaningful way to ensure the MIPPA requirements and RadSite Standards are adhered to, and to help problem-solve any situations that might be detrimental to the practitioners and their patients.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the medical director job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.1.

Standard 4.2 – Interpreting Physician Responsibilities

4.2.1 The interpreting physician shall carry out the following functions:

A. When applicable, observing, assisting and performing clinical examinations in compliance with the requirements established by the medical director;

B. Interpreting and reporting results of examinations;

C. Reporting any medical errors, mishaps, or near misses to the medical director stemming from any source including, but not limited to, personnel and equipment performance; and

D. Other duties assigned by the medical director (or supervising physician) or other responsibilities required by the ADI Standards.

Further Explanation

The intent of this standard is to ensure the interpreting physician interprets the clinical images for and documents all cases. It also is imperative that the interpreting physician actively promote patient safety even if they are not on-site with the patient.

Other duties of the interpreting physician may include consultation with technologist staff for protocol optimization and provide in-service training aimed at quality and safety improvements. The role of interpreting physician should be monitored by the medical director (and the supervising physician if applicable) and subject to peer review through a QA Program.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the interpreting physician job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.2.

Standard 4.3 – Imaging Technologist Responsibilities

4.3.1 The imaging technologist shall carry out the following functions:

A. Prepare and operate imaging systems appropriately;

B. Properly position patients to effectively record the requested diagnostic images;

C. Properly use protective coverings to protect patients and themselves from excess radiation exposure;

D. Properly prepare and administer contrast media during the procedure (which includes but is not limited to double checking the physician's order, using the proper dosage and method of administration).

E. Follow the policies, procedures, and safety protocols established by the medical director or generated by federal, state and local requirements, and by other oversight or accrediting agencies;

F. Report any medical errors, mishaps, or near misses stemming from any source including but not limited to personnel and equipment performance, to the medical director (and if applicable to the supervising physician);

G. Implement the quality control processes required by the RadSite Standards;

H. Educate patients about safety concerns inherent to ionizing radiation and contrast administration;

I. Comply with all applicable federal, state and local regulations regarding the operation of the applicable imaging systems;

J. Maintain the current credentials necessary to operate the applicable imaging systems; and

K. Maintain the necessary experience or training as set forth above in standard 3.5.

Further Explanation

The intent of this standard is to identify the scope of duties for imaging technologists working for the imaging supplier.

Per RadSite policy, imaging suppliers may use remote technologists for CT and MRI scans but prohibits the use of remote technologists for nuclear medicine imaging. Contact RadSite for a copy of its remote imaging technology policy.

RadSite requires that all IV contrast injection and sedation procedures be actively supervised by properly licensed and qualified imaging personnel who are on-site with the patient.

RadSite expects each imaging supplier to proactively ensure that they are meeting the requirements associated with any overlapping federal, state or local regulations related to remote imaging. For example, California has certain requirements regarding what type of professional can administer IV contrast, which are not required in other jurisdictions.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the imaging technologist job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.3.

Standard 4.4 – Imaging Manager Responsibilities

4.4.1 The imaging manager shall:

A. Have a comprehensive understanding of the principles of imaging system safety for each of the ADI modality used by the imaging supplier, and which the imaging manager oversees;

B. Ensure compliance with the policies and procedures pertaining to imaging system safety;

C. Have reporting accountability to the medical director (or supervising physician);

D. Know and follow the priority reporting procedures for any equipment malfunctions, mishaps, and medical errors to the appropriate entities, including the medical (or supervising physician); and

E. Help implement or maintain a quality control program.

Further Explanation

The intent of this standard is to ensure the applicant's consistent oversight of operations and imaging system safety at each imaging facility for all ADI services. One individual may be sufficient to cover multiple locations provided each site is properly supervised by the imaging manager. This means that the imaging manager is spending sufficient on-site time at each location. This could be demonstrated by adequate daily communication with the staff at each location and designating an individual at each location who is in charge of the imaging system safety program when the imaging manager is not on-site.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the imaging manager job description, which demonstrates that the individual fulfills the duties and responsibilities defined under Standard 4.4.

Standard 4.5 – Medical Physicist (MR Scientist) Responsibilities

4.5.1 When working for an imaging supplier, each medical physicist or MR scientist shall:

A. Be familiar with and apply equipment manufacturer specifications and patient safety requirements;

B. Perform periodic evaluations of the imaging systems by using phantoms or test-objects;

C. Monitor the provision of patient specific dose measurements, patient radiation doses, and equipment performance, through periodic inspections and evaluations;

D. Produce comprehensive medical physicist reports;

E. Provide consulting support to the imaging supplier;

F. Report any equipment malfunctions, mishaps, safety breeches, and concerns to the medical director and any other designated staff member;

G. Assist in the creation of patient and staff education and training programs related to radiation and/or MRI safety; and

H. Conduct one or both of the following surveys depending on the type of ADI imaging system:

i. For CT and nuclear medicine, a radiation protection survey documenting that there is an appropriate shielding plan, that the shielding is in place in accordance with the shielding plan, and that the shielding plan has been properly modified if any significant changes have occurred at the practice since the plan was developed, or

ii. For MRI, a patient safety and equipment survey documenting key protections have been developed and implemented, and that the MRI safety plan has been properly modified if any significant changes have occurred at the practice since the plan was developed.

Further Explanation

The intent of this standard is to require that all imaging suppliers have each of their imaging systems evaluated by a trained and certified medical physicist or MR scientist at regular periodic intervals. The ADI application requests information regarding the minimum requirements of the medical physicist's education, training, and certification levels.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit the medical physicist/MR scientist job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.5.

Standard 4.6 – Imaging Safety Officer Responsibilities

4.6.1 **General Requirement**. The imaging supplier shall appoint an imaging safety officer to oversee and implement a Patient and Personnel Safety Program. This position can be served by a radiation safety officer (RSO) or MR safety officer (MRSO) depending on the type of ADI modalities being used by the imaging supplier.

4.6.2 **Job Responsibilities.** Each imaging safety officer (or RSO/MRSO) as applicable to each type of ADI system shall:

A. Establish written policies and procedures covering the Patient and Personnel Safety Program;

B. Serve on the imaging safety committee;

C. Provide annual training in radiation safety to meet ALARA (As Low As Reasonably Available) practices;

D. Ensure the facility is following all federal and state regulations, including the maintenance of a radioactive materials (RAM) license;

E. Monitor all activities that involve the use of radioactive materials, ionizing radiation, MRI magnets or other imaging related activities;

F. Supervise quality control (QC) of nuclear equipment;

G. Monitor radiation personnel exposure records;

H. Maintain an inventory of all radioactive materials; and

I. Review and modify imaging exam protocols for radiation dose optimization in accordance with industry and societal standards.

4.6.3 **Policy Requirements**. The imaging safety officer (or RSO/MRSO) shall ensure that policies and procedures are established and enforced that address the following as appropriate for the type of ADI system:

A. For CT, PET, and SPECT:

i. Implement dosimetry monitoring, with reporting of cumulative radiation exposure, in accordance with the frequency requirements of the local jurisdiction (if required locally);

ii. Require protective shielding to be used, as appropriate, by staff members to protect themselves, fellow staff members throughout the facility, patients, and the public from radiation exposure;

iii. Ensure that imaging equipment shall be installed in an appropriately shielded enclosure in order to promote adequate radiation protection to staff and designate this enclosure as a controlled (staff-only) area;

iv. Automatically record radiation dose calculations by the imaging system and present to the imaging technologist as a digital readout in any standardized format, and automatically incorporate into the electronic record in a manner in which it is instantly and machine-readably accessible to both clinicians and physicists for future review;

v. Require the calculated patient radiation dose to be inclusive of all acquired images, including repeats;

vi. When the radiation dose read out is presented to the imaging technologist, ensure that the calculated radiation dose is appropriate for the exam being performed;

a) In the event that the calculated radiation dose exceeds a predefined reference threshold, additional documentation and investigation is required (including consultation with a medical physicist), and

b) When practical, consider thyroid shielding to reduce patient radiation, without obscuring relevant anatomy (For example: this can be effective for CT scans of the brain).

B. For MRI:

i. Implement patient safety assessment which includes reviewing all absolute and relative contraindications,

ii. Training required by personnel permitted to enter areas where radiologic services are provided, and

iii. Assess MRI environment including safety scanning protocols, access restrictions, authorized personnel, patient consent procedures, non-ferromagnetic equipment, suite cleaning, acoustic noise levels, contrast administration, and emergency protocols.

Further Explanation

The intent of this standard is to ensure each imaging supplier assigns responsibility to a trained individual who is empowered to oversee and safeguard the welfare of personnel and patients. It is imperative the imaging safety officer, both RSO and MRSO, work closely with the entire staff of the imaging facility to ensure a safe environment for patients, staff, and others who visit or work at each imaging facility.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit a sample imaging safety officer job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.6.

Section V: Policies and Procedures

Standard 5.1 – Policies and Procedures

5.1.1 **General Requirement**. The imaging supplier shall maintain and comply with written policies and procedures that govern the key elements of its clinical and business operations.

5.1.2 **Specific Requirements**. The imaging supplier shall perform the following activities related to its written policies and procedures (hereinafter referred to as the "policies"):

A. *Scope and Documentation*.

i. Draft and maintain all policies covering key business operations such as human resource protocols and other requirements included in the RadSite Standards,

ii. Draft and maintain all policies covering key clinical workflows such as scan protocols and other requirements included in the RadSite Standards,

iii. Document and maintain policies electronically or on paper,

iv. Document the original effective date and the most recent revision dates of each policy, and

v. View all policies through a master list;

B. *Updates.* Review, update and document all changes to the policies at least annually;

C. *Peer Review***.** Have all policies reviewed and signed off by the medical director(s) and imaging manager(s);

D. *Staff Requirements***.**

i. Notify all staff impacted by any new or revised policies,

ii. Hold staff training meetings at least quarterly, and

iii. Document staff attendance at training sessions.

Further Explanation

The intent of this standard is to ensure that continuing attention is given to developing, approving, maintaining, and revising written policies and procedures. In addition, it is imperative that the written policies and procedures be shared with key personnel throughout each imaging facility. Applicants need to show a formal process of updating the policies and documenting the changes along the way.

The standard also is aimed at ensuring appropriate utilization and documentation of clinical imaging workflows in the form of implementing clinical policies and procedures. The phrase "outside clinical peers" means one or more practitioners who are not employed directly by the imaging supplier and have medical expertise that is covered by a particular clinical policy.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit two samples of current clinical policies and procedures used by the imaging supplier. If applying for more than one modality, they must submit at least one current clinical policy and procedure for each modality.

Standard 5.2 – Regulatory Compliance Program

5.2.1 The imaging supplier shall implement a regulatory compliance program that monitors and ensures compliance with federal, state and local regulations.

Further Explanation

The intent of this standard is to ensure that ADI suppliers comply with all applicable regulatory requirements, including nationally recognized practice standards such as requirements issued by the:

- Nuclear Regulatory Commission (NRC).
- National Institute of Standards and Technology (NIST).
- Centers for Devices and Radiation Health (CDRH).

This standard also requires that imaging suppliers comply with state and local requirements such as state practitioner licensing requirements and local zoning ordinances.

Standard 5.3 – Complaint Resolution Process

5.3.1 The imaging supplier must maintain a formal system to receive and respond to complaints in a timely manner. When addressing complaints, the imaging supplier shall do the following:

A. Review, investigate, resolve and respond to all complaints involving patient or staff safety in an expedited manner, typically within 24 hours, or by the next working day;

B. Respond to non-urgent complaints within thirty (30) days;

C. Report any sentinel event to the proper authorities (Note: A sentinel event is defined as any medical error or event in a healthcare setting that result in serious injury or death to a patient or a hazard to the general public, which is not related to the natural course of the patient's illness);

D. Report all sentinel events to RadSite;

E. Must document details of the investigation findings, remediation efforts taken and communication with the complainant and the senior management team of the imaging supplier about the complaint;

F. Inform patients of their rights to submit a complaint and the process for doing so;

G. Respond to complaints in a time frame indicative of the seriousness of the issue;

H. Address any compliance issues such as privacy; and

I. Create staff education and training programs based upon patient safety complaints and concerns.

Further Explanation

The intent of this standard is to ensure patients are treated fairly and that patient concerns are addressed in a timely and respectful manner. The grievance process shall include documentation of remediation and evidence of communicating the findings to both the aggrieved parties and the senior management team at the imaging supplier.

Standard 5.4 – Storage Requirements

5.4.1 **General Requirement**. The imaging supplier shall store diagnostic images and other patient-specific information in a confidential and secure manner to allow appropriate retrieval of the files for subsequent review.

5.4.2 **Specific Requirements**. Specifically, the imaging supplier shall undertake the following safeguards:

A. Store a hard copy or use a digital storage system for images;

B. Provide appropriate long-term storage for more than 98% of primary images archived for at least seven years;

C. Provide appropriate long-term storage for more than 98% of primary images archived for minors until patient has reached adulthood; and

D. Use and update periodically an image retention policy or manual.

5.4.3 **Privacy/Security of Stored Records**. Storage adequacy is defined through HIPAA and HITECH unless the State in which the Facility operates requires more stringent methods.

Further Explanation

The intent of this standard is to ensure diagnostic images are securely stored and preserved for subsequent review.

Section VI: Quality and Patient Safety

Standard 6.1 – Quality Assurance Program

6.1.1 **QA Program Requirements.** The imaging supplier shall maintain a comprehensive quality assurance (QA) program that meets the following requirements:

A. *General Requirements*

i. Is overseen by a quality assurance committee or another formal panel established by the imaging supplier that includes participation by the medical director,

ii. Tracks, analyzes, and remediates complaints, grievances, concerns, and errors,

iii. Monitors the manufacturer requirement notices for non-imaging and imaging systems,

iv. Implements a clinical peer review program for assessment of diagnostic accuracy in medical imaging reporting,

v. Establishes and maintains a medical outcomes audit program to follow-up on positive and negative results, which includes correlating those results with the interpreting physician's findings;

B. *Policies*

i. Periodically updates written policies and procedures,

ii. Operates according to written policies and procedures that are specific to the applicable imaging systems and are reviewed annually by the medical director (and if applicable the supervising physician), and include elements related to utilization review of ordered exams, prescreening of scheduled patients, protocol optimization, image quality analysis, reporting policy, and peer review;

C. *Clinical Protocols*

i. Incorporates established clinical standards for imaging appropriateness in accordance with recommendations and guidelines of the peer review literature and professional societies and/or organizations, and are updated annually, with notations regarding the sources being used and the changes to department policy,

ii. Identifies, implements, and benchmarks clinical policies,

iii. Requires that all imaging exam protocols should be created in accordance with established professional standards, technology guidelines (based on the recommendations of the imaging manufacturer), clinical indication for the exam, and individual patient attributes,

iv. Contain elements requiring that, in the event that patient prescreening identifies a potential problem with exam performance, including patients that are pregnant or possibly pregnant, direct consultation between the imaging supplier and referring clinician should be performed and documented for clarification of outcome.

D. *Additional Requirements*

i. Requires that all communications between the imaging supplier and the patient (or their legal guardian) should be formally documented in the patient's clinical record;

ii. Creates staff education and training programs, which shall include imaging systems requirements and the analysis of measured QA deficiencies, and

iii. Helps ensure compliance with other quality requirements pursuant to the RadSite Standards.

6.1.2 Peer Review Requirements When Using a Single Interpreting Physician.

A. When a practice contains a single interpreting physician or practitioner, the QA program shall be conducted by a qualified, independent third party, which shall be a peer familiar with these requirements and be affiliated with an accredited facility.

B. The third party shall annually review a random sample of studies. The sample size shall be at least the smaller of 5% of studies or 20 studies. It must contain at least one example of each anatomical area that the facility images (e.g., a facility imaging hands, knees, and feet must include all three).

Further Explanation

The intent of this standard is to ensure each imaging supplier has a structured approach to reviewing its processes, so its business and clinical decisions promote operational integrity, clinical efficacy, and patient safety. The QA program also must address operational challenges that stem from all sources of complaints, grievances, and errors, but especially those originating from patients.

The imaging supplier's quality assurance committee can be a standalone committee or a sub-group of the organization. The committee must include the medical director (and one or more supervising physicians) and utilize a communication channel to update the entire organization of key quality assurance issues.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit a QA policy and procedures.

Standard 6.2 – Patient and Personnel Safety Program

6.2.1 **General Requirements**. The imaging supplier shall implement a patient and personnel safety program, conduct training at least annually, and document staff attendance at training. The imaging supplier must also document that the patient and personnel safety program meets the following requirements:

A. Operates in accordance with written policies and procedures;

B. Is updated annually;

C. Includes the assignment of an imaging safety officer or radiation safety officer (RSO) to each imaging facility (this individual may hold other roles, particularly in small practices);

D. Monitors all staff for occupational radiation exposure as required by federal and state regulations;

E. Promotes proper radiation utilization, in accordance with ALARA (As Low As Reasonably Achievable) and other radiation safety principles;

F. Compliance with Image Wisely guidelines (for CT and NM imaging suppliers) and signing the pledge annually;

G. Compliance with Image Gently guidelines (for CT and NM imaging suppliers who are scanning pediatric patients) and signing the pledge;

H. Reliance on Choosing Wisely recommendations to avoid unnecessary medical tests, treatments and procedures;

I. Implements patient identification procedures;

J. Implements safeguards for radiation and contrast media dosage;

K. Implements pregnancy and pediatric screening procedures and protocols;

L. Annually educates and trains staff on radiation safety and use of imaging medicine and equipment;

M. Relies on medication adherence guidelines;

N. Addresses safety concerns which pose an immediate jeopardy to the accredited imaging supplier's patients or a hazard to the general public;

O. Posts radiation safety standards in each imaging facility;

P. Requires the use of dosimeter devices by staff to monitor radiation exposure;

Q. Ensures access to emergency equipment, supplies, and personnel in accordance with federal, state and local regulations;

R. If applicable, requires a BLS, ACLS or ARLS certified licensed practitioner to be present and continuously monitor a patient undergoing IV contrast, along with the procedure being supervised by a qualified physician or non-physician practitioner in close proximity to the patient and immediately available [see direct supervision as defined by CFR §410.32(b)(3)(ii)], with immediate access to a crash cart and other life-sustaining measures;

S. If applicable, requires an ACLS or ARLS certified licensed practitioner to be present and continuously monitor, including an electrocardiogram (ECG), a patient undergoing conscious sedation, along with the procedure being supervised by a qualified physician (or a qualified dentist) [see personal supervision as defined by CFR §410.32(b)(3)(iii)]), with immediate access to a crash cart and other life-sustaining measures;

T. Has access to spill confinement and decontamination resources;

U. Establishes annual image volume thresholds for each imaging system;

V. Requires the timely reporting of a sentinel event to the proper authorities, as required by law and applicable professional society standards, along with following all internal reporting directives; and

W. Creation of a patient educational program related to medical imaging quality and safety.

6.2.2 **Program Scope.** The imaging supplier shall implement a Patient and Personnel Safety Program which includes the following information and activities:

A. The imaging supplier shall:

i. Provide written Patient and Personnel Safety Program manuals,

ii. Conduct safety program training at least annually,

iii. Document staff attendance at safety program training sessions, and

iv. Document on-going compliance with the safety program.

B. The Patient and Personnel Safety Program must include following issues and Occupational Safety and Health Administration (OSHA) topics:

i. Adverse drug reactions;

ii. OSHA: Blood pathogens and exposure control;

iii. OSHA: Infection control;

iv. OSHA: Safety standards;

v. Medical practice standards supported by training and certification requirements such as Advanced Cardiovascular Life Support;

vi. Evacuation plans that cover both facility-wide and locally contained emergencies; and

vii. Issues associated with radiation safety.

6.2.3 **Substance Abuse Prevention**. The imaging supplier shall maintain a drug-free workplace and demonstrate compliance with a substance abuse policy covering all employees and contractors. The program shall include, at minimum:

A. The facility's written policy regarding a drug-free workplace;

B. Supervisor training empowering supervisors to police and enforce the policy;

C. Employee training informing employees of this policy;

D. Employee assistance for substance abuse;

E. Substance abuse testing; and

F. Sanctions for employees or contractors failing to comply with these requirements.

6.2.4 **Mentally Healthy Workplace.** The imaging supplier shall maintain a healthy workplace and demonstrate compliance with a mentally healthy workforce policy covering all employees and contractors.

A. The program shall include, at minimum:

i. A written policy regarding a mentally healthy workforce,

ii. Supervisor training empowering supervisors to police and enforce the policy,

iii. Employee training informing employees of this policy, and

iv. Remedies for employees or contractors failing to comply with the mentally healthy workforce program.

B. The program may include an Employee Assistance Program (EAP) that provides for optional testing for mental health issues and referrals for mental health counseling and treatment as necessary.

Further Explanation

The intent of this standard is to ensure the imaging supplier has implemented a comprehensive patient and personnel safety program, including formal radiation safety processes and procedures as part of its QA and QC programs.

Imaging suppliers shall access and be familiar with the following resources:

- Information regarding Image Wisely, an initiative of the ACR, AAPM, RSNA and ASRT for radiation safety in adult medical imaging, is available at http://www.imagewisely.org. At a minimum, the medical director or supervising physician shall submit a pledge annually for each location.

- Information regarding Image Gently, an initiative of the Alliance for Safety in Pediatric Imaging, is available at http://www.pedrad.org/associations/5364/ig/. If the imaging supplier does pediatric imaging, the medical director or supervising physician must have filled out the pledge.

- Information regarding Choosing Wisely, an initiative of the ABIM Foundation's goal to advance a national dialogue on avoiding unnecessary medical tests, treatments, and procedures, is available at http://www.choosingwisely.org/.

Under Standard 6.2.1(Q), if the qualified supervising physician or non-physician practitioner is not in the same location as the patient receiving contrast, the certified licensed practitioner who is present with the patient must be ACLS certified.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit key policies addressing:

- Patient and personnel safety program, addressing the elements listed above in Standard 6.2.1;

- OSHA requirements listed above in Standard 6.2.2; and

- Healthy workforce or substance abuse policy for its personnel, addressing the elements listed above in Standard 6.2.3 and Standard 6.2.4.

The imaging supplier shall submit the following document(s):

- A current Imaging Wisely email verification, certificate or Honor Roll screen shot; and

- A recent Image Gently certification document for imaging suppliers who see pediatric patients.

Standard 6.3 – Medical Imaging Policies

6.3.1 The imaging supplier shall implement medical imaging policies that are documented in writing or electronic form and require:

A. The actual presence of a qualified medical physician or practitioner pursuant to Standard 6.2 when a contrast medium is used or sedation is required for a patient with immediate access to a supervising physician;

B. Interpretation of all studies on an appropriate computer or electronic communication device that provides the image quality necessary for proper interpretation;

C. File maintenance of a formal final written or electronic report for each and all imaging studies performed; and

D. Formal documentation of all final image examinations by an interpreting physician or practitioner, especially when the final report is dictated and translated by a transcriptionist.

Further Explanation

The intent of this standard is to ensure the imaging supplier is using current and evidence-based medical imaging policies, procedures, and guidelines for its ADI services.

Document Submission

The applicant or accredited imaging supplier undergoing reaccreditation audit shall submit policies and procedures supporting its medical imaging policies, addressing the elements listed above in Standard 6.3.

Standard 6.4 – Patient Access

6.4.1 The imaging supplier shall implement patient access policies and procedures that are documented in writing or electronic form and require:

A. Obtaining imaging services in a timely manner at a reasonably convenient location;

B. Providing reasonable access to patients for their health information including imaging records in accordance with the organization's medical record policy; and

C. Establishing a patient notification system for emergencies.

Further Explanation

The intent of the standard is to ensure patients have appropriate access to ADI services, are informed of their options, receive explanations about informed consent and their rights and responsibilities, and are treated with respect.

This standard requires timely and consistent patient communications (or their emergency contacts) which are proportionate to the issue that is being addressed. For example, an immediate communication (such as a phone call) is appropriate to address emergencies (e.g., an adverse reaction to IV contrast or sedation). For routine communications, a variety of communication avenues may be used (such as a text reminder for an upcoming appointment). The key is to make sure there is a systematic approach to communications used within the practice that is HIPAA compliant.

Standard 6.5 – Patient Confidentiality

6.5.1 The imaging supplier shall implement patient confidentiality policies and procedures for responding to requests by patients, payers, and other third parties for records that are documented and require:

A. Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and

B. Ensure that Protected Health Information (PHI) is only:

i. Made accessible to authorized personnel, such as those involved in the diagnosis and treatment of the patient, and

ii. Disclosed to others as permitted by federal and state regulations.

Further Explanation

The intent of this standard is to declare and ensure that PHI is only accessible to authorized personnel, and others with proper patient consent, in order to protect each patient's confidentiality.

Standard 6.6 – Financial Integrity

6.6.1 **General Requirement**. The imaging supplier shall not promote any:

A. Financial conflicts that jeopardize the patient's best interests and welfare; and

B. Inappropriate incentives or kickbacks associated with patient referrals.

6.6.2 **Regulatory Compliance**. The imaging supplier must comply with any federal and state regulations concerning financial integrity, including the Stark Law.

6.6.3 **Financial Policies**. The imaging supplier shall establish financial integrity policies that are documented in writing or electronic form that prohibit:

A. Financial conflicts that jeopardize the patient's best interests and welfare;

B. Any inappropriate incentives or kickbacks associated with patient referrals;

C. Financial incentives to refer patients for more procedures or specific facilities, including incentives to referring providers, any referring provider's employees, relatives, or associates;

D. Any contracts or agreements such as time slot-leasing arrangements for the equipment that has the potential to produce a negative impact on the patient's best interests and welfare;

E. The use of improper incentives such as ones to encourage the premature or preferential use of a new machine or contrast agent; and

F. Paying compensation based on the number of imaging services a provider refers to an imaging facility.

Further Explanation

The intent of this standard is to ensure the maintenance of the financial and operational integrity of ADI services by the imaging supplier and preserve and promote the patient's best interests and welfare.

The issue of inappropriate imaging referrals is an important public policy concern, including the deployment of time slot-leasing arrangements as a way to circumvent legitimate imaging practices. In order to do time slot-leasing, a facility that has excess imaging capacity typically enters into a formal lease agreement with referring providers. The lease agreement designates how many time slots will be leased by the parties each month and for what flat amount. It also gives the number of minutes in the time slots to be leased. The leasing party must pay for these slots whether used or not — thus a lease of time, not a lease of the use of a machine. The leasing party is allowed to mark-up the time slot and bill directly under the "in practice exemption" of the Stark Law. This allows referring providers to perform the scans, make a profit, and not actually purchase the entire piece of equipment. This is illegal in several states with the U.S. Inspector General's Office on the lookout for such arrangements. This practice is considered a way to circumvent the protective limitations in the Stark Law.

Section VII: Technical Quality

Standard 7.1 – General Requirements

7.1.1 **Reporting Requirements**. For each imaging system as further defined in Section VII, the imaging supplier must submit the following:

A. *Physics Report and Phantom Image Requirements***.**

i. The most recent annual medical physics report, which must be dated within 12 months of the application submission date for each imaging system, and

ii. Phantom testing details for image quality and dose (for both adults and children) for each imaging system;

B. *Image Study Submission Requirements*.

i. Image studies of:

a) Actual patients imaged by the imaging system within six months prior to the submission of the application,

b) The protocol and corresponding clinical reports for each individual imaging examination performed and submitted, and

c) The best work of as many current staff members as possible.

ii. For a general ADI accreditation:

a) Three exams for each ADI system under review,

b) One additional pediatric image study must be submitted if the imaging supplier does pediatric imaging (i.e., a patient who is between 0 and 15 years of age) if 2% or more of the total caseload of exams are pediatric, and

c) One image shall include the use of IV contrast, if applicable to the imaging supplier;

iii. For each clinical specialty designation:

a) Submit two or more imaging specialty area, with each study representing a different type of exam within the designated specialty,

b) One additional pediatric image study must be submitted for the additional specialty areas(s) if the imaging supplier does pediatric imaging and (i.e., a patient who is between 0 and 15 years of age) 2% or more of the total caseload of exams are pediatric, and

c) One image shall include the use of IV contrast if applicable to the imaging supplier;

Image Exam Submission Requirements (Table 2)		
Specialty Areas	Submission Requirement Details	Image Exam Total
General ADI Accreditation	Three image exams	3
One Specialty Module	Two specialty image exams, plus two general	4
Plus Two Specialty Modules	Two image exams for each specialty area, plus one general	5
Plus Three Specialty Modules	Two image exams for each specialty area (with three or more modules, a general image exam is no longer required)	6
Each Additional Specialty Module	Add two image exams for each specialty area	+2 for each specialty area
For Pediatric Imaging (if the imaging supplier's caseload is 2% or more for pediatric exams)	Add one additional pediatric study for general ADI accreditation and each additional specialty designation	+1 for each applicable specialty area

C. *Imaging Report Requirements*. For each image study, the imaging report shall cover the following standardized elements:

i. Demographics

a) Facility name and address,

b) Patient identifiers:

1) Name

2) Date of birth

3) Gender

4) Medical record number,

c) Name of ordering physician,

d) Name or type of exam,

e) Date and time of exam,

f) Date and time of dictation,

g) Date and time of transcription,

h) Name of interpreting physician, and

i) Signature of the interpreting physician.

ii. Report elements/descriptions

a) Clinical history,

b) All techniques and procedures used to obtain the images,

c) Use of contrast and/or radiopharmaceuticals including method of administration and volume,

d) Any known patient reactions,

e) Possible limitation(s),

f) Specific clinical questions,

g) Comparison with relevant studies or reports,

h) Key findings,

i) Medical observations/conclusions:

(i) Specific diagnosis when possible

(ii) Differential diagnosis when appropriate

(iii) Note follow up or additional exams when appropriate

(iv) Note any significant patient reactions as applicable.

7.1.2 **Uploading.** All images shall be submitted in DICOM format (or through a DICOM wrapper) via RadSite's upload utility.

Further Explanation

The accreditation reviewers shall score each imaging system as follows depending on the ADI modality. The reviewer will grade the following:

- **Physics Review:**
  - Medical physics report.
  - Phantom image sets (using approved or recognized phantoms).
  - Patient radiation dose structured reports from the sample image studies submitted.
  - Statement from the medical physicist assessing the extent to which the ALARA principle has been followed during the prior year.

- **Image Quality Review:**
    - Sample clinical images.
    - Corresponding clinical reports.
    - Corresponding protocols (procedures; including exam parameters).
    - Computer-generated, standardized report format.

For each imaging system to pass the physics and image quality review, each imaging system must meet all the requirements applicable to it detailed in Section VII and on the RadSite Online Portal.

Standard 7.2 – CT Physics Evaluation

7.2.1 **CT Physics Testing.** The applicant must provide reports of annual physics testing of all CT systems (i.e. testing that is performed on the CT system by a qualified medical physicist) for which accreditation is being sought.

A. The annual physics testing must meet the following minimum requirements:

i. CT number accuracy,

ii. Slice thickness verification,

iii. CT number uniformity,

iv. CT noise measurement,

v. High contrast spatial resolution,

vi. Low contrast detectability,

vii. Review of the site's CT quality assurance program, and

viii. Patient radiation dose for clinically utilized scans;

B. The annual physics testing must be performed within 12 months of the application submission date;

C. The annual physics testing must be performed by a qualified medical physicist.

7.2.2 **CT Specific Requirements.** Imaging suppliers must submit the following to meet the CT physics review requirements:

A. Completed site CT protocol data for each imaging system for the procedures specified, containing the following information:

i. Patient radiation dose information,

ii. Dose length product (DLP), and

iii. The CT dose index (CTDI) information necessary for medical physicist's dose evaluation of the site's protocols.

B. Phantom images used for the annual physics report (which typically include an adult abdomen protocol, adult head protocol, pediatric abdomen protocol and pediatric head protocol);

C. The protocol the imaging supplier uses to produce the submitted images must match the site's actual CT protocol review sheet;

D. Submission of the patient radiation dose report for each exam (The images obtained while measuring the CTDI values do not need to be submitted); and

E. The evaluation of submitted images shall include images obtained from vendor-supplied phantoms or commercially available phantoms (Note: For the phantom to be acceptable, the requirements listed in this Standard must be able to be evaluated. Phantoms that are acceptable include the Catphan phantoms, GAMMEX 464 Phantom, and the AAPM CT Performance Phantom with Low Contrast):

i. CT number uniformity of water equivalent material: The CT number should not vary more than +/- 10 from edge to edge (Note: Additionally, the edge measurements must agree with the center measurement within +/- 5. Units are CT Number).

ii. CT number accuracy is evaluated for the phantom – using a test object that has at least four materials with different CT values. The deviation from the known CT number of the material must be less than 10% if not otherwise specified below. Two of the materials must be water equivalent and air equivalent (air surrounding the phantom is acceptable). Other acceptable materials are polyethylene (LDPE), PMMA (acrylic), bone equivalent, polycarbonate, polystyrene, and nylon. To pass the CT number accuracy portion, water, air and 75% of the other tested materials must be within specifications. If the CT number falls outside of a specified range, a minor deficiency will be noted. Measurements shall cover:

a) The water equivalent region for all phantoms must measure 0 +/- 7 at all energies,

b) The air equivalent region for all phantoms must measure -1000 +/-50 at 120 kVp,

c) For the GAMMEX 464 phantom:

1) Acrylic – 122 +/- 15
2) Bone – 910 +/- 60
3) Low density polyethylene (LDPE) – -95 +/- 12.

d) For the Catphan Phantoms:

1) Teflon – 950 +/- 60
2) Acrylic – 122 +/- 15
3) Polystyrene – -35 +/- 7
4) Delrin – 340 +/- 25
5) Low density polyethylene (LDPE) – -95 +/- 12
6) Polymethylpentene (PMP) – -200 +/- 40.

e) For the AAPM CT Performance Phantom:

1) Acrylic – 122 +/- 15
2) Polystyrene – -35 +/- 7
3) Low density polyethylene (LDPE) – -95 +/- 12.

f) For vendor phantoms or other commercially available phantoms that have additional material present, the CT number accuracy will be evaluated based on vendor parameters. The measured value must be +/- 10% of the stated value of the material. Note: The vendor phantom manual must be submitted if a vendor phantom is utilized.

iii. CT noise is evaluated using a review of the annual medical physics report.

iv. The images are reviewed for artifacts. Artifacts are evaluated as either:

a) Minor = Artifacts present without inhibiting diagnostic interpretation (minor deficiency), or

b) Severe = Artifacts that degrade image quality and inhibit diagnostic interpretation (major deficiency)**.**

v. Contrast is evaluated on the phantom images according to the following parameters:

a) Low contrast detectability using the site's adult head and abdomen protocols and the site's pediatric head protocol.

1) If a vendor phantom is utilized, the manual should state the acceptable low contrast detectability limits.

2) For commercially available phantoms, 6 mm diameter or less objects with a 6 CT number or less difference from the background must be visible:

   i) For the GAMMEX 464 phantom, this equates to the first set of cylinders in Module 2 being visible,

   ii) For the CATPHAN Phantoms, this equates to being able to visualize the 6 mm diameter cylinders of the Supra-Slice targets in the low contrast modules,

   iii) For the AAPM CT Performance Phantom, this equates to being able to visualize the 6 mm holes or smaller in the Low Contrast Insert (Part No 610-06),

   iv) For vendor-supplied phantoms, documentation must be submitted verifying the ability of the phantom to meet these low contrast standards.

b) High contrast spatial resolution. The high contrast resolution for the site's submitted protocols shall be greater than 6 lp/cm or equivalent.

Further Explanation

The intent of this standard is to define the exact criteria and requirements that will be used to evaluate the physics quality of the CT systems.

Accreditation failure would occur if the images submitted do not pass the measurements in this standard including if the site's protocol radiation doses are over the limits or severe artifacts are visible on any images.

Note: The quality control (QC) program should produce a documented, time-stamped record (preferably electronically stored) of all equipment testing and calibration, along with the identity of the responsible party.

Document Submission

For each CT imaging system for which the applicant or accredited imaging supplier undergoing reaccreditation audit desires accreditation, the applicant or accredited imaging supplier shall submit the most recent medical physicist report and corresponding phantom images.

Standard 7.3 – CT Image Quality Evaluation

7.3.1 **CT Summary.** The following elements for each CT imaging system shall be reviewed:

A. Clinical images including quality and specialty protocols;

B. Facility imaging policies;

C. Radiation exposure; and

D. Specialty imaging guidelines including pediatric protocols (if applicable).

7.3.2 CT Specialty Examinations

A. The following CT examinations qualify for specialty certification:

i. Angiography (or "CTA") – The use of CTA in the evaluation of blood vessel disease is often a routine part of the evaluation of patients suspected of having vascular disorders. This includes evaluations of the cerebral, neck, cardiac and chest, abdomen and pelvic vasculature.

ii. Body – This type of CT imaging includes the chest, abdomen and pelvis.

iii. Cardiac – This involves imaging of the heart, pericardium, and aorta, and may include cardiac functional evaluation.

iv. Maxillofacial – This type of CT imaging helps diagnose diseases, injuries and defects involving the hard and soft tissues of the oral and maxillofacial region and may include imaging of the skull, including the base of the skull, upper airway, and paranasal sinuses.

v. Musculoskeletal – This involves CT of the bones and joints including the shoulder, elbow, wrist, hip, knee, and ankle as well as other imaging of the upper and lower extremities. Musculoskeletal imaging also includes evaluations of the soft tissues such as muscles and tendons.

vi. Neurologic – Neurologic imaging using CT includes evaluations of the bone and soft tissues of the brain, neck, and the spine.

B. In addition to the clinical specialty modules, imaging suppliers who provide pediatric imaging must submit at least one pediatric image exam per CT imaging system.

Note: The use of CT scanning in children, ages 0 – 15, is of particular concern because children are more susceptible to the potential adverse effects of ionizing radiation than adults. Imaging facilities that provide CT imaging must demonstrate the implementation of pediatric protocols to improve radiation protection for children.

7.3.3 CT Clinical Image Requirements

A. Each imaging supplier is required to submit a sample set of clinical images with the accompanying clinical report and protocols for each type of CT imaging system for which they are requesting accreditation. Each clinical study should include:

i. The clinical indications for the examination,

ii. All images obtained and post-processed -- including additional planes and 3D images,

iii. Image exams submitted must have occurred within the six months prior to submission of the application (unless the CT imaging system is a new install, and images were not previously available. In this scenario, images may be submitted upon acquisition in tandem with the accreditation application),

iv. If the imaging system has been upgraded or modified, the images submitted cannot predate any upgrade or modification, and

v. The imaging study clinical interpretation (clinical report of the study);

B. These images will be assessed for the following items:

i. Demographic Data

a) Patient-identifying information:

1) Full name

2) Date of Birth

3) Gender

4) Medical record number,

b) Name of institution,

c) Date and time of examination, and

d) Equipment type.

ii. Image Characteristics:

a) Slice thickness appropriateness,

b) Appropriate use of reconstruction,

c) CT noise,

d) Artifact evaluation,

e) Anatomic coverage,

f) Anatomic orientation labels,

g) Field of view,

h) Radiation dose (displayed and appropriate),

i) Scan time.

C. Appropriate use or non-use of contrast agents.

7.3.4 **Scan Parameters.** The CT imaging system scan parameters shall include the following:

A. *Type of Exam*: Exam types include angiography, body, cardiac, maxillofacial, musculoskeletal and neurologic;

B. *Anatomic Coverage*: Superior and inferior extent of the examination;

C. *Field of View Size*: Anatomical regions included in scan;

D. *Resolution*: Matrix size dependent on the type of scan;

E. *Contrast*: Indications, dose, injection rate, and scan delay, if used;

F. *Effective Detector Row Thickness*: This parameter determines the reconstructed section thickness that cannot be smaller than the effective detector row thickness;

G. *Radiation Exposure*: mAs, and kVp with CT dose, and if available, index volume ($CTDI_{vol}$) in mGy;

H. *Intravenous Contrast*: Only non-ionic contrast agents should be used and injected volume should be appropriate for the patient and the study (Note: Pediatric injected volume should be calculated based on 2.0 ml/kg or less);

I. *Injection Rate*: Should be appropriate for the study;

J. *Acquisitions:* Single phase, multi-phase, delay or equilibrium;

K. *Oral Contrast*: To be used as needed for stomach and bowel opacification;

L. *Slice Thickness*: Appropriate to the study being performed;

M. *Reconstruction:* Orthogonal reconstructions should be routinely performed, along with additional reconstructions when additional diagnostic benefit can be achieved; and

N. *Reconstruction Kernel:* Appropriate to the examination, minimum of 3mm, except for maximum intensity projection (MIP) reconstructions for chest CT.

7.3.5 **Image Selection.** The imaging supplier must submit a minimum of three adult image case studies and protocols, as well as one pediatric image case study (if 2% or more of the total caseload of exams are pediatric) for each CT imaging modality for which they are seeking accreditation. In addition, one of the exams must include IV contrast if applicable.

The image studies must be chosen from the following examination options in the table below:

CT Adult and Pediatric Examination Choices		
Angiography	Body	Cardiac
• Aorta • Carotid • Intracranial • Peripheral • Pulmonary • Renal	• Abdomen • Chest • Pelvis	• Calcium scoring • Coronary artery • Cardiac function • Ischemia
Maxillofacial	Musculoskeletal	Neurologic
• Oral cavity/teeth • Soft tissue of the neck • Paranasal sinuses • Upper airway • TMJ • Base of the skull • Skull	• Ankle • Cervical • Elbow • Extremity/Joint • Hip • Knee • Lumbar • Shoulder • Wrist	• Brain • Head/Neck • Nerves • Spine

7.3.6 **Radiation Exposure.** The imaging supplier must be aware of and actively participate in the principles associated with ALARA (As Low As Reasonably Achievable). Each imaging facility must demonstrate that it operates under a policy of limiting radiation while obtaining diagnostic quality examinations. The CT dose index volume ($CTDI_{vol}$) can be used to calculate the approximate mGy dose to patients. In order for a facility to pass accreditation the mGy dose should be as follows:

A. For Adult Studies:

i. 75 mGy or less for adult brain,

ii. 30 mGy or less for adult chest (for single run),

iii. 30 mGy or less for adult abdomen,

iv. 25 mGy or less for adult pelvis;

B. For Pediatric Studies:

i. 40 mGy or less for pediatric brain of a 1-year-old,

ii. One of the following --

a) 10 mGy or less for 40-pound pediatric patient's abdomen scan using a 32 cm phantom, or

b) 20 mGy or less for 40-pound pediatric patient's abdomen scan using a 16 cm phantom;

C. The phantom must be scanned at comparable dosage to demonstrate contrast at dose.

7.3.7 **Additional CT Specialty Requirements**

A. Cardiac CT (CCT) and Coronary CT Angiography (CCTA) scans shall use the following parameters and equipment:

i. Complete gantry rotation should take no longer than 0.42 seconds,

ii. Tube heat capacity must allow for a single < 20 second acquisition,

iii. Minimum section thickness should be ≤ 1.0 mm,

iv. The CT unit used for CCTA must allow display and interpretation of the full 12 bits (from - 1000 to 3095 Hounsfield Units) of attenuation information,

v. The display field of view must be sufficient to allow an assessment of the vasculature of interest, the end-organ, and adjacent tissues,

vi. For cardiac and ascending aortic CTA, an ECG-gated acquisition should be performed that allows retrospective reconstruction of the scan volume at multiple phases through the cardiac cycle,

vii. A dual-headed power injector that can be programmed for both volume and flow rate must be used for CCTA examinations,

viii. An independent workstation capable of creating volume rendered or shaded-surface displays, maximal intensity projections (MIP), and multi-Planar reconstructions must be available for CCT or CCTA analysis, and

ix. Each workstation should also allow direct measurement of vascular dimensions and, when appropriate, path lengths and angles; and

B. CT Colonography (CTC or VC) scans shall use the following parameters and equipment:

i. Sixteen (16) slice or greater multi-detector computed tomography (MDCT),

ii. Each exam must be able to scan entire abdomen and pelvis in a single breath hold with a slice thickness of ≤2.5mm,

iii. Images must be reconstructed at a slice thickness of ≤1.5 mm,

iv. Each workstation must have specific CT colonography software, and

v. The software must be capable of simultaneously integrating 2D and 3D images of the colon.

Further Explanation

The intent of this standard is to define the exact criteria and requirements that will be used to evaluate clinical image quality. For each imaging system for which the applicant desires accreditation, the applicant must submit three clinical image studies (including sample images and clinical reports) and corresponding protocols, as well as one additional pediatric image study if the imaging system is used on pediatric patients.

Standard 7.4 – MRI Physics Evaluation

7.4.1 **MRI Physics Testing.** The applicant must provide reports of annual physics testing of all MRI systems (i.e. - testing that is performed on the MRI system by a qualified medical physicist) for which accreditation is being sought. The annual physics testing must meet the following minimum requirements:

A. The annual physics testing must include the following components:

i. Magnetic field homogeneity,

ii. Geometric accuracy,

iii. Slice thickness,

iv. High contrast spatial resolution,

v. Low contrast detectability,

vi. Slice position accuracy,

vii. Percent intensity uniformity (PIU),

viii. Signal ghosting percentage (SGP),

ix. SNR, SGP, and PIU testing of all clinically utilized coils,

x. Review of the documentation regarding the imaging supplier's *MRI Quality Assurance Program and the MRI Safety Policies and Procedures,* and

B. The annual physics testing must be performed within 12 months of the application submission date; and

C. The annual physics testing must be performed by a qualified medical physicist or MR scientist.

7.4.2 **MRI Specific Requirements.** The Imaging supplier must submit the following additional information in connection with the annual MRI physics testing/review:

A. Completed MRI protocol review sheets for the procedures specified for all locations.

B. Phantom images must be acquired using their normal brain T1 and T2 acquisitions. In addition, the imaging supplier should submit: 1) a T1 spin echo exam with a TR=500 ms and a TE= 20 ms with a 256 matrix and a FOV of 250; and 2) a dual echo T2 exam with a TR = 2000 ms and TE – 20, 80 ms with a 256 matrix and a FOV of 250. Note for:

i. The J.M. Specialty Parts phantom, eleven slices of 5 mm with a 5.0 mm slice gap will be utilized to cover the phantom, and

ii. The MagPhan SMR170 phantom, 5 mm slices with no slice gap should be utilized to cover the entire phantom.

C. The protocol the imaging supplier uses to produce the submitted images must match the imaging supplier's actual MRI protocol review sheet.

D. The evaluation of submitted images shall include the imaging supplier's imaging system clinical images and phantom images, if applicable, using the following parameters:

i. Magnetic Field Homogeneity – Manufactures specifications must be met (typically over a 35 cm diameter spherical volume should be < 0.5 ppm Root Mean Square or < 2.0 ppm peak to peak).

ii. Geometric Accuracy - This measurement should not deviate by more than 3% from known distance in all three planes.

iii. Slice Thickness Accuracy – The measured slice thickness for spin echo sequences should be within +-15% of the prescribed thickness for 5 mm or greater.

iv. High Contrast Spatial Resolution – Object sizes that are at least one theoretical pixel width in size and separated by at least one-pixel width (1 mm will be the default based on how the phantom images are set up).

v. Low Contrast Detectability –

a) For field strengths less than 2.0T, objects with a diameter of 4 mm or less with a contrast difference of 1.5% or less must be visualized. For the J.M. Specialty Parts phantom, this is equivalent to visualizing nine (9) spokes out of the forty (40) spokes present in slices 8-11 of the phantom.

b) For field strengths greater than 2.0T, objects with a diameter of 2 mm or less with a contrast difference of 1.5% or less must be visualized. For the J.M. Specialty Parts phantom, this is equivalent to visualizing thirty-seven (37) spokes out of the forty (40) spokes present in slices 8-11 of the phantom.

vi. Slice Position Accuracy – The measured slice position should agree within +- 4 mm of the actual slice position on slices one (1) and eleven (11) for both T1 and T2 data sets.

a) Percent Intensity Uniformity (PIU) ≥ 87% for 2T or lower, ≥ 82% for units higher than 2T.

b) Signal Ghosting Percentage (SGP) is evaluated for the Phantom: SGP must be less than 2.0%.

vii. Artifacts -- The images are reviewed for artifacts. Artifacts are evaluated as either:

a) Minor = Artifacts present of little technical concern, or

b) Severe = present of major technical concern.

Standard 7.5 – MRI Image Quality Evaluation

7.5.1 **Summary.** The following elements for each MRI imaging system shall be reviewed:

A. Clinical images including quality, specialty protocols and artifacts;

B. Facility imaging policies;

C. Field strength requirements (as referenced in Standard 2.3.2); and

D. Specialty imaging guidelines including pediatric protocols (if applicable).

7.5.2 **Specialty Examinations**

A. The following MRI examinations qualify for certification

i. Angiography (or "MRA") – The use of MRA in the early detection and characterization of blood vessel disease is often a routine part of the evaluation of patients suspected of vascular disorders. This includes evaluations of the cerebral vasculature, neck vessels, cardiac and chest vasculature, and vessels of the abdomen and pelvis as well as the extremities.

ii. Body – This type of MRI imaging includes the neck, chest, abdomen, and pelvis.

iii. Breast Imaging – MRI of the breast is often indicated when other imaging methods are inconclusive or contraindicated and may be particularly valuable in the early detection of malignancies.

iv. Cardiac – This imaging methodology involves imaging of the heart, pericardium, aorta, and may include cardiac functional evaluations.

v. Functional -- This includes Functional MRI (fMRI) and Diffusion Tensor imaging and spectroscopy.

vi. Musculoskeletal – This involves MRI of the joints including the shoulder, elbow, wrist, hip, knee, and ankle as well as imaging of the hand and foot. Musculoskeletal imaging also includes evaluations of the bones and muscles.

vii. Neurologic – This includes evaluations of the bone and soft tissues of the brain, neck, and the spine.

B. In addition to the clinical specialty modules, imaging suppliers who provide pediatric imaging must submit at least one pediatric image exam per MRI imaging system.

7.5.3 **Clinical Imaging Requirements.**

A. In addition to the MRI systems undergoing a detailed physics review, each facility is required to submit a sample set of clinical images with the accompanying clinical report for each type of MRI examination for which they are requesting utilization. This set of clinical images should include:

i. The clinical indications for the examination,

ii. All sequences obtained on the patient,

iii. The radiology report provided for the examination,

iv. Image exams submitted must have occurred within the past six months prior to the application (unless the MRI imaging system is a new install, and images were not previously available. In this scenario, images may be submitted upon acquisition in tandem with the accreditation application),

v. If the imaging system has been upgraded or modified, the images submitted cannot predate any upgrade or modification, and

vi. The imaging study clinical interpretation (clinical report of the study);

B. These images will be assessed for the following items:

i. Demographic data

a) Patient-identifying information (e.g., first & last names, medical record number):

1) Full name
2) Date of birth
3) Gender
4) Medical record number,

b) Name of institution,

c) Date and time of examination, and

d) Equipment type;

ii. Image Characteristics

a) Geometric accuracy,

b) High-contrast spatial resolution,

c) Low-contrast detectability,

d) Existence of artifacts, and

e) Signal uniformity.

7.5.4 **Scan Parameters**

A. *Type of Exam*: Exam types include angiography, body, breast, cardiac, functional, musculoskeletal, neurologic;

B. *Anatomic Coverage*: Superior and inferior extent of the examination;

C. *Field of View Size*: Anatomical regions included in scan;

D. *Resolution*: Matrix size is dependent on the type of scan and varies considerably among different MRI exams;

E. *Slice Thickness*: Volumetric vs. non-volumetric scan (are slices contiguous);

F. *Orientation of Scan*: e.g., axial, sagittal, coronal, or oblique (a combination of these);

G. *Type of Sequence*: e.g., T1, T2, IR, GRE, PD, diffusion:

i. Whether fat saturation is being utilized and type of fat saturation sequence, and

ii. Anatomic vs. functional sequence or both;

H. *Intravenous Contrast*: Indications, dose, injection rate, and scan delay, if used:

i. Macrocyclic contrast preferred over linear contrast agents and injected volume should be appropriate for the patient (Note: Pediatric injected volume should be calculated differently than adults),

ii. Injection rate should be appropriate for the study,

iii. Multiphase imaging with dynamic contrast injection,

iv. Use of specific contrast agents such as hepato-specific paramagnetic contrast agents, and

v. Use of glucagon or other anti-peristaltic medications;

I. *Cardiac or Respiratory Gating*; and

J. *Oral Contrast*: To be used as needed for stomach and bowel opacification.

7.5.5 **Image Selection.** The imaging supplier must submit a minimum of three adult image studies and protocols, as well as one pediatric image study (if 2% or more of the total caseload of exams are pediatric) for each MRI imaging system they are seeking accreditation. In addition, one of the exams must include IV contrast if utilized. The image studies must be chosen from the following examination options in the table on the next page:

MRI Adult and Pediatric Examination Choices		
Angiography	**Body**	**Breast**
• Aorta • Carotid • Intracranial • Peripheral • Pulmonary • Renal	• Abdomen • Chest • Pelvis	• Breast
Cardiac	**Functional**	**Musculoskeletal**
• Coronary artery • Cardiac function • Ischemia	• Diffusion tensor imaging • Spectroscopy	• Ankle • Cervical • Elbow • Extremity/Joint • Hip • Knee • Lumbar • Shoulder • Wrist
Neurologic		
• Brain • Functional • Head/Neck • Nerves • Spine		

Standard 7.6 – Nuclear Medicine Physics Evaluation

7.6.1 **Physics Testing.** The applicant must provide reports of annual physics testing of all nuclear medicine systems (i.e. testing that is performed on the nuclear medicine system by a qualified medical physicist) for which accreditation is being sought. The annual physics testing must meet the following minimum requirements:

A. Basic Testing Requirements:

i. Quarterly phantom testing performed by qualified staff pursuant to NRC and other applicable nuclear medicine requirements,

ii. The annual physics testing must be performed within 12 months of the application submission date, and

iii. The annual physics testing must be performed by a qualified medical physicist.

B. *Gamma Camera Imaging (Planar): Physics Testing.* The annual physics testing must include the following components:

i. Intrinsic uniformity,

ii. System uniformity,

iii. Intrinsic spatial resolution,

iv. System spatial resolution,

v. Count rate sensitivity,

vi. Visual inspection of camera, and

vii. Review of nuclear medicine technologist's quality control tests;

C. *Gamma Camera Imaging (Planar): Specific Requirements.* The imaging suppliers must submit the following additional information in connection with the annual Gamma Camera Imaging physics testing/review:

i. Completed the site's nuclear medicine protocol review sheet for the procedures specified,

ii. Tc-99m or Co-57 intrinsic or extrinsic uniformity images of 10 million counts for each camera head. If Tl-201 is utilized by the facility, Tl-201 uniformity images are also required for each camera head,

iii. Intrinsic or extrinsic resolution images of 5 million counts utilizing a resolution phantom:

a) If a four-quadrant bar phantom is utilized, the smallest bars must be less than 3 mm, and

b) If utilizing a performance phantom with resolution rods, the phantom must contain a series of rods with diameters less than 8 mm.

iv. The evaluation of submitted images shall include the imaging supplier's imaging system clinical images and phantom images, if applicable, using the following parameters:

a) Planar uniformity

1) A review of the screen capture of the CFOV Integral and Uniformity Percentages, if available, obtained from the intrinsic or extrinsic uniformity images for each camera head. Percentages must be within the vendor's recommendations. Visual inspection of the images should not reveal any abnormal intensity areas.

2) Percentages must be within the vendor's recommendations. Visual inspection of the images should not reveal any abnormal intensity areas. Extrinsic CFOV Integral values <= 5.0%. Extrinsic CFOV integral values greater than 5.0% but less than 10% result in a minor deficiency. Intrinsic CFOV Integral values <= 4.0%. Intrinsic CFOV Integral values greater than 4.0% but less than 8% result in a minor deficiency.

b) *Planar spatial resolution.* A review of the screen capture of a 5 million count bar phantom acquisition utilizing Co-57 sheet source for extrinsic resolution or a 5 million count bar phantom acquisition utilizing a Tc-99m source for intrinsic resolution:

1) Intrinsic resolution images must result in the ability to see 3.0 mm bars or equivalent. For extrinsic bar resolution images, the 3.5 mm bars or equivalent must be visualized, and

2) For extrinsic phantom images 8 mm diameter rods or smaller must be visualized.

c) *Planar artifacts.* The images are reviewed for artifacts. If an artifact is present, the artifact will be classified as:

1) Minor = Artifacts present without inhibiting diagnostic interpretation, or

2) Severe = Artifacts that degrade image quality and inhibit diagnostic interpretation.

v. To pass Nuclear Medicine Planar accreditation, the unit must meet spatial resolution requirements and can only have a minor deficiency in either uniformity or artifact evaluation.

D. *Single Photon Emission Computed Tomography (SPECT) Images: Physics Testing.* The annual physics testing must include the following components:

i. Intrinsic uniformity,

ii. System uniformity,

iii. Intrinsic spatial resolution,

iv. System spatial resolution,

v. Count rate sensitivity,

vi. Visual inspection of camera,

vii. Center of rotation, and

viii. Review of nuclear medicine technologist's quality control tests.

E. *Single Photon Emission Computed Tomography (SPECT) Images: Specific Requirements.* The imaging suppliers must submit the following additional information in connection with the annual SPECT physics testing/review:

i. Completed the site's nuclear medicine protocol review sheet for the procedures specified.

ii. Phantom images acquired as described in "Nuclear Medicine/SPECT Phantom Acquisition Instructions."

iii. The imaging supplier shall submit all images in digital electronic format or converted to compact disc (CD) or digital video disc (DVD) recordings. Each image must include Region of Interests (ROIs) measurements placed where required for particular acquisitions, including mean ROIs and Standard deviation ROIs.

iv. The evaluation of submitted images shall include the imaging supplier's imaging system clinical images and phantom images, if applicable, using the following parameters:

a) SPECT system uniformity

(i) A review of the screen capture of the CFOV Integral Uniformity Percentages obtained from a 10 million count Tc-99m flood. (see guidelines above), and

(ii) A review of the screen capture of the CFOV Integral Uniformity Percentages obtained from a 10 million count Tl-201 flood if Tl-201 is utilized. (see guidelines above).

b) *SPECT system spatial resolution*. A review of the screen capture of a 5 million count bar phantom acquisition utilizing Co-57 sheet source for extrinsic resolution or Tc-99m for intrinsic resolution, and a static performance phantom acquisition utilizing a Tc-99m source (see guidelines above). If Tl-201 is utilized, an intrinsic resolution image acquired using Tl-201 will be reviewed.

c) *SPECT artifacts.* The images are reviewed for artifacts. Artifacts are evaluated as either:

(i) Minor = Artifacts present without inhibiting diagnostic interpretation, or

(ii) Severe = Artifacts that degrade image quality and inhibit diagnostic interpretation.

d) *Additional requirements.* The Tc-99m SPECT images will be evaluated for spatial resolution, uniformity and contrast resolution:

(i) SPECT uniformity: The uniformity will be evaluated to determine if any artifacts are present. If minor artifacts are visible in only a few slices, the uniformity results in a minor deficiency.

(ii) SPECT spatial resolution:

1) For the Flanged and Flangeless Jaszczak Phantom series (excluding the small flangeless phantom), the 11.1 mm rods must be visible, and

2) For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom Inserts 4 cold rods and 2 sets of hot rods must be visible.

(iii) SPECT contrast resolution:

1) For the Flanged and Flangeless Jaszczak Phantom series (excluding the small flangeless phantom), the 19.1 mm sphere must be visible, and

2) For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom Inserts three spheres must be visible.

F. *Positron Emission Tomography (PET) Images: Physics Testing.* The annual physics testing must include the following components:

i. Spatial resolution,

ii. Uniformity,

iii. Contrast resolution,

vi. SUV evaluation, and

vii. Review of nuclear medicine technologist's quality control tests.

G. *Positron Emission Tomography (PET) Images: Specific Requirements.* The imaging suppliers must submit the following additional information in connection with the annual SPECT physics testing/review:

i. A completed PET protocol review sheet for the procedures specified for each site

ii. Phantom images acquired as described in "PET Phantom Acquisition Instructions."

iii. The PET images will be evaluated for uniformity and spatial resolution, and lesion detection under the following parameters:

a) *PET uniformity*: The uniformity will be evaluated qualitatively to determine if any artifacts or abnormalities are present. If minor artifacts are visible in only a few slices, the uniformity is considered adequate.

b) PET spatial resolution:

(i) For the Flanged and Flangeless Deluxe Jaszczak Phantom series (excluding the small flangeless phantom), spatial resolution will be determined by evaluating the rod section of the phantom and the 11.1 mm rods must be visible,

(ii) For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom inserts, the 11 mm rods must be visible, and

(iii) All other phantoms must be approved and have a method of measuring spatial resolution to at least 11 mm.

c) *PET lesion detection*:

(i) Lesion detectability will be determined from the cylinders/spheres containing radioactive material. For all approved phantoms including the Jaszczak Deluxe phantom and the NEMA NU-2 PET phantom, a 2.5:1 or 4:1 activity ratio will be utilized and is described in the "PET Phantom Acquisition Instructions."

(ii) For the NEMA NU-2 PET phantom, the 13 mm "hot" cylinder should be visualized.

(iii) For the Jaszczak Deluxe phantom, the 12 mm "hot" cylinder should be visualized.

(iv) For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom Inserts the 12 mm "hot" cylinder must be visible.

(v) SUV will be measured for each "hot" cylinder and for the background to determine the accuracy of SUV measurements:

1) Mean SUV background values should be between 0.85 and 1.15, and

2) The maximum SUV of the large "hot" cylinder should be between 3.5 and 4.5 for the 4:1 ratio and 1.8 and 2.8 for a 2.5:1 acquisition ratio.

d) *PET artifacts*. The images are reviewed for artifacts. Artifacts are evaluated as either:

(i) Minor = Artifacts present without inhibiting diagnostic interpretation, or

(ii) Severe = Artifacts that degrade image quality and inhibit diagnostic interpretation.

Further Explanation

The intent of this standard is to define the exact criteria and requirements that will be used to evaluate physics quality of each imaging system. For each imaging modality and system for which the applicant (or accredited imaging suppler undergoing reaccreditation) desires accreditation, they must submit the most recent medical physicist report and corresponding phantom images.

PET or PET/CT imaging systems utilizing sodium iodide detector systems are unacceptable regardless of configuration.

PET/CT scanners are encouraged to be used for nuclear medicine studies. However, for imaging suppliers utilizing a PET only scanner, fusion software purchased or upgraded in the last five (5) years must be used on every case. If the last major software upgrade is more than five (5) years old, written confirmation is required from the service engineer confirming that the unit has the most up-to-date software upgrade available.

Standard 7.7 – Nuclear Medicine Image Quality Evaluation

7.7.1 **Summary.** The following elements for each nuclear medicine imaging system shall be reviewed:

A. Clinical images including quality and specialty protocols;

B. Facility imaging policies;

C. Patient safety protocols including radiation exposure and NRC requirements; and

D. Specialty imaging guidelines including pediatric protocols (if applicable).

7.7.2 **Specialty Examinations**

A. The following nuclear medicine examinations qualify for specialty certification:

i. General – This includes most imaging studies not covered below such as bone, renal, hepatobiliary, lung and thyroid,

ii. Cardiac – This involves imaging of the heart such as myocardial perfusion, MUGA, viability, and fractional flow reserve – among other types of cardiac imaging exams,

iii. Infection – This covers technetium and indium white blood cell imaging and PET studies for evaluation of infection,

iv. Neurologic – Neuroimaging using nuclear medicine exams includes evaluation of the brain and Cerebrospinal Fluid (CSF) such as studies for brain function, brain death, CSF dynamics, dementias, seizure disorders, and Parkinson's – among other types of neurologic imaging exams, and

v. Oncology – This involves nuclear medicine imaging for neoplasms of the bone marrow, lungs, breast, ovaries, colon, skin, head and neck; and

B. In addition to the clinical specialty modules, imaging suppliers who provide pediatric imaging must submit at least one image exam per nuclear medicine imaging system.

Note: The use of nuclear medicine scanning in children, ages 0 – 15, is of particular concern because children are more susceptible to the potential adverse effects of ionizing radiation than adults. Imaging facilities that provide nuclear medicine imaging must demonstrate the implementation of pediatric protocols to improve radiation protection for children.

7.7.3 Clinical Image Requirements

A. Each imaging supplier is required to submit a sample set of clinical images with the accompanying clinical reports and protocols for each type of nuclear medicine imaging system for which they are requesting accreditation. Each set of clinical images should include:

i. The clinical indications for the examination,

ii. All images obtained or post-processed including additional planes and/or 3D images,

iii. Image exams submitted must have been obtained within the six months prior to the application submission date (unless the nuclear medicine imaging system is a new install, and images were not previously available. In this scenario, images may be submitted upon acquisition in tandem with the accreditation application),

iv. If the imaging system has been upgraded or modified, the images submitted cannot predate any upgrade or modification, and

v. The imaging study clinical interpretation (clinical report of the study); and

B. These images will be assessed for the following items:

i. Demographic Data:

a) Patient-identifying information (full name, date of birth, gender & medical record number),

b) Name of institution,

c) Date and time of examination, and

ii. Image Characteristics:

a) Images correspond to those expected for the radiopharmaceutical administered,

b) No image artifacts due to improper preparation of radiopharmaceuticals,

c) No image artifacts due to issues with the scintillation camera including energy window, resolution, linearity, and non-uniformity,

d) Study appropriate for clinical indication,

e) Adequate signal to noise ratio,

f) Proper reconstructions when indicated and proper views (e.g., anterior, posterior, laterals, posterior and anterior obliques for perfusion scan),

g) Report clarity and accuracy based on clinical indication and images,

h) Adequate anatomic orientation and location labels,

i) Adequate field of view, and

j) Scan time/information density appropriate for exam.

7.7.4 **Scan Parameters.** The nuclear medicine imaging system scan parameters include the following:

A. *Anatomic Coverage*:

i. Correct area of the body imaged, and

ii. Superior and inferior extent of the examination;

B. *Indication:* Appropriate for clinical indication;

C. *Field of View Size*: Anatomical regions in scan; and

D. *Acquisitions*: Planar, SPECT or a combination.

7.7.5 **Image Selection**

A. Each imaging supplier seeking accreditation for nuclear medicine must indicate each type of nuclear medicine examination for which they desire accreditation selecting from:

i. Planar/SPECT, or

ii. PET/CT (Note: All PET/CT machines must undergo accreditation for both PET and CT criteria if the site would ever perform a diagnostic CT scan rather than just using the CT for attenuation correction or anatomic localization); and

B. The imaging supplier must submit a minimum of three adult image studies and protocols, as well as one pediatric image study (if 2% or more of the total caseload of exams are pediatric) for each nuclear medicine imaging system they are seeking accreditation. In addition, one of the exams must include IV contrast if applicable. The image studies must be chosen from the following examination options in the table below:

Planar/SPECT Adult and Pediatric Examination Choices	
General	Cardiac
• Bone • Liver/spleen • Hepatobiliary study • Renal • Ventilation/perfusion scan • Gastric emptying • Thyroid uptake/scan	• MUGA • Myocardial Ischemia

PET or PET/CT Adult and Pediatric Examination Choices			
Cardiac	Infection	Neurologic	Oncology
• Viability • Ischemia	• Vascular stent infection • Fever unknown origin • Osteomyelitis	• Dementia • Parkinson's	• Lymphoma • Breast cancer • Lung cancer • Colon cancer • Melanoma • Pancreatic cancer • Esophageal cancer • Gastric cancer

Further Explanation

The intent of this standard is to define the criteria and requirements that will be used to evaluate clinical image quality. For each imaging system for which the applicant desires accreditation, the applicant must submit three clinical image studies (including sample images and clinical reports) and corresponding protocols as well as one additional pediatric image study if the imaging system is used on pediatric patients.

Standard 7.8 – Corrective Action for Imaging System Deficiencies

7.8.1 The imaging supplier shall address any problems or substantive deficiencies with each imaging system by:

A. Reporting the issue to the medical director, along with any supervising physician and imaging managers;

B. Providing updates on the issue to imaging supplier staff as necessary to carry out their duties and to care for patients;

C. Implementing corrective actions if the imaging system is not performing within manufacturer's specifications or according to evidence-based guidelines as appropriate to the seriousness of the deficiency or problem;

D. Removing the imaging system from patient service if there is an identified patient safety issue until it meets or exceeds performance requirements; and

E. Documenting all key activities including the appropriate risk-related time frames and reported to the appropriate agencies and individuals.

Further Explanation

The intent of this standard is to verify that the imaging supplier has and implements a corrective action plan to address any imaging system deficiencies or issues that may arise. The site shall maintain a logbook tracking issues, actions taken, changes to the equipment, and service calls. During a random on-site audit of the facility, RadSite may request to see a corrective action policy, logs of deficiency reports, and any other documentation of corrective action activities as related to this standard.

Appendix A: Acronyms

AAHP – American Academy of Health Physics

AAPM – American Association of Physicists in Medicine

ABIM – American Board of Internal Medicine

ABMP – American Board of Medical Physics

ABR – American Board of Radiology

ABSNM – American Board of Science in Nuclear Medicine

ACC – American College of Cardiology

ACCF – American College of Cardiology Foundation

ACGME -- Accreditation Council for Graduate Medical Education

ACLS -- Advanced Cardiac Life Support

ACFME – Accreditation Council for Graduate Medical Education

ACP – American College of Physicians

ACR – American College of Radiology

ADI – Advanced Diagnostic Imaging

AHA – American Heart Association

ARLS -- Advanced Radiology Life Support

AEC – Automatic Exposure Controls

ALARA – As Low as Reasonably Achievable

AO – Accreditation Organization

AOBIM -- American Osteopathic Board of Internal Medicine

AOBR – American Osteopathic Board of Radiology

ARMRIT – American Registry of Magnetic Resonance Imaging Technologists

ARRT – American Registry of Radiologic Technologists

ASRT – American Society of Radiologic Technologists

BLS – Basic Life Support

CAD – Computer-Aided Diagnosis

CBCT – Cone Beam Computed Tomography

CBNC – Certification Board of Nuclear Cardiology

CCTA – Coronary CT Angiography

CD – Compact Disk

CDE – Continuing Dental Education

CE – Continuing Education

CME – Continuing Medical Education

CMS – Center for Medicare and Medicaid Services

COCATS – Core Cardiovascular Training Statement

CT – Computed Tomography

DEA – Drug Enforcement Agency

DICOM – Digital Imaging and Communications in Medicine

DOB – Date of Birth

DVD – Digital Video Disc

FAIUM – Fellow of the American Institute of Ultrasound in Medicine

FSRU – Fellow of the Society of Radiologists, Ultrasound

HIPAA – The Health Insurance Portability and Accountability Act

HR –Human Resource(s)

MAP – MIPPA Accreditation Program

MIPPA – Medicare Improvements for Patients and Providers Act of 2008

MR – Magnetic Resonance

MRI – Magnetic Resonance Imaging

MRSO – Magnetic Resonance Safety Officer

MITA – Medical Imaging & Technology Alliance

N/A – Not Applicable

NEMA – National Electrical Manufacturer Association

NM – Nuclear Medicine

NMTCB - Nuclear Medicine Technology Certification Board

NPI – National Provider Identifier

NPPES – National Plan and Provider Enumeration System

NRC – Nuclear Regulatory Commission

OSHA – Occupational Safety and Health Administration

PACS – Picture Archiving and Communication System

PET – Positron Emission Tomography

PHI – Protected Health Information

QA – Quality Assurance

QC – Quality Control

RCVT – Registered Cardiovascular Technologist

RDCS – Registered Diagnostic Cardiac Sonographer

RDMS – Registry of Diagnostic Medical Sonographer

RSNA – Radiological Society of North America

RSO – Radiation Safety Officer

RVS – Registered Vascular Specialist

RVT – Registered Vascular Technologist

SCCT – Society of Cardiovascular Computed Tomography

SSN – Social Security Number

SPECT – Single Photon Emission Computed Tomography

SUV – Standardized Uptake Value

U.S. – United States

Appendix B: Time Frame Summary

Summary of Time Frames		
Issue	**Time Frame**	**Description**
Application Timeline	90 days	Upon RadSite's receipt of signed Application Agreement and payment, the applicant has 90 days or three months (whichever is longer) to complete the application, with the potential for one 30-day extension if a documented written request is submitted.
Request for More Information	30 days	The applicant will have thirty (30) days from receipt of RadSite's "Request for More Information" to respond.
Corrective Action Period	60 days	The applicant will have sixty (60) days from the date that a corrective action period notification is received to remedy the deficiencies and resubmit materials to RadSite for re-examination and re-scoring.
Incomplete Application	90 days	Applicant does not sufficiently complete the application process within ninety (90) days of RadSite's receipt of signed application agreement and cleared payment. In some instances, this time period may be longer if the applicant has received an extension pursuant to RadSite policy.
Initial Determination	90 days	Once the application is completed in full, RadSite will make its initial determination in ninety (90) days or less.
Full Accreditation	3 years	Accreditation period is three (3) years from date of ADI accreditation achievement.
Waiting Period: First Failure	90 days	If the applicant does not receive full accreditation due to a failure or persistence of an incomplete application: the applicant cannot apply again for RadSite's ADI Accreditation Program until ninety (90) days after the date of the first "Notice of Failure".
Waiting Period: Second Failure	180 days	If the applicant does not receive full accreditation due to a failure or persistence of an incomplete application: the applicant cannot apply again for RadSite's ADI Accreditation Program until one hundred eighty (180) days after the date of the second failure.

Out of Service Notification	90 days	In the event that one or more imaging systems are taken out of service, the applicant must provide RadSite with updated information within Ninety (90) days of the equipment's out-of-service date.
New Equipment	60 days	New imaging system equipment brought online during the ADI accreditation must be registered with and reviewed by RadSite within sixty (60) days of being brought online and before being used on any patients.
Reconsider: First Level	30 days	The applicant can request a reconsideration of an adverse decision to the Accreditation Committee within thirty (30) days of the applicant's receipt of the "Notice of Failure" or other adverse determination impacting the applicant's accreditation status.
Appeals Process: Second Level	45 days	The second appeal can be filed with the RadSite Advisory Board within forty-five (45) days of the applicant's receipt of the adverse determination to the Level 1 re-consideration appeal.
Random On-Site Audits for Applicants and Accredited Organizations	None	RadSite is under no obligation to provide notice for random on-site audits for applicants or accredited organizations and may audit these facilities at any time.
On-Site Audits for Applicants	None required	RadSite will perform an on-site visit of all applicants and will make reasonable best efforts to schedule the visit at a time that is convenient for the facility. However, RadSite is under no obligation to provide notice for such on-site audits for applicants and may audit these facilities at any time. Note: The Application still must be completed within the ninety (90) day window granted to all applicants.
For Cause On-Site Audits	None or 24 hours	If a complaint or issue involves a serious patient safety concern, RadSite is obligated to initiate a for-cause audit with no prior announcement. If the complaint or issue involves an important but less serious concern, RadSite is not obligated to provide any notice regarding the impending for-cause audit.
Notice of Material or Adverse Change	14 days	Notify RadSite within fourteen (14) days of any material or adverse change to its business operations that may directly impact the scope of the ADI accreditation.

Appendix C: On-Site Audit Checklist

General Description	Sample Site Audit Checklist Items	Score
General Facility Information	• Name • Address	
ADI Information	**Accredited Modalities/Serial Numbers (Console and Gantry)** • CT • MRI • PET • SPECT	
Regulatory	**Compliance program that monitors federal and state regulations** • RC license, if applicable • State inspection	
Personnel	**Credentialing Program** • Review policies • Pull sample credentialing files to check for complete primary and secondary verification • Check re-credentialing every three years	

	Medical Director Qualifications
	• State license
	• Copy of board certification(s)
	• Proof of qualification by training or experience
	• Proof of satisfaction of supervision requirements
	• Proof of continuing education
	• Job description
	  ○ Job title
	  ○ Description of job responsibilities
	  ○ Minimum qualifications of education, training, and professional experience
	  ○ Appropriate licensure or certification requirements	

	Interpreting Physician Qualifications
	• State license
	• Copy of board certification(s) or eligibility
	• Proof of continuing education
	• Job description
	  ○ Job title
	  ○ Description of job responsibilities
	  ○ Minimum qualifications of education, training, and professional experience
	  ○ Appropriate licensure or certification requirements	

	Imaging Technologist Qualifications	

	• ARRT, ARMRIT or NMTCB certification
	• Copy of BCLS/ACLS certification (if applicable)
	• Copy of state license (if applicable)
	• Job description
	  ○ Job title
	  ○ Description of job responsibilities
	  ○ Minimum qualifications of education, training, and professional experience
	  ○ Appropriate licensure or certification requirements	

	Imaging Manager Qualifications
	• Job description
	  ○ Job title
	  ○ Description of job responsibilities
	  ○ Minimum qualifications of education, training, and professional experience
	  ○ Appropriate licensure or certification requirements
	• Copy of CV or resume
	• Copy of licenses or certifications (if applicable)
	• Materials to demonstrate that the imaging manager requirements have been satisfied	

	Medical Physicist (MR Scientist) Qualifications
	• Evidence of relationship with facility (e.g., contract)
	• Job description
	  ○ Job title
	  ○ Description of job responsibilities	

	○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements • If available: ○ Copy of board certification (if applicable) ○ State license (if required)	
	Imaging Safety Officer (aka Radiation Safety Officer or MRSO) Qualifications • Job description ○ Job title ○ Description of job responsibilities ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements • Review documents establishing active imaging safety program	
Policies	**General Requirements** • Maintain a master list of all policies and procedures and document all major clinical workflows in writing or electronically • Annual review, and as appropriate updating, all clinical policies, procedures, and scan protocols under the medical director's supervision • Review policies and procedures to review for effective dates, including the date of the most recent revision, while documenting all changes • Ensure clinical policies and procedures reviewed and signed off by both the medical director and imaging manager at least annually	

	• Documentation of staff training and attendance at least annually	
	Imaging System Policies • Any policy describing imaging supplier's imaging system maintenance program or a written narrative describing the provider's existing approach to its program • QC logs of all imaging systems • Verify policies are reviewed at least annually and more frequently if needed	
	Clinical Policies • Review samples of current clinical policies used by the imaging provider • Verify policies are reviewed at least annually and more frequently if needed • Interview staff to test knowledge base • The actual presence of qualified medical staff when a contrast medium is used, or sedation is required for a patient (if applicable) • Interpretation of all studies on an appropriate computer or electronic communication device that provides the image quality necessary for proper interpretation • File maintenance of a formal final written or electronic report for each and all imaging studies performed and • Formal documentation of all final image examinations by an interpreting physician, especially when the final report is dictated and translated by a transcriptionist • Satisfaction of applicable additional requirements (see sections).	
Quality Assurance	**Quality Assurance Program** • Any QA policy and procedure which demonstrates the imaging supplier:	

	○ Operates according to written policies and procedures that are reviewed annually by the medical director ○ Be overseen by a quality assurance committee or another formal committee of the imaging supplier that includes participation by the medical director and if applicable one or more supervising medical providers ○ Track, analyze, and remediate complaints, grievances, concerns, and errors ○ Oversee quality control (QC) program, including appropriate remediation protocols for any known substantive deficiencies ○ Oversee imaging system training and other relevant educational programs ○ Help monitor manufacturer requirement notices for non-imaging and imaging systems (stationary and mobile) and update policies and procedures ○ Help identify, implement, and benchmark clinical policies and ○ Help ensure compliance with other quality requirements including the RadSite Standards.	
Safety Program	**Patient and Personnel Safety Program** • Any patient and personnel safety policies demonstrating that the imaging provider addresses the following: ○ Operates in accordance with written policies and procedures ○ Ensures that the patient and personnel safety program is updated at least annually ○ Includes the assignment of an imaging safety officer to each imaging facility	

	○ Monitors all staff for occupational radiation exposure as required by federal and state requirements ○ Promotes the proper use of radiation shielding in accordance with ALARA (As Low As Reasonably Achievable) and other radiation safety principles ○ Implements patient and procedure identification protocols ○ Implements safeguards for radiation and contrast media dosage ○ Implements pregnancy and pediatric screening protocols ○ Annually educates and trains staff on radiation safety and use of imaging medicine and equipment ○ Relies on medication adherence guidelines ○ Posts radiation safety standards in each imaging facility ○ Requires the use of dosimeter devices by staff to monitor radiation exposure ○ Ensures access to emergency equipment, supplies and personnel ○ Requires an ACLS or BLS certified medical professional to be at the facility when a patient is undergoing IV contrast with immediate access to a licensed physician ○ Requires an ACLS certified physician to supervise the procedure when a patient is undergoing conscious sedation ○ Has access to spill confinement and decontamination resources ○ Establishes annual image volume thresholds for each imaging system and	

	○ Requires the timely reporting of a sentinel event to the proper authorities – along with following all internal reporting directives. • OSHA Polices: ○ Adverse drug reactions ○ OSHA: Blood pathogens and exposure control ○ OSHA: Infection control ○ OSHA: Safety standards ○ Advanced Cardiovascular Life Support ○ Evacuation plans that cover both facility-wide and locally contained emergencies and ○ Other specialty issues associated with radiation safety.	
Drug Abuse Prevention	**Drug Abuse Policy** • The imaging supplier's written policy regarding a drug-free workplace • Supervisor training empowering supervisors to police and enforce the policy • Employee training empowering employees to comply with the policy • Employee assistance for substance abuse • Substance abuse testing and • Sanctions for employees or contractors failing to comply with these requirements	
Mental Health Policy	**Mental Health Policy** • The imaging suppliers written policy regarding mental health support	

	• Supervisor training empowering supervisors to implement resources to support employees • Employee training empowering employees to take advantage of resources when dealing with depression, anxiety and other mental health conditions	
Logs	**Documentation** • Training logs for all staff members • Log of complaints/grievances and resolution	
Storage	**Storage Policies** • Store a hard copy or electronic filing system for images • Provide appropriate long-term storage for more than 98% of primary images archived for at least seven years • Provide appropriate long-term storage for more than 98% of primary images archived for minors until patient has reached adulthood • Use and update periodically an image retention manual • Proper PHI handling	
Equipment	**Imaging System Performance** • Provide a vendor specific QC/user manual which discusses the QC requirements for all ADI systems used • Regular QC for each imaging system • Current third-party physics report	
Exams	**Protocols** • Following evidence-based pathway such as ACR • Copies of all protocols used on a regular basis • Detailed reports	

Personnel	**Credentialing Program** • Review policies • Pull sample credentialing files to check for complete primary and secondary verification • Check re-credentialing every three years	

Appendix D: Technical References

All of the technical requirements set forth in Section VII of the Standards have undergone a rigorous review process to ensure that each standard is consistent with industry best-practice and requires a high level of quality from all successfully accredited imaging suppliers. Several RadSite Standards Committees, made up of a team of national experts in their respective fields, meet regularly to review current best-practices, analyze the most recent literature, and discuss requirements set by other nationally recognized standards-setting organizations in order to determine the appropriate values for each technical component requirement. For the convenience of its applicants, RadSite has compiled a list of third-party references that support and validate the values defined in the RadSite accreditation standards. In some instances, RadSite requirements may be more stringent than those set by other organizations.

CT

- **AAPM Report #100**
  Available at: http://www.aapm.org/pubs/reports/RPT_100.pdf

- **CATPHAN 500-600 manual**
  Available at: http://www.phantomlab.com/library/pdf/catphan500-600manual.pdf

- **ACR CT Phantom Testing Instructions**
  Available at:
  http://www.acr.org/~/media/ACR/Documents/Accreditation/CT/PhantomTestingInstruction.pdf

- **AAPM Report #9**
  Available at: http://www.aapm.org/pubs/reports/RPT_09.pdf

- **IAEA Training Material on Radiation Protection in Diagnostic and Interventional Radiology Part 18**

- **ACR CT Accreditation Program Clinical Image Quality Guide**
  Available at: http://www.acr.org/~/media/ACR/Documents/Accreditation/CT/ImageGuide.pdf

- **AAPM Adult Routine Chest CT Protocols Version 1.0**
  Available at: http://www.aapm.org/pubs/CTProtocols/documents/AdultRoutineChestCT.pdf

- **AAPM Adult Routine Abdomen/Pelvis CT Protocols Version 1.0**
  Available at: http://www.aapm.org/pubs/CTProtocols/documents/AdultAbdomenPelvisCT.pdf

- **AAPM Adult Routine Head CT Protocols Version 1.1**
  Available at: http://www.aapm.org/pubs/CTProtocols/documents/AdultRoutineHeadCT.pdf

- **AAPM Adult Brain Perfusion CT Protocols Version 1.1**
  Available at: http://www.aapm.org/pubs/CTProtocols/documents/AdultBrainPerfusionCT.pdf

MRI

- **Magphan Manual**
  Available at: http://www.phantomlab.com/library/pdf/magphan_manual_042402.pdf

- **Quality assurance methods and phantom for magnetic resonance imaging: Report of AAPM nuclear magnetic resonance Task Group No. 1; Med. Phys. 17 (2) Mar 1990**
  Available at: http://www.aapm.org/pubs/reports/rpt_28.pdf

Nuclear Medicine

- **NEMA NU 2 Report (2007)**

- **NEMA NU 1 Report (2001)**

- **IAEA Human Health Series Quality Assurance for PET and PET/CT Systems (2009)**
  Available at: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1393_web.pdf

- **IAEA Quality Control Atlas for Scintillation Camera Systems (2003)**
  Available at: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1141_web.pdf w