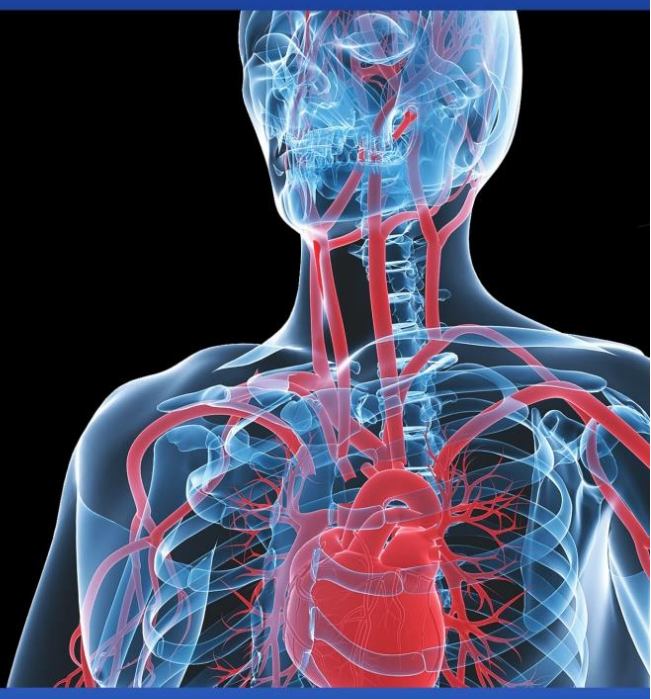
RadSite MAP Accreditation Standards

Version 2 (MAP v 2.2)



RadSite, LLC
326 First Street
Suite 28
Annapolis, Maryland 21043
Phone: (443) 440-6007
Email: info@RadSiteQuality.com

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.

Table of Contents

About RadSite

The mission of RadSite is to promote quality-based practices for *imaging systems* across the United States and its territories. Working together with private payers, hospitals and provider systems, RadSite has certified over 23,000 imaging facilities operating at least 60,000 *imaging systems* for several private payers. RadSite is expanding its activities and resources to serve patients, providers, payers, government agencies, and other industry stakeholders.

RadSite offers both quality certification and accreditation programs for *imaging providers*. The RadSite Assessment Program (RAP) certifies *imaging providers* in accordance with the quality and performance standards recognized by several health plans. The RAP Program benchmarks key standards associated with the safe and successful operation of imaging facilities, for each *imaging system* within those facilities, to promote quality, safety and business efficiency practices.

After several years of *standards* development, RadSite recognized the need for a new accreditation program to help *imaging providers* comply with the *Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).* Under *MIPPA*, *imaging providers (aka suppliers*) who offer Advanced Diagnostic Imaging (ADI Services to Medicare beneficiaries are required to be accredited by January 2012. RadSite's new *MIPPA* Accreditation Program (MAP), which is built upon the foundation of the initial RAP certification criteria, is a more detailed and formal accreditation program for those ADI imaging modalities required to be certified by *CMS* and other payers. The MAP Accreditation Program requires a more thorough documentation and verification process of facilities and licensure, and includes a technical evaluation component to assess the quality and performance of *imaging systems*.

Applicants may apply for RAP certification, or *MIPPA*-compliant accreditation through the MAP program. Those *imaging providers* that have a current RAP certification have already submitted most of the foundational facility and licensure information to meet MAP Standards. In recognition of their efforts and commitment towards imaging quality, existing RAP-certified facilities will receive a discounted rate for MAP Accreditation.

RadSite Assessment Program (RAP)

Launched in 2005, the RadSite Assessment Program (RAP) was created to promote quality-based *standards* and practices for imaging facilities and systems. The RAP Certification Program quickly became one of the largest quality-based benchmarking and network credentialing programs for facilities and *imaging systems* in the United States. RAP Certification verifies that facility staff and clinical workflows meet appropriate quality and safety standards. RAP requires that each *imaging facility* is supervised by qualified personnel including a *Medical Director, Interpreting Physician, Imaging Manager, and Imaging Technologist* – all with specific delegated functions. The RAP Certification Program was launched to help health plans, self-funded plans, and other payers promote quality-driven imaging services that produce consistent and positive outcomes.

The RAP program incorporates a web-enabled assessment that provides easy access for *imaging providers*. In addition to the online assessment, RadSite performs ransom desktop and on-site audits for *imaging providers* who hold RAP Certification to ensure continued compliance with RAP Standards.

MIPPA Accreditation Program (MAP)

MIPPA mandates a series of accreditation requirements for facilities providing ADI services. *The Center for Medicare and Medicaid Services (CMS)* requires that all *imaging providers* 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 by January 1, 2012 in order to be eligible for future reimbursement.

RadSite's MAP Standards are built upon the foundation of the RAP Certification Standards, expanding the scope of the RAP quality and safety criteria to meet *CMS* requirements and other industry best practices. For example, the MAP Standards include a technical component evaluation that assesses the performance of each *imaging system* and examines the quality of the images that each *imaging system* produces. RadSite additionally requires applicants to submit *medical physicist reports* and specific case studies for each *imaging system* to ensure quality.

While the RAP Certification Program covers a full range of imaging modalities, including both low and high tech diagnostic imaging, the MAP Accreditation Program currently is limited to the ADI services covered by *MIPPA.* At a minimum, the MAP Accreditation Program will maintain standards that are equal to those of the Medicare program as delineated in *MIPPA* and section 1834(e) of the Social Security Act. Based on market demand, RadSite is prepared to expand the scope of the MAP Standards to cover additional types of imaging in the near future. The RAP and MAP assessment process will continue to evolve based on changes and improvements in imaging practices and trends.

Governance and Location

In September 2010, RadSite, LLC was incorporated as a separate legal entity from its parent company, HealthHelp. This separation was executed to prepare for independent, unbiased expansion of its quality-based mission, and to be more easily be recognized by *CMS* as an "accrediting organization" under *MIPPA.*

An independent governance structure has been established to supervise RadSite's quality-based activities. Management and Advisory Committees include an independent Advisory Board, Standards Committee, and Accreditation Committee. RadSite's corporate charter dictates that the Advisory Board and Committees are represented by a range of stakeholders including clinicians, technologists, consumers, regulators, manufacturers and other interested parties. Going forward, RadSite will issue an annual public solicitation for nominations to participate on its Advisory Board and Committees on at least an annual basis. All RadSite Board and Committee members are appointed based on a formal nomination process.

RadSite's offices are located in Annapolis, MD.

Why RadSite?

RadSite is well established with many years of experience certifying imaging providers and systems. RadSite has unique expertise in evidence-based practices of imaging services through its founding organization, HealthHelp.

RadSite is uniquely positioned to work with *CMS*, *imaging providers*, *patients* and other interested parties because it:

- Is governed by a committee system comprised of a wide-range of stakeholder groups;
- Uses an evidence-based approach to promote best practices for *imaging systems*;
- Develops *standards* that are subject to external peer review, which includes a formal *standards* review process, beta testing and inter-rater reliability assessments;
- Includes national experts and other interested parties without membership requirements or fees to get involved as committee volunteers;
- Streamlines the application process by using an online assessment form;
- Offers fair and reasonable pricing;
- Is committed to ensuring that all of its certification and accreditation programs are "best-in-class";
- Is structured as a single source of certification that encompasses *MIPPA* and insurance company reimbursement requirements; and
- Incorporates *CMS* feedback in the design and operations of its accreditation processes.

Beyond its RAP and MAP programs, RadSite is committed to promoting a number of *patient*-safety initiatives. For example, RadSite has published the *Consumer Guide to Imaging Modalities*, a complimentary publication which can be downloaded at www.RadSiteQuality.com. In addition, RadSite helped underwrite and publish the fourth edition of the *Medical Imaging Consultant*, one of the leading reference publications for guiding physicians towards best practices in the ordering of imaging procedures. The *Medical Imaging Consultant* is a primary reference for documenting the levels of radiation exposure from different imaging procedures.

Application Instructions

Accreditation Checklist

Quick Start

Throughout the application process, RadSite customer service representatives are available to assist you with any questions that you might have. Representatives can be reached at (443) 440-6007 from 8 a.m. to 4 p.m. ET. Representatives are not available on weekends or federal holidays.

- To initiate the MAP Accreditation process, contact RadSite to receive the application information:
  - Complete the initial questionnaire, which provides RadSite with an overview of the applicant's imaging practice;
  - Review the terms and conditions of the MAP Accreditation Agreement and the Business Associate (BA) Agreement, and execute the agreement(s);
  - In consultation with a RadSite representative, calculate payment via the instructions in the application materials;
  - Submit the initial application materials and payment;
  - A RadSite accreditation coordinator will contact you to verify the scope of the applicant's imaging practice and review the process; and
  - Additional documents will be sent to the applicant to complete the application process.

- Complete the accreditation application within 90 days, or three months (whichever is longer). This includes submitting:
    - All required and requested documents (e.g., job descriptions, key policies and procedures); and
    - All applicable *medical physicist reports*, *phantom* and *test-object images*, or clinical data set images required for the technical quality review.

RadSite MAP Accreditation Application Process:

1. **Accreditation Scope and Materials.**
    - Contact RadSite at (443) 440-6007 or info@radsitequality.com to receive the application materials, which can be mailed, emailed or downloaded from a secure website.
    - Note: RadSite MAP Accreditation is issued to each *Imaging Facility* by Advanced Diagnostic Imaging (ADI) Service as explained in more detail below. Applications for integrated *imaging providers* operating as a single Tax ID Number (TIN) can be bundled, however, each facility will be accredited individually and each facility is subject to successful review of all *imaging systems* in each modality being accredited in that facility.

2. **Standards Review.**
    - Contact RadSite at (443) 440-6007 or info@radsitequality.com to receive a copy of the MAP Standards.
    - Review the free webinar at www.radsitequality.com/the_radsite_approach/webinars (optional).
    - Log on to RadSite's website to learn more about *imaging systems* best practices (optional) www.RadSiteQuality.com.
    - Contact a RadSite customer service representative at (443) 440-6007 or your assigned accreditation coordinator at any time if you have any questions.

3. **Agreement & Payment.**
    - Fill out and sign the Application Agreement, including a Business Associate (BA) Agreement, and send the executed Agreements back to RadSite per the instructions on the form.
    - In consultation with a RadSite representative, calculate and submit payment via the instructions in the application materials.
    - Note: An applicant may view current accreditation pricing and small and rural provider discounts online at www.RadSiteQuality.com. An online pricing calculator tool[1] is also provided to assist applicants with estimating the cost of their accreditation, however; final and official pricing will be determined through consultations with a RadSite Accreditation Coordinator or other representative.

4. **Application Timeline.** Upon RadSite's *receipt* of a signed Application Agreement and cleared payment, the applicant has 90 days or three months (whichever is longer) to complete and submit the application. Applicants may request one 30-day extension by submitting a written request. Additional materials will be sent to each applicant to facilitate completing the application.

5. **Application Materials.**
    - Fill out the online application.
    - Collect additional information as requested via the MAP *Standards*.
    - Submit *clinical, phantom* and *test-object images*, along with other documents, via RadSite's upload utility.
    - Note: Each applicant must take precautions to protect 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, all submitted images must be de-identified by selecting anonymize on RadSite's automated upload utility or otherwise removing PHI by the applicant before the information is sent. Contact your accreditation coordinator if you need additional information on recommended HIPPA and confidentiality recommendations and how to best send in information to RadSite.

6. **Technical Component Review**. As each applicant fills out the application, they must submit each of the following for each *imaging system*:
    - The most recent annual *medical physicist report* for each *imaging system*.
    - *Phantom* testing for image quality and dose (for both adults and children) for each imaging system. A complete explanation of the *phantom* testing requirements is provided for each modality under Standard 7.2.
    - For each *CT, MRI or PET* unit, as well as for general *Nuclear Medicine,* at least three case studies (including one child 0-15 years of age if the unit is used for pediatric *patients* and no more than one normal case per body system) must be submitted for each type of clinical examination performed on the imaging unit. A complete explanation of the *clinical image* requirements is provided for each modality under Standard 7.3.
    - Case studies must be of actual *patients* imaged on the imaging unit within the prior six months, must be accompanied by the facility's protocol for that examination, as well as corresponding clinical reports, and must represent the best work of as many current staff members as possible.
    - See *Standards* for additional information and/or contact your accreditation coordinator.

7. **Submitting the Completed Application**.
    - The application must be completed within ninety (90) days or three months of cleared payment, whichever is longer.
    - Submit *clinical, phantom and test-object images*, along with other documents, via RadSite's upload utility, or secure email, as detailed in the instructions.
    - See Appendix B for a detailed list of timelines.

8. **Request for More Information**.
    - If the application has been completely filled in and *clinical, phantom and test-object images* have been submitted in a timely manner, then RadSite will make its initial accreditation determination within 120 days or less, from the date of submission.
    - An incomplete application is subject to denial of Accreditation.
    - If the application is complete, but revisions are required, RadSite will send the applicant a "*Request for More Information."* 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 120 days from the date of the request to make an accreditation decision.

9. **Accreditation Decision**.
    - A summary of each applicant with scores is blinded and forwarded to the Accreditation Committee for review and consideration.
    - Accreditations are issued based on successful review of a combination of each *imaging facility* and successful review of all *imaging systems* in at least one submitted ADI modality. All *imaging systems* in each submitted modality must pass all reviews in order for that modality to be accredited.
    - If one or more *imaging systems* associated within a modality do 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 MAP *Standards*, it must be removed from service prior to accreditation.
    - RadSite will notify each applicant in writing of its decision.
    - Accreditation determinations include: Full Accreditation and 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).

Throughout the accreditation process, individuals should contact RadSite's Customer Service Department with any questions at info@RadSiteQuality.com or 443-440-6007.

Process and Scoring

Process

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

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

Accreditation Scoring

MAP accreditation determinations are issued for each of the applicant's imaging facilities for each *ADI imaging* modality requested. All *imaging systems* for a requested modality must pass in order for the modality to pass. An *imaging facility* may pass for one modality, but not another. (Note: The MAP Accreditation Program and *CMS* require that a non-performing *imaging system* be taken out of service when the system does not meet the MAP *Standards* if the applicant desires to keep *imaging systems* of the same *ADI* modality accredited at a particular location. A written attestation statement from the *medical director* or senior official affiliated with the imaging affirming that the failing imaging system has been removed from service as of a certain date and is no longer being used on patients must be submitted to RadSite before accreditation can be awarded.)

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" (e.g., *imaging provider* does not use a *mobile imaging system*). In some cases, the applicant will need to submit additional information

explaining why a particular standard does not apply. Any "N/A" submitted will be presented to the Accreditation Committee for review. If an "N/A" response is confirmed by the Committee, the applicant's accreditation will not be penalized on that *Standard*.

Each *imaging system* will be scored separately. The scores for each *imaging system* are then combined by each *ADI* modality at a particular *imaging facility*. The separate imaging scores are totaled and then averaged. A final score is calculated for each *imaging facility*.

Accreditation Determinations

- **Full Accreditation**
  - The applicant passes 100% of the *standards.*
  - Accreditation period is three years from date of MAP Accreditation achievement.
- **Corrective Action Period**
  - A *Corrective Action Period* applies when an applicant fails to pass, but is close to passing. This is an interim step in the accreditation process and does not represent a pass or a fail.
  - To qualify for a *Corrective Action Period*, the applicant must meet at least 75% of the *Standards.*
  - The applicant will have 60 days from *receipt* of the *Corrective Action Period* notice to remedy the deficiency(ies) 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 does not sufficiently complete the application process within 90 days of RadSite's *receipt* of signing the Application Agreement and payment.
  - No accreditation status is issued.
- **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 MAP Accreditation Program until:

- 90 days after the date of the first occurrence (i.e., failure or incomplete);
- 180 days after the date of the second occurrence.

To have a specific *imaging facility* accredited, all *imaging systems* covered by each *MIPPA* imaging modality must be reviewed and awarded a passing score by RadSite. If any particular *imaging system* fails to pass RadSite *Standards*, RadSite is obligated to notify *CMS* about this finding. The *imaging provider* must take each deficient *imaging system* out of service immediately and provide RadSite a written attestation statement from the *medical director* or senior official affiliated with the *imaging provider* confirming that such *imaging system* was taken out of service as of a certain date. RadSite may issue a MAP Accreditation certificate for each *imaging facility* by modality only if all *imaging systems* for that specific modality have passed the MAP *Standards* and/or if the failing *imaging system* has been removed from service.

In the event that an *imaging system* is taken out of service due to deficiencies specified in a failure notice and the applicant later desires to bring the deficient *imaging system* back into service, the applicant must provide RadSite with updated information documenting that the deficiencies have been addressed to meet MAP *Standards*. RadSite accreditation reviewers may request additional supporting documentation and evidence to substantiate that the *imaging system* is in full compliance.

New *imaging system* equipment brought online during the MAP Accreditation must be registered with and reviewed by RadSite within 60 days of being brought online. A supplemental application must be filled out and an additional accreditation fee must be paid. Contact RadSite for additional information. Only *imaging providers* with a Full Accreditation will receive an accreditation certificate for each *imaging facility* that passes based on each *MIPPA* modality. *Imaging providers* are not accredited through MAP if they receive the following status: *Corrective Action Period*, Incomplete and/or Failure.

Pursuant to the *MIPPA* requirements, RadSite will send *CMS* its current list of accredited organizations. Also, RadSite must advise *CMS* of all applicants who have failed the MAP Accreditation pursuant to the *MIPPA* regulations.

Appeals Process

Each applicant has two levels of appeal:

- **Appeal Level 1**
  - The applicant can request a "re-consideration" of an initial *adverse determination*.
  - The applicant can appeal in writing an *adverse determination* to the Accreditation Committee if the applicant files the appeal within 30 days of the applicant's *receipt* of the *Notice of Failure*. The applicant must submit a written explanation with documentation necessary to explain the basis of the appeal.
- **Appeal Level 2**
  - If the applicant is not satisfied with the Level 1 re-consideration determination by the Accreditation Committee, the applicant can file a second appeal.
  - The second appeal can be filed with the RadSite Board of Advisors within 45 days of the applicant's *receipt* of the *adverse determination* to the Level 1 re-consideration appeal.

RadSite will rule on Level 1 appeals within 30 days and Level 2 appeals within 45 days. The Level 2 decision of the Board of Advisors is the final determination and is not subject to further appeal within RadSite.

Audits and Surveys

During the application process and the three-year accreditation interval, *imaging providers* may be subject to random audits to ensure compliance with the MAP *Standards*. All applicants or accredited *imaging providers* are audited during the three-year accreditation period.

Audit and Survey Overview	
Desktop Audits of Applicants and Accredited Organizations	In addition to the regular documentation that is required and peer reviewed during the MAP Accreditation process, RadSite reserves the right to request additional documentation at any time during the accreditation process (both during the application process and after the accreditation certificate is issued). Additional documentation typically is required to ensure certain elements of the MAP *Standards* are being implemented by the *imaging provider*. Expenses: RadSite will cover the labor costs of any additional desktop audits. However, it is the responsibility of the *imaging provider*, either as an applicant or as an accredited organization, to cover the costs of submitting any additional materials or information requested.
Random On-Site Audits of Applicants and Accredited Organizations	RadSite or *CMS* will perform a random on-site audit of every applicant or accredited *imaging supplier* during the application process, or during the course of the three-year accreditation period, to ensure compliance with RadSite *Standards.* RadSite reserves the right to schedule any on-site audit as soon as possible and without providing any prior notification to the *imaging supplier*. Expenses: RadSite will not charge an *imaging supplier* any additional fees for random on-site audits.
On-Site Visits of Applicants	RadSite may perform an on-site visit of in-process applicants in order to expedite the completion of the application process and final determination. RadSite reserves the right to schedule any on-site visit as soon as possible and without providing any prior notification to the applicant, but may, at its own discretion, coordinate the scheduling of an on-site visit at a time that is convenient for the applicant. Expenses: RadSite will not charge in-process applicants any additional fees for random on-site visits.
For-Cause Audits of Accredited Organizations	If a complaint against an accredited organization is filed with RadSite or referred by a federal, state, or professional organization to RadSite, and RadSite determines that the complaint merits further investigation, RadSite reserves the right to initiate an audit of such accredited organization. Such audits may be in the form of a desktop audit or on-site audit. If RadSite determines 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 organization's *patients* or a hazard to the general public), RadSite is obligated to initiate an on-site audit without providing any advance notification to the accredited organization. If, as a result of the desktop audit, RadSite determines complaint involves a serious *patient* safety concern, RadSite reserves the right to conduct a "for cause" on-site audit.

	Expenses: If a "for cause" on-site audit is conducted and the complaint against the accredited organization is validated, the accredited organization will pay RadSite fees of $1,000 per diem charge plus reasonable travel costs, but no more than $2,500. If a desktop audit is conducted and the complaint against the accredited organization is validated (whether through the desktop audit or a subsequent for-cause on-site audit in connection with the same complaint), the accredited organization will pay RadSite fees to cover administrative costs, but not more than $1,000. However, if the complaint is found to be unsubstantiated, RadSite will cover the expenses.
Scheduling Process for On-Site Audits	RadSite reserves the right to schedule any on-site audit as soon as possible and without providing any prior notification to the applicant.
Corrective Action Plan	Depending on the specific deficiencies, if any, that arise during an accreditation cycle impacting any of the MAP *Standards*, RadSite reserves the right: (1) to create and enforce a Corrective Action Plan ; and (2) to revoke or suspend the accreditation as it relates to the *imaging provider*, an *imaging facility*, a designated ADI service, and/or an *imaging system.* Per the specifications of the Corrective Action Plan, RadSite will monitor the remediation efforts of the accredited organization. If the deficiencies continue, the RadSite Accreditation Committee may revoke or suspend the accreditation as it relates to the *imaging provider*, an *imaging facility*, a designated ADI service, and/or an *imaging system.* Accredited organizations 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 at any time appropriate federal, state, and local authorities 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 organization's *patients* or a hazard to the general public).

Throughout the accreditation cycle, accredited organizations must notify RadSite of any substantive changes in the *imaging provider's* operations, clinical workflows, or any of its *imaging systems* that could impact any of the MAP *Standards.* Applicants also 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 MAP *Standards.*

Applicants must notify RadSite:

- Within fourteen (14) days of any *material or adverse change to its business operations* that may directly impact the scope of the MAP accreditation; and
- Within two (2) days of any issues impacting *patient* safety.

Definitions

Defined terms are italicized in the MAP *Standards*.

- **Advanced Diagnostic Imaging (ADI) Services** are the radiological services, imaging scans, and imaging studies provided by using *Magnetic Resonance Imaging (MRI), Computed Tomography (CT), Nuclear Medicine* (including *Gamma Camera* and *SPECT*), *Positron Emission Tomography (PET)* 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 MAP Accreditation; award of a MAP accreditation status less than what the applicant anticipated; revocation of MAP Accreditation; suspension of MAP 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 physician 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 MITA XR-29-2013 requirement 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 Operations Change (adverse change or material change)** pertains to a change within an applicant's facility that affects the business or product status and represents elements the applicant is obliged to report to RadSite. Material changes include elements such as revisions or alterations in the company name, address, and ownership or the moving of a facility. An example of an adverse element is 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 *Medicare Improvements for Patients and Providers Act* and the *MIPPA* accreditation requirements.

- **Clinical Images** is a collection of images of a *patient* obtained during an imaging procedure using an *imaging system*. Clinical image case studies submitted to RadSite as part of the technical component review under Standard 7.3 must be accompanied by corresponding *patient* reports and protocols used during the examination.

- **Computed Tomography (CT)** is a non-invasive test that combines 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. CT *imaging systems* are one of modalities that are covered by *MIPPA*.

- **CT Dose Check** is a NEMA MITA XR-29-2013 requirement which incorporates two features—dose notifications and dose alerts—that warn operators and physicians when dose exceeds established thresholds.

- **Corrective Action Period** is an interval of 60 days from the date of the applicant's *receipt* of the Corrective Action Period notice. The 60-day Corrective Action Period is the window of time the Applicant is afforded within the MAP Accreditation process to remedy the identified deficiencies and resubmit application materials to RadSite for re-examination and re-scoring.

- **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 MITA XR-29-2013 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.

- **Gamma Camera,** also called a "scintillation" or "anger" camera, is an *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 provider has at least one *imaging system*; also referred to as a "*Site."*

- **Imaging Manager** is the individual responsible for the safe and effective supervision of personnel and *imaging systems,* including the implementation of policies and procedures.

- **Imaging Provider,** also known as a "Supplier," provides ADI services through the operation of one or more *imaging systems* at one or more imaging facilities.

- **Imaging System(s)** refers to medical imaging equipment including *MRI, CT, Nuclear Medicine* and other modalities covered under *MIPPA.*

- **Interpreting Physician** is any Doctor of Medicine, Osteopathy, Chiropractic or Podiatry who interprets the imaging study. The professional should be qualified for medical imaging interpretation and *patient* diagnosis and have an active medical *license*, which carries no restriction relevant to the MAP 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.

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

- **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 *patient* movement during the procedure than plain x-ray or CT studies and may result in better identification of certain aspects of anatomy and disease. MRI imaging systems are one of the medical imaging modalities covered by *MIPPA*.

- **Medical Director,** also known as a *"supervising physician,"* is a *board-certified* physician who provides guidance, leadership, oversight and quality assurance to an *imaging provider's* clinical and business operation.

- **Medical Imaging Technologist** is a trained and *licensed* medical professional who creates medical images of the human body to aid *radiologists* and other physicians 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. Medical Imaging Technologists work in a variety of settings including hospitals, clinics, medical laboratories, nursing homes, and private practice locations.

- **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 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.

- **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 bill passed by Congress and signed into law on July 15, 2008. Section 135(a) of *MIPPA* established the new accreditation requirement for ADI services. Subsequently, *CMS* published regulations to implement this accreditation requirement, and these regulations detail the program elements associated with this accreditation requirement such as those contained in the RadSite MAP 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.

- **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 physician 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 who has not met the MAP *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 provider* can re-apply for MAP 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 *Gamma Camera* and *PET*. Nuclear Medicine scanning techniques include planar/conventional, *SPECT*, and Cardiac applications. Nuclear Medicine *imaging systems* are one of the medical imaging modalities covered by *MIPPA*.

- **Occupational Safety and Health Administration (OSHA)** is a federal agency of the United States that regulates issues related to workplace safety and health.

- **Patient** is an individual who is receiving or has received medical imaging services from an *imaging provider*.

- **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 usually 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 *test-object* to help assess the performance of an *imaging system*.

- **Planar Imaging** is a scanning technique used with a *Gamma Camera*.

- **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 *MIPPA*.

- **Practitioners** are clinical staff personnel (both employees and independent contractors) who provide clinical services to *patients* at each *imaging provider* location. See also Licensed Practitioner.

- **Quality Assurance (QA) Program** is the systematic monitoring and evaluation of key business and clinical workflows associated with an *imaging provider* to maximize the probability that acceptable *standards* of quality and safety are being attained by ADI services and provided to *patients.*

- **Quality Control (QC) Program** is a systematic monitoring and evaluation process by which *imaging providers* 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 individual, *Medical Physicist, Medical Imaging Technologist, Practitioner,* or *Radiologist* 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.

- **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.

- **Receipt** refers to the receipt of an official notice from RadSite by an applicant 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 weekday that is not a federal holiday; or (2) the applicant presents reasonable contrary proof.

- **Reference adult and pediatric protocols** are a NEMA MITA XR-29-2013 requirement that include a set of pre-loaded parameters on a CT system that can be selected by the operator 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 requesting additional details about the *imaging provider's* activities, processes or programs to ensure the provider is meeting MAP *Standards.* Typically, *imaging providers* 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 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.

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

- **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. This information is typically presented as cross-sectional slices through the *patient's* body part or organ, but these virtual or digital images can be freely reformatted or manipulated as required.

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

- **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 an *imaging facility*. See also for *Medical Director*.

- **Test-Object** is a passive device or geometric shape used to evaluate performance specifications of medical *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 MAP *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;" and
- 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 Provider Information
10 Points

1.1 Standard — Organizational Information

2 Points

1.1.1 The *imaging provider* shall provide background information including:
- 1.1.1.1 Location of *imaging provider's* corporate headquarters;
- 1.1.1.2 Location of all *imaging facilities*, including *mobile imaging systems* that are identified by the facility or each facility that bills for the use of a *mobile ADI system*;
- 1.1.1.3 Identification of all *imaging systems* at each *imaging facility*;
- 1.1.1.4 Identification of all *imaging systems* that are being excluded from the MAP accreditation application; and
- 1.1.1.5 *National provider identifier* (NPI) numbers and other information required by *CMS* of all the healthcare providers who are using the *imaging systems* for *ADI services* at each location.

1.1.2 The *imaging provider* shall also provide additional background information regarding the *imaging provider's* scope of services in regards to:
- 1.1.2.1 The clinical setting of each *imaging facility*;
- 1.1.2.2 *Patient* and general populations served; and
- 1.1.2.3 Any additional imaging services that are not within the scope of *ADI services*.

Further Explanation

The intent of the standard is to obtain the information necessary to evaluate the merits of the *imaging provider* and its *imaging systems* for purposes of MAP Accreditation. The application for MAP Accreditation requests specific information regarding the *imaging provider's* business name, contact information, *NPI* numbers, *CMS* specific information required by *MIPPA*, types of *imaging provider* offerings (e.g., in-*patient* versus out-*patient* populations, stationary versus mobile equipment, and *ADI services* rendered), and other information relevant to the MAP *Standards*.

1.2 Standard — Imaging Provider Specialty

2 Points

Instruction: The standard only applies if the *imaging provider* specializes in providing certain types of *imaging services* (e.g., cardiac scans). If the *imaging provider* does not focus on one or more areas of specialization, this standard shall be marked "N/A" on the application form.

1.2.1 If the *imaging provider* specializes in providing certain types of imaging services, the *imaging provider* shall provide documentation demonstrating that its staff and providers follow evidence-based medical guidelines in the appropriate diagnostic and therapeutic uses of these services.

1.2.2 If the *imaging provider* specializes in providing certain types of imaging services, the *imaging provider* shall have the necessary expertise in administering these services and interpreting the images produced.

Further Explanation

The intent of the standard is to ensure that each *imaging provider* 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 provider* for imaging studies such as Cardiology, Chiropractic, Family Practice, Gastroenterology, Internal Medicine, Neurology, Neurosurgery, Obstetrics-Gynecology, Oncology, Orthopedic surgery, Osteopathy, Obstetrics/Gynecology, Podiatry, Pulmonology, Radiology, Rheumatology, Urology and any others not named here.

1.3 Standard — Imaging Facility Requirements

2 Points

1.3.1 Each *imaging provider's imaging facility* shall ensure that it:
- 1.3.1.1 Meets local zoning laws and ordinances;
- 1.3.1.2 Complies with federal, state and local requirements regarding radiation and occupational safety protocols;
- 1.3.1.3 Offers appropriate and safe access and privacy for *patients*;
- 1.3.1.4 Uses separate areas with restricted access for the interpretation of imaging studies in order to ensure *patient* confidentiality;
- 1.3.1.5 Maintains the secure storage and transfer of *patient* records;
- 1.3.1.6 Properly stores radioactive materials and other medical supplies; and
- 1.3.1.7 If applicable, meets Nuclear Regulatory Commission (NRC) and/or state licensing requirements regarding safe materials handling.

Further Explanation

The intent of the standard is to ensure each *imaging provider's imaging facility* is in compliance with federal, state and local ordinances and licensing requirements. The application requests the *imaging provider* to provide supporting information as detailed in the accreditation application related to each *site*, including information relating to *nuclear medicine imaging systems*.

1.4 Standard — Mobile Imaging Systems

2 Points

Instruction: The standard only applies if the *imaging provider* uses one or more *mobile imaging systems*. If the *imaging provider* does not own, contract or use a *mobile imaging system*, this standard shall be marked "N/A" on the application form.

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

1.4.2 If the *imaging provider* leases the *mobile imaging system*(s), the *imaging provider* shall have a written agreement with the owner of the *imaging system*(s) that:
- 1.4.2.1 Ensures continuity of services;
- 1.4.2.2 Permits all applicable *standards* and regulatory requirements to be met; and
- 1.4.2.3 Allows the *imaging provider* to audit all aspects of the *mobile imaging system* operations in an appropriate and timely manner.

1.4.3 The *imaging provider* shall follow the same safety procedures when using *mobile imaging systems* as it does with *imaging systems* at stationary locations, 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:
- 1.4.3.1 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;
- 1.4.3.2 Using properly *licensed* and professional staff necessary to support proper use, as defined below in *Standards* Sections 3 and 4;
- 1.4.3.3 Ensuring appropriate cleaning of the *mobile imaging system* including an infection control program;
- 1.4.3.4 Implementing *patient* safety policies and procedures for handling medical emergencies and urgencies along with necessary basic and advanced first aide equipment such as crash/code cart and/or a direct communication link to handle resuscitations and other life-sustaining measures; and
- 1.4.3.5 Ensuring proper, sufficient, and safe back-up power supply.

Further Explanation

The intent of the standard is to ensure all *mobile imaging systems* meet 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 more than one *imaging provider* and move from one *imaging facility* or location to the next. Each *imaging provider* must follow the same *quality control* checks for both fixed *imaging systems* and *mobile imaging systems*. For example, applicants using *mobile 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 operators; 3) access to back-up power supply; 4) maintenance of temperature levels in the *mobile imaging system* space; and 5) protections taken to ensure *patient* privacy.

1.5 Standard — Non-Imaging System Requirements

2 Points

1.5.1 The *imaging provider's non-imaging systems* shall:
- 1.5.1.1 Meet manufacturer's safety recommendations and procedures;
- 1.5.1.2 Meet all federal, state, and local regulations;
- 1.5.1.3 Meet or exceed all non-safety manufacturer's recommendations;
- 1.5.1.4 Have regular inspections scheduled and performed;
- 1.5.1.5 Have maintenance and service records maintained; and
- 1.5.1.6 Have periodic *quality control* testing.

Further Explanation

The intent of the standard is to ensure each *non-imaging system* at each location is installed, operated and maintained according to the requirements of the manufacturer and federal, state and local government agencies. In addition, the applicant needs to ensure that both its *imaging and non-imaging systems* are included in the *imaging provider's quality assurance* program.

Section II: Imaging Systems
10 Points

2.1 Standard — Imaging System Requirements

10 Points

2.1.1 The *imaging provider* shall provide information on all *imaging systems* supporting *ADI services* to demonstrate the proper installation, calibration, use, maintenance and trouble-shooting of *imaging systems* according to manufacturer recommendations and in compliance with all federal, state and local requirements.

2.1.2 Each *imaging system* shall demonstrate that they meet the applicable manufacturer's recommendations for quality control testing, as further defined in Standard 7.

2.1.2.1 For *CT imaging systems* (if applicable):

A. Air Calibrations
B. Slice Thickness
C. High-contrast (spatial) resolution
D. Low-contrast resolution
E. Noise level
F. Artifact-free status
G. CT number accuracy and linearity

2.1.2.2 For *MRI imaging systems* (if applicable):

A. Maximum level for static magnetic field strength (Bo)
B. Gradient magnetic field strength (dB/dt)
C. Radiofrequency power deposition (specific absorption rate)
D. Auditory noise levels
E. Center frequency
F. Table positioning
G. Setup and scanning
H. Geometric accuracy
I. High-contrast resolution
J. Low-contrast resolution
K. Artifact analysis
L. Printer quality control
M. Visual checklist
N. Slice position accuracy
O. Slice thickness accuracy

2.1.2.3 For *nuclear medicine – Gamma Camera* with *planar imaging* (if applicable):

A. Collimator resolution
B. Intrinsic resolution
C. Extrinsic resolution
D. Count rate linearity
E. Edge packing

2.1.2.4 For *nuclear medicine – Gamma Camera* with *SPECT imaging* (if applicable):

A. Includes 2.1.2.3 above

B. Image reconstruction algorithms
C. System safety interlocks
D. Spatial resolution
E. Uniformity
F. Dose calibrators
G. *SPECT* tomographic uniformity, contrast, and spatial resolution
H. *SPECT* center-of-rotation for multi-detector registration calibration
I. *SPECT* high-flood counts for uniformity correction

2.1.2.5 For *nuclear medicine – PET imaging systems* (if applicable):

A. Coincidence timing window
B. Photon attenuation correction
C. Dead time
D. Random or scatter coincidence
E. Noise equivalent count rate
F. Sensitivity
G. Dose calibrators

2.1.3 Each *imaging system* shall demonstrate that it:

2.1.3.1 Meets all federal, state and local requirements as required by law;

2.1.3.2 Undergoes a routine maintenance and operation plan that includes:

A. Regularly scheduled annual inspections
B. Appropriate cleaning and disinfecting of medical equipment after each *patient*
C. Preventive maintenance
D. Maintenance of service records
E. Safe power hook-up, machine recalibration, and temperature monitoring.

2.1.3.3 Beginning January 1, 2016, all CT imaging systems must identify whether they meet the standards set forth by NEMA's MITA (National Electrical Manufacturers Association's Medical Imaging and Technology Alliance) XR-29-2013 Smart Dose requirements as follows:

A. *DICOM Radiation Dose Structured Report*- 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. *CT Dose Check*, which incorporates two features—dose notifications and dose alerts—that warn operators and physicians when dose exceeds established thresholds.
C. *Automatic exposure controls (AEC)*- 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. *Reference adult and pediatric protocols*- a set of pre-loaded parameters on a CT system that can be selected by the operator to complete a particular clinical task, such as capturing an image of the abdomen.

Required Document Submission

2.1.4 As the applicant fills out the application, they must submit additional materials for each *imaging system* as defined under Standard 7.

2.1.5 The applicant must either: 1) submit any policy describing *imaging provider's imaging system* maintenance program; or 2) submit a written narrative explaining *imaging provider's* existing approach to its *quality control program* to ensure appropriate and safe use of *ADI services* for *patients*. For additional information regarding *imaging system* material submission and scoring, see Standards 7.2 and 7.3.

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 providers* to provide specific information related to each *MIPPA*-covered *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 case studies performed by each *imaging system*
- A *medical physicist report*

The *imaging provider* must implement *patient* safety policies and procedures including, but not limited to, properly shielding the *patient*, using qualified operators, 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
19 Points

Note: An individual working for the *imaging provider* can hold more than one position, but normal conflict of interest policies 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.

3.1 Standard— General Staffing Requirements

1 Point

3.1.1 The *imaging provider* shall:
- 3.1.1.1 Maintain an employee manual that is updated at least annually and distributed to staff;
- 3.1.1.2 Implement a grievance process for employees;
- 3.1.1.3 Maintain written job descriptions for all staff members involved in the delivery of *ADI services*; and
- 3.1.1.4 Document in each job description:
  - A. Job title
  - B. Description of job responsibilities
  - C. Minimum qualifications of education, training and professional experience
  - D. Appropriate licensure or certification requirements, and
  - E. Identification of supervisor or otherwise reference reporting responsibilities.

Further Explanation

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

3.2 Standard— Credentialing of Professional Licensure and Qualifications

3 Points

3.2.1 The *imaging provider* shall ensure that all *imaging practitioners* are qualified to carry out their respective job functions by:
- 3.2.1.1 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* has credentials
- 3.2.1.2 The verification process for *imaging practitioners* shall include at least:
  - A. History of education, professional training, licensure, certifications, and *board certification* status;
  - B. Primary verification of credentials from granting institutions covering state licensing boards, specialty certification boards (if applicable), and the highest

level of education;

C. Secondary verification of credentials from societies, professional organizations, or trade organizations;
D. Work history for a minimum of the last five years (or since last credentialed by the organization);
E. Review of professional liability claims;
F. Review of grievances history;
G. Listing of any and all sanctions, admonishments and penalties imposed by any agencies such as, but not limited to, hospitals, licensing boards and government entities;
H. Evidence of valid and current Drug Enforcement Agency (DEA) certificate or state-controlled substance certificate, if applicable;
I. Proof of professional liability insurance, ability to self-insure, or other coverage as required by the state, if applicable;
J. Current hospital affiliations or privileges, if applicable;
K. Reviewing the *licenses* or credentials of all *imaging practitioners* at least once every year; and
L. Implementing corrective action in response to *adverse changes* in certification, licensure or status.

3.2.2 The facility shall notify RadSite of any *material changes* in licensure or certification status of all imaging personnel within 30 days of such changes

Required Document Submission

3.2.3 The *imaging provider* must submit policies and procedures supporting its credentialing program, addressing the elements listed above in Standard 3.2.

Further Explanation

The intent of this standard is to ensure *imaging providers* only hire or contract with qualified *licensed practitioners*, and that current credentials and qualifications are regularly verified through an enforced credentialing policy. Each *imaging provider* must credential providers through a formal program which is supported by a documented policy or written narrative describing the *imaging provider's* approach to credentialing its staff. If there is a deficiency in *licensed practitioner's* qualifications, the *imaging provider* 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.*

3.3 Standard — Medical Director Qualifications

3 Points

3.3.1 The *imaging provider* shall employ or contract with one or more *medical directors* or *supervising physicians* who:

3.3.1.1 Are responsible for the clinical oversight of the *imaging provider*, its *imaging facilities*, and its *ADI services*;
3.3.1.2 Meet the following qualifications or requirements:

A. Have a current, unrestricted *license* to practice medicine within the state of the *imaging provider's* location, or multiple current, unrestricted *license*s if required by federal, state or local regulations or by other practice requirements (or if the *license* is restricted, the *imaging provider* has a process to ensure job functions do not violate the restrictions imposed by the State Board)
B. Must be *board-certified* in a specialty as described in Standards 3.3.2 and 3.3.3.

3.3.1.3 Possess continuing experience as documented from interpretation and reporting of examinations; and

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

3.3.2 The *medical director(s)* or *supervising physician(s)* shall meet one of the following two requirements:

3.3.2.1 *Board-certified* in radiology by a recognized specialty group in radiology (e.g., American Board of Radiology, American Osteopathic Board of Radiology or American Chiropractic Board of Radiology); or

3.3.2.2 *Board-certified* in a related specialty with documentation of supervised training in the interpretation and reporting of imaging examinations.

3.3.3 If the *imaging provider* is authorized to perform *Nuclear Medicine* imaging, the *medical director(s) or supervising physician(s)* also shall be:

3.3.3.1 Trained in the procedures of *Nuclear Medicine*

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

Required Document Submission

3.3.4 Submit sample *medical director/supervising physician* credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.3.

Further Explanation

The intent of the standard is to ensure that an appropriately trained, *licensed* and experienced physician is overseeing all clinical and *quality assurance* aspects of the *imaging provider's ADI services*. The MAP application requests information regarding the *standards* for the roles and responsibilities of the *medical director(s)* and/or *supervising physician(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).*

The MAP application requests information about whether the *imaging provider* directly employs the *medical director(s)/supervising physician(s)* or contracts for these position(s) through a consulting firm or other contractual situation.

3.4 Standard — Interpreting Physician Qualifications

3 Points

3.4.1 The *imaging provider* shall employ or contract with one or more qualified *interpreting physicians* that have:

3.4.1.1 A current, unrestricted l*icense*(s) to practice medicine within the state of the *imaging provider* location (or if the *license* is restricted, the *imaging provider* has a process to ensure job functions do not violate the restrictions imposed by the State Board)

A. *Board certification* or *eligibility* from a recognized specialty group in radiology (including, but not limited to, American Board of Radiology, American Osteopathic Board of Radiology, and American Chiropractic Board of Radiology); or *board certification* or *eligibility* in another specialty with documentation of supervised training in the interpretation and reporting of examinations;

3.4.1.2 Completion of either an accredited diagnostic radiology residency program, or any other medical residency program with documentation of imaging training;

3.4.1.3 Continuing experience as documented from interpretation and reporting of examinations; and

3.4.1.4 Continuing education as required by medical licensing and *board certification* or *board eligibility*.

Required Document Submission

3.4.2 Submit sample *interpreting physician* credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.4.

Further Explanation

The intent of this *Standard* is to ensure appropriately trained, *licensed* and experienced physicians are interpreting and reporting results of examinations resulting from use of all modalities covered by *MIPPA.* The MAP Application requests information about whether the *imaging provider* directly employs the *Radiologist(s)* interpreting the *clinical images* or contracts with a radiology group through a consulting firm or other contractual situation. Information regarding each physician's specialty type(s), licensing, residency training, board eligibilities and certifications, and other identifying information such as *National Provider Identifier (NPI)* also is requested.

3.5 Standard — Medical Imaging Technologist Qualifications

3 Points

3.5.1 The *imaging provider* shall employ or contract with one or more *medical imaging technologists* to operate the *imaging systems* for *ADI services* and to obtain medical images of optimal diagnostic quality.

3.5.2 The *medical imaging technologist(s)* shall:

3.5.2.1 Have a registration or certification from the American Registry of Radiologic Technologists (ARRT), American Registry of Magnetic Resonance Imaging Technologists (ARMRIT), or Nuclear Medicine Technology Certification Board (NMTCB);

3.5.2.2 Be trained and/or hold current, unrestricted registration(s) or be *licensed* in each of the modalities performed;

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

3.5.2.4 Continue to complete ongoing education as required by the *license*, certification and *medical director's* directives.

Require Document Submission

3.5.3 Submit sample *medical imaging technologist* credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.5.

Further Explanation

The intent of the standard is to ensure an appropriately trained, *licensed* and experienced *medical imaging technologist* is utilized for obtaining medical images from *patients*. The MAP application also requests information regarding whether or not the *medical imaging technologist* is qualified to produce diagnostic imaging or participate in procedures involving *nuclear medicine* if applicable to the *imaging provider's* scope of imaging services.

3.6 Standard — Imaging Manager Qualifications

3 Points

3.6.1 The *imaging provider* 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 provider*.

3.6.2 Specifically, each *imaging manager* shall have:

3.6.2.1 One of the following levels of education and/or experience –

A. American Registry of Radiologic Technologists (ARRT), a 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 provider* is located

B. Certified Radiology Administrator (CRA), or

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

3.6.2.2 Completed continuing education as required by licensing and certification or *medical director/supervising physician's* directives.

Required Document Submission

3.6.3 Submit sample *imaging manager* credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.6.

Further Explanation

The intent of the standard is to ensure properly qualified individuals help oversee the operation and safety policies and procedures supporting each *imaging facility*. If appropriate precautions are taken, one *imaging manager* can supervise more than one *imaging facility*.

3.7 Standard — Medical Physicist (MR Scientist) Qualifications

3 Points

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

- 3.7.1.1 Evaluate the technical quality and appropriate functional capacities of each *imaging system;* and
- 3.7.1.2 Produce *medical physicist reports* for each *imaging system*.

3.7.2 The *imaging provider* shall contract or employ *medical physicists* who have:

- 3.7.2.1 A master's degree or higher in physics, physical science, or a closely related field;
- 3.7.2.2 An active *license* to provide services as a *medical physicist* or MR scientist in the states where licensure is applicable; and
- 3.7.2.3 *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*. The MR scientist is not required to meet this standard.

Further Explanation

The intent of the 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 provider* is meeting any state and federal regulatory requirements governing the role and qualifications of *medical physicists*. Benchmarks include education, training and certification levels.

3.8 Standard — Radiation Safety Officer Qualifications

3 Points

3.8.1 The *imaging provider* shall contract or employ a *radiation safety officer* who is:

- 3.8.1.1 Certified by a specialty board whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State
- 3.8.1.2 Has satisfactorily completed training in radiation safety, regulatory issues, and emergency procedures for the imaging systems in use in the *imaging facility*.

Required Document Submission

3.8.2 Submit sample *radiation safety officer* credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.8.

Further Explanation

The intent of the standard is to ensure properly qualified individuals help implement the radiation safety program in the *imaging facility*.

*Standard 3.8 – Radiation Safety Officer does not pertain to facilities with MRI only.

Section IV: Professional Oversight
18 Points

4.1 Standard — Medical Director Responsibilities

3 Points

4.1.1 The *medical director* or the *supervising physician* shall carry out the following functions:

4.1.1.1 Oversee the development of written policies and procedures including guidelines for *patient* safety, pediatric and pregnant *patients*, as well as medically compromised *patients* ;

4.1.1.2 Ensure that only qualified *practitioners* are hired;

4.1.1.3 Ensure the compliance with policies and procedures regarding:

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

B. Appropriate physician oversight as required by *standards* of practice and regulations regarding the dispensing or administering such pharmacological agents;

4.1.1.4 Consult with and supervise senior managers who are affiliated with the *imaging provider;*

4.1.1.5 Follow-up with *medical physicist* or *medical physicist report* recommendations;

4.1.1.6 Supervise the *imaging provider's* risk management program to ensure optimal *patient* health and safety; and

4.1.1.7 Participate in, review and approve the MAP Accreditation process, which includes:

A. Notifying RadSite within 14 days of any material or *adverse change* to its *business operations* that may directly impact the scope of the MAP Accreditation

B. 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, and

C. Addressing any substantive deficiencies related to the MAP *Standards.*

Required Document Submission

4.1.2 Submit sample *medical director/supervising physician* job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.1.

Further Explanation

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

4.2 Standard — Interpreting Physician Responsibilities

3 Points

4.2.1 The *interpreting physician* shall carry out the following functions:

4.2.1.1 Interpreting and/or performing clinical examinations in compliance with the requirements established by the *medical director/supervising physician;*

4.2.1.2 Reporting results of examinations;

4.2.1.3 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

4.2.1.4 Other duties assigned by the *medical director/supervising physician* or required by the MAP Standards.

Required Document Submission

4.2.2 Submit sample *interpreting physician* job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.2.

Further Explanation

The intent of the standard is to ensure the *imaging provider* is using qualified personnel to interpret *clinical images* and documenting all cases. It also is imperative that the *interpreting physician* actively promote *patient* safety even if they are not on-s*ite* with the *patient.* Other duties may include consultation with technologist staff for protocol optimization, and engaging in staff education and in-service training aimed at quality and safety improvements. The role of *interpreting physicians* should be monitored by the *medical director/supervising physician* and subject to peer review through a *QA Program.*

4.3 Standard — Medical Imaging Technologist Responsibilities

3 Points

4.3.1 The *medical imaging technologists* shall carry out the following functions:

4.3.1.1 Prepare and operate *imaging systems* appropriately;

4.3.1.2 Properly position *patients* to effectively record the requested diagnostic images;

4.3.1.3 Follow the policies, procedures, and safety protocols established by the *medical director/supervising physician* or generated by federal, state and local requirements, and by other oversight or accrediting agencies;

4.3.1.4 Report any medical errors, mishaps or near misses to the *medical director*/*supervising physician* stemming from any source including but not limited to personnel and equipment performance;

4.3.1.5 Implement the *quality control* processes required by the MAP *Standards; and*

4.3.1.6 Assist in patient education related to safety concerns inherent to ionizing radiation and contrast administration.

Required Document Submission

4.3.2 Submit sample *medical imaging technologist* job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.3.

Further Explanation

The intent of the standard is to identify the scope of duties for *medical imaging technologists* working for the *imaging provider*.

Radiology technology certifications recognized by RadSite for the MAP Accreditation Program include:

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

If an individual has another radiology technology certification currently not referenced in the MAP *Standards*, 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.

4.4 Standard — Imaging Manager Responsibilities

3 Points

4.4.1 The *imaging manager* shall:

4.4.1.1 Have a comprehensive understanding of the principles of *imaging system* safety for each of the *ADI services* modalities used by the *imaging provider* which the *imaging manager* oversees;

4.4.1.2 Ensure compliance with policies and procedures pertaining to *imaging system* safety;

4.4.1.3 Have reporting accountability to the *medical director/supervising physician;*

4.4.1.4 Know and follow the priority reporting procedures for any equipment malfunctions, mishaps and medical errors to the appropriate entities, including the *medical director/supervising physician;* and

4.4.1.5 Help implement the *quality control program*.

Required Document Submission

4.4.2 Submit sample *imaging manager* job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.4.

Further Explanation

The intent of the 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* (e.g., devoting sufficient time on-site at each location, demonstrating adequate daily communication with staff at each location, and designating an individual on-site who is in charge of *imaging system* safety program when the *imaging manager* is not on-site*)*.

4.5 Standard — Medical Physicist (MR Scientist) Responsibilities

3 Points

4.5.1 When working for an *imaging provider*, each *medical physicist* or MR scientist for MRI units shall:

- 4.5.1.1 Be familiar with and apply equipment manufacturer specifications and *patient* safety requirements;
- 4.5.1.2 Perform periodic evaluations of the *imaging systems* by using *phantoms or test-objects;*
- 4.5.1.3 Monitor through periodic evaluations, including the provision of patient specific dose measurements, *patient* radiation doses and equipment performance.(Not applicable for MR scientist);
- 4.5.1.4 When and where appropriate, re-calibrate *imaging systems;*
- 4.5.1.5 Produce comprehensive *medical physicist reports;*
- 4.5.1.6 Provide consulting support to the *imaging provider;*
- 4.5.1.7 Report any equipment malfunctions, mishaps, safety breeches, and concerns to the *medical director* and any other designated *imaging provider* staff member; and
- 4.5.1.8 Assist in the creation of patient and staff education and training programs related to radiation safety.

Required Document Submission

4.5.2 Submit sample *medical physicist/MR scientist* job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.5.

Further Explanation

The intent of the standard is to require that all *imaging providers* evaluate each *imaging system* by a trained and certified *medical physicist* or MR scientist at regular periodic intervals. The MAP Application requests information regarding the minimum requirements of the *medical physicist's* education, training and certification levels.

4.6 Standard — Radiation Safety Officer (RSO) Responsibilities

3 Points

4.6.1 The *imaging provider* shall appoint a *radiation safety officer (RSO)* to oversee and implement a *Patient* and Personnel Safety Program if the applicant has a radioactive materials *license*.

4.6.2 Each *RSO* shall:

- 4.6.2.1 Provide annual training in radiation safety to meet ALARA practices;
- 4.6.2.2 Serve on the radiation safety committee;
- 4.6.2.3 Ensure the facility is following all state required practices to maintain the RAM *license*;
- 4.6.2.4 Review all activities that involve the use of radioactive materials;
- 4.6.2.5 Supervise *quality control (QC)* of nuclear equipment;
- 4.6.2.6 Monitor personnel exposure records;
- 4.6.2.7 Maintain inventory of all radioactive materials; and
- 4.6.2.8 Review and modify imaging exam protocols for radiation dose optimization in accordance with industry and societal standards.

Required Document Submission

4.6.3 If the applicant has a radioactive materials *license*, the applicant must submit a sample *Radiation Safety Officer* job description demonstrating that the individual fulfills the duties and responsibilities defined under Standard 4.6.

Further Explanation

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

Section V: Policies and Procedures
18 Points

5.1 Standard — Written Policies and Procedures

3 Points

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

5.1.2 Specifically, the *imaging provider* shall:
- 5.1.2.1 Maintain a master list of all policies and procedures;
- 5.1.2.2 Update all policies and procedures with effective dates, including the date of the most recent revision; and
- 5.1.2.3 Have all clinical policies and procedures reviewed and signed off by both the *medical director* and *imaging manager* at least annually.

Further Explanation

The intent of the standard is to ensure 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 *medical director* and *imaging manager* may be the same individual.

5.2 Standard — Clinical Policies

6 Points

5.2.1 Regarding imaging clinical policies, the *imaging provider* shall:
- 5.2.1.1 Maintain and document all major clinical workflows in writing or electronically;
- 5.2.1.2 Annually review and update all clinical policies and procedures under the *medical director/supervising physicia*n's supervision;
- 5.2.1.3 Document all changes;
- 5.2.1.4 Notify all staff impacted by any new or revised clinical policies and procedures;
- 5.2.1.5 Train staff at least annually;
- 5.2.1.6 Utilize outside clinical peers to support and/or review all clinical policies and procedures; and
- 5.2.1.7 Document staff attendance at training sessions.

Required Document Submission

5.2.2 Submit two samples of current clinical policies and procedures used by the *imaging provider*.

Further Explanation

A clinical policy is any document that describes in detail the process for performing an imaging scan on a *patient*. These documents may include step-by-step instructions or a general policy and procedure to be followed by the *imaging provider* while conducting a scan.

The intent of the standard is to ensure 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 provider* and have medical expertise that is covered by a particular clinical policy.

5.3 Standard — Regulatory Compliance Program

3 Points

5.3.1 The *imaging provider* shall implement a compliance program that monitors federal, state and local regulatory requirements.

Further Explanation

The intent of this standard is to ensure compliance with regulatory and manufacturing requirements – along with other nationally recognized and mandatory practice *standards*, including but not limited to 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 providers* comply with state and local requirements such as state practitioner licensing requirements and local zoning ordinances.

5.4 Standard — Complaint Resolution Process

3 Points

5.4.1 Regarding complaints related to an urgent or *patient* safety issue, the *imaging provider* shall:
- 5.4.1.1 Handle and respond to all such complaints in an expedited manner, typically within 24 hours, or next working day;
- 5.4.1.2 Report any *sentinel event* to the proper authorities;
- 5.4.1.3 Maintain a formal system to receive and respond in a timely manner to grievances;
- 5.4.1.4 Inform *patients* of their rights to submit a complaint;
- 5.4.1.5 Respond to complaints in a timeframe indicative of the seriousness of the issue;
- 5.4.1.6 Address any compliance issues such as privacy; and
- 5.4.1.7 Create staff education and training programs based upon patient safety complaints and concerns.

Further Explanation

The intent of the 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 provider*.

5.5 Standard — Storage Requirements

3 Points

5.5.1 The *imaging provider* 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.

5.5.2 Specifically, the *imaging provider* shall undertake the following safeguards:
- 5.5.2.1 Store a hard copy or use a digital storage system for images;
- 5.5.2.2 Provide appropriate long-term storage for more than 98% of primary images archived for at least seven years;
- 5.5.2.3 Provide appropriate long-term storage for more than 98% of primary images archived for minors until *patient* has reached adulthood; and
- 5.5.2.4. Use and update periodically an image retention policy or manual.

5.5.3. 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 the standard is to ensure diagnostic images are securely stored and preserved for subsequent review.

Section VI: Quality and Patient Safety
25 Points

6.1 Standard — Quality Assurance Program

3 Points

6.1.1 The *imaging provider* shall maintain a comprehensive *quality assurance (QA) program* that includes the following actions:

- 6.1.1.1 Operates according to written policies and procedures that are reviewed annually by the *medical director/supervising physician;*
- 6.1.1.2 Is overseen by a quality assurance committee or another formal panel of the *imaging provider* that includes participation by the *medical director/supervising physician;*
- 6.1.1.3 Tracks, analyzes and remediates complaints, grievances, concerns and errors;
- 6.1.1.4 Oversees *quality control (QC) program*, including appropriate remediation procedures for any known substantive deficiencies;
- 6.1.1.5 Oversees *imaging system* training and other relevant educational programs;
- 6.1.1.6 Helps monitor manufacturer requirement notices for *non-imaging* and *imaging systems* (stationary and/or *mobile*) and updates policies and procedures;
- 6.1.1.7 Helps identify, implement and benchmark clinical policies; and
- 6.1.1.8 Helps ensure compliance with other quality requirements including the MAP *Standards.*
- 6.1.1.9 Creates staff education and training programs based upon analysis of measured QA deficiencies.
- 6.1.1.10Implements of clinical peer review program for assessment of diagnostic accuracy in medical imaging reporting.

Required Document Submission

6.1.2 Submit a *QA* policy and procedure.

Further Explanation

The intent of the *standard* is to ensure each *imaging provider* 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 provider's* quality assurance committee can be a standalone committee or a sub-group of the organization. The committee must include the *medical director/supervising physician* and utilize a communication channel to update the entire organization of key quality assurance issues.

6.2 Standard — Patient and Personnel Safety Program

10 Points

6.2.1 The *imaging provider* shall implement a *patient* and personnel safety program, conduct training at least annually, document staff attendance at training, and document on-going compliance with the program that addresses the following requirements:

6.2.1.1 Operates in accordance with written policies and procedures;
6.2.1.2 Ensures that the patient and personnel safety program is updated at least annually;
6.2.1.3 Includes the assignment of a *radiation safety officer (RSO)* to each *imaging facility;*
6.2.1.4 Monitors all staff for occupational radiation exposure as required by federal and state requirements;
6.2.1.5 Promotes the proper use of radiation shielding in accordance with ALARA (As Low As Reasonably Achievable) and other radiation safety principles;
6.2.1.6 Implements *patient* identification procedures;
6.2.1.7 Implements safeguards for radiation and contrast media dosage ;
6.2.1.8 Implements pregnancy and pediatric screening procedures and protocols;
6.2.1.9 Annually educates and trains staff on radiation safety and use of imaging medicine and equipment;
6.2.1.10 Relies on medication adherence guidelines;
6.2.1.11 Posts radiation safety *standards* in each *imaging facility;*
6.2.1.12 Requires the use of dosimeter devices by staff to monitor radiation exposure;
6.2.1.13 Ensures access to emergency equipment, supplies and personnel including a crash cart or other life-sustaining measures;
6.2.1.14 Requires an ACLS-certified individual to be present, and continuously monitor a *patient* undergoing IV contrast or sedation;
6.2.1.15 Has access to spill confinement and decontamination resources ;
6.2.1.16 Establishes annual image volume thresholds for each *imaging system;*
6.2.1.17 Requires the timely reporting of a *sentinel event* to the proper authorities – along with following all internal reporting directives; and
6.2.1.18 Creation of a patient educational program related to medical imaging quality and safety.

6.2.2 The *imaging provider* shall implement a *Patient* and Personnel Safety Program with written manuals, conduct training at least annually, document staff attendance at training, and document on-going compliance with the program that covers at least the following issues and Occupational Safety and Health Administration (*OSHA*) topics:
6.2.2.1 Adverse drug reactions;
6.2.2.2 *OSHA*: Blood pathogens and exposure control;
6.2.2.3 *OSHA*: Infection control;
6.2.2.4 *OSHA*: Safety *standards*;
6.2.2.5 Advanced Cardiovascular Life Support;
6.2.2.6 Evacuation plans that cover both facility-wide and locally-contained emergencies; and
6.2.2.7 Other specialty issues associated with radiation safety.

6.2.3 The *imaging provider* 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:
6.2.3.1 The facility's written policy regarding a drug-free workplace;
6.2.3.2 Supervisor training empowering supervisors to police and enforce the policy;
6.2.3.3 Employee training empowering employees to comply with the policy;
6.2.3.4 Employee assistance for substance abuse;
6.2.3.5 Substance abuse testing; and
6.2.3.6 Sanctions for employees or contractors failing to comply with these requirements.

6.2.4 The *imaging provider* shall maintain a healthy workplace, and demonstrate compliance with a healthy mental workforce policy covering all employees and contractors. The program shall include, at minimum:

6.2.4.1 A written policy regarding a healthy mental workforce;
6.2.4.2 Supervisor training empowering supervisors to police and enforce the policy;
6.2.4.3 Employee training empowering employees to comply with the policy;
6.2.4.4 Employee assistance for mental health;
6.2.4.5 Optional mental health testing; and
6.2.4.6 Remedies for employees or contractors failing to comply with the healthy mental workforce program.

Required Document Submission

6.2.5 The *imaging provider* must submit a key policy supporting its *patient* and personnel safety program, addressing the elements listed above in Standard 6.2.1.

6.2.6 The *imaging provider* must submit a key policy addressing the *OSHA* requirements listed above in Standard 6.2.2.

6.2.7 The *imaging provider* must submit a key healthy workforce or substance abuse policy for its personnel, addressing the elements listed above in Standard 6.2.3 and/or Standard 6.2.4.

Further Explanation

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

Applicants may want to consider accessing the following resources:

- Information regarding Image Gently, an initiative of the Alliance for Safety in Pediatric Imaging, is available at http://www.pedrad.org/associations/5364/ig/.
- 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.

6.3 Standard — Medical Imaging Policies

3 Points

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

6.3.1.1 The actual presence of qualified medical staff when a contrast medium is used or sedation is required for a *patient*;
6.3.1.2 Interpretation of all studies on an appropriate computer or electronic communication device that provides the image quality necessary for proper interpretation;
6.3.1.3 File maintenance of a formal final written or electronic report for each and all imaging studies performed; and
6.3.1.4 Formal documentation of all final image examinations by an *interpreting physician*, especially when the final report is dictated and translated by a transcriptionist.

Required Document Submission

6.3.2 The *imaging provider* must submit policies and procedures supporting its medical imaging policies, addressing the elements listed above in Standard 6.3

Further Explanation

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

6.4 Standard — Patient Access

3 Points

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

- 6.4.1.1 Obtaining imaging services in a timely manner at a reasonably convenient location;
- 6.4.1.2 Providing reasonable access to *patient* health information including imaging records in accordance with the organization's medical record policy;
- 6.4.1.3 Establishing a *patient* notification system; and
- 6.4.1.4 Promoting a consumer complaint and grievance process through which *patients* can file a complaint or raise a concern easily and without barriers.

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.

6.5 Standard — Patient Confidentiality

3 Points

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

- 6.5.1.1 Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and
- 6.5.1.2 Protected health information (PHI) can only be accessible to authorized personnel involved in the diagnosis and treatment of the *patient* and disclosed to others as permitted by federal and state law.

Further Explanation

The intent of the standard is to declare and ensure that PHI is only accessible to authorized personnel in order to protect each *patient's* confidentiality.

6.6 Standard — Financial Integrity

3 Points

6.6.1 The *imaging provider* shall not promote any:
- 6.6.1.1 Financial conflicts that jeopardize the *patient's* best interests and welfare; and
- 6.6.1.2 Inappropriate incentives or kick-backs associated with *patient* referrals.

6.6.2 The applicant must comply with any state and federal law concerning financial integrity, including the Stark Law.

6.6.3 The *imaging provider* shall establish financial integrity policies that are documented in writing or electronic form that prohibit:
- 6.6.3.1 Financial conflicts that jeopardize the *patient's* best interests and welfare;
- 6.6.3.2 Any inappropriate incentives or kick-backs associated with *patient* referrals;
- 6.6.3.3 Financial incentives to refer *patients* for more procedures or specific facilities, including incentives to referring physicians, any referring physician's employees, relatives or associates;
- 6.6.3.4 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;
- 6.6.3.5 The use of improper incentives such as ones to encourage the premature or preferential use of a new machine or contrast agent; and
- 6.6.3.6 Ordering physician compensation based on the number of imaging services he or she 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 provider,* 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 practice. In order to do *slot-leasing*, a facility that has excess imaging capacity typically enters into a formal lease agreement with referring physicians. 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 amount 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 physicians 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
100 Points per Imaging System

7.1 Standard - General Requirements

7.1.1 For each *imaging system* the applicant must submit the following:

7.1.1.1 The most recent annual *medical physicist report* for each *imaging system*;

7.1.1.2 *Phantom* testing for image quality and dose (for both adults and children) for each imaging unit (note: a complete explanation of the *phantom* testing requirements is provided for each modality under Standard 7.2);

7.1.1.3 For each *CT, MRI or PET* unit, as well as for general *Nuclear Medicine*, at least three case studies (including one child 0-15 years of age if the unit is used for pediatric *patients* and no more than one normal case per body system) must be submitted for each type of clinical examination performed on the imaging unit (note: a complete explanation of the *clinical image* requirements is provided for each modality under Standard 7.3); and

7.1.1.4 Case studies must be of actual *patients* imaged on the imaging unit within the prior six months, must be accompanied by the facility's protocol for that examination, as well as corresponding clinical reports, and must represent the best work of as many current staff members as possible.

Further Explanation

The accreditation reviewers shall score each *imaging system* as follows depending on the Advanced Diagnostic Imaging (ADI) modality. The reviewer will grade the following:

- Physics Review
  - Medical physics report
  - *Phantom image sets*
- Image Quality Review
  - Sample *clinical images*
  - Corresponding clinical reports
  - Corresponding protocols

For each *imaging system* to pass the physics and image quality review, each imaging system must meet all the requirements detailed in Standards 7.2 and 7.3. Note: Sample scoring sheets demonstrating how these criteria are evaluated are included in Appendices C and E.

7.2 Standard - Physics Quality Evaluation

7.2.1 Computed Tomography (CT)

7.2.1.1 CT Physics Testing

A. Annual physics evaluation of CT imaging modalities means testing that is performed on the CT imaging system by a qualified medical physicist and that includes at a minimum the following factors:

1. CT number accuracy

2. Slice thickness verification
3. CT number uniformity
4. CT noise measurement
5. High contrast spatial resolution
6. Low contrast detectability
7. Review of the site's CT quality assurance program.
8. *Patient* radiation dose for clinically utilized scans

B. *Imaging providers* must submit the following to meet the CT physics review requirements:
   1. Submission of the most recent *medical physics* report for each *imaging system* under accreditation review (must be within the past 12 months).
   2. Completed site *CT* protocol data for each *imaging system* for the procedures specified, containing the *patient* radiation dose information, especially dose length product (DLP) and CT dose index (CTDI) information necessary for *medical physicist's* dose evaluation of *site*'s protocols.
   3. *Phantom images* used for the annual physics report.
      a. *Phantom* imaged with the typical adult abdomen protocol.
      b. *Phantom* imaged with the typical adult head protocol.
      c. *Phantom* imaged with the typical pediatric abdomen protocol.
      d. *Phantom* imaged with the typical pediatric head protocol.
   4. Examples of the examinations of an anatomic part specified by RadSite through a random selection process.
   5. The protocol the applicant used to produce the submitted images must match the *site'*s actual CT protocol review sheet.
   6. The *patient* radiation dose report for each exam.

C. The *imaging provider* shall submit all images in DICOM format via RadSite's upload utility, or compact disc (CD).

D. The evaluation of submitted images shall include:
   1. Images obtained from vendor-supplied *phantoms* or commercially available *phantoms* are acceptable if items a-e can be evaluated. *Phantoms* that are acceptable include the Catphan *phantoms* (various models), GAMMEX 464 *Phantom*, and the AAPM CT Performance *Phantom* with Low Contrast Insert.
      a. 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.
      b. 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.
         i. The water equivalent region for all *phantoms* must measure 0 +/- 5 at all energies.

ii. The air equivalent region for all *phantoms* must measure -1000 +/-50 at 120 kVp.
iii. For the GAMMEX 464 *phantom*
    a) Acrylic – 122 +/- 12
    b) Bone – 910 +/- 60
    c) Low density polyethylene (LDPE) – -95 +/- 12
iv. For the Catphan *Phantoms*
    a) Teflon – 950 +/- 60
    b) Acrylic – 122 +/- 12
    c) Polystryene – -35 +/- 7
    d) Delrin – 340 +/- 25
    e) Low density polyethylene (LDPE) – -95 +/- 12
    f) Polymethylpentene (PMP) – -200 +/- 40
v. For the AAPM CT Performance *Phantom*
    a) Acrylic – 122 +/- 12
    b) Polystryene – -35 +/- 7
    c) Low density polyethylene (LDPE) – -95 +/- 12
vi. 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.
    a) The vendor *phantom* manual must be submitted, if a vendor *phantom* is utilized.

c. CT noise is evaluated using a review of the annual *medical physics* report.
d. The images are reviewed for artifacts. Artifacts are evaluated as either:
    i. Minor = Artifacts present without inhibiting diagnostic interpretation (minor deficiency); or
    ii. Severe = Artifacts that degrade image quality and inhibit diagnostic interpretation (major deficiency)**.**
e. Contrast is evaluated on the *phantom images* according to the following parameters:
    i. Low contrast detectability using the *site*'s adult head and abdomen protocols and the *site'*s pediatric head protocol.
        a) If a vendor *phantom* is utilized, the manual should state the acceptable low contrast detectability limits.
        b) For commercial 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 to of the *phantom* to meet these low contrast *standards*

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

E. Note:
1. Accreditation failure if the images submitted do not pass as specified above.
2. Accreditation failure occurs if *site*'s protocol radiation doses are over the limits.
3. Accreditation failure occurs if severe artifacts are visible on any images.

7.2.2 Magnetic Resonance Imaging (MRI) Testing

7.2.2.1 *MRI* Physics Testing

A. Annual Physics Testing of *MRI* systems means testing that is performed on the *MRI* system by a qualified medical physicist and that includes at a minimum the following factors:
1. Magnetic Field Homogeneity
2. Geometric Accuracy
3. Slice Thickness
4. High Contrast Spatial Resolution
5. Low Contrast Detectability
6. Slice Position Accuracy
7. Percent Intensity Uniformity (PIU)
8. Signal Ghosting Percentage (SGP)
9. SNR, SGP, and PIU testing of all clinically utilized coils
10. Review of the documentation regarding the applicant's *MRI Quality Assurance Program and the MRI Safety Policies and Procedures.*

B. The *Imaging providers* must submit the following to meet the MRI physics review requirements:
1. Submission of the most recent Annual *Medical Physics* report (must be within 12 months of submission date)
2. The *MRI* system's Annual *Medical Physics* Testing is performed by a qualified medical physicist
3. All *Sites* have completed the *Site*'s *MRI* Protocol Review Sheet for the procedures specified
4. *Site*'s *phantom images* acquired using their normal brain T1 and T2 acquisitions.
   a. For 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.*
   b. For the MagPhan SMR170 *phantom*, 5 mm slices with no slice gap should be utilized to cover the entire *phantom.*
5. The protocol the applicant used to produce the submitted images must match the *site'*s actual *MRI* protocol review sheet.

C. The *imaging provider* shall submit all images in DICOM format via RadSite's upload utility, or compact disc (CD).The evaluation of submitted images shall include the imaging provider's *imaging system clinical images* and *phantom images*, if applicable, using the following parameters:
1. 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)
2. Geometric Accuracy should not deviate by more than 2% from known distance in all three planes

3. Slice Thickness Accuracy – The measured slice thickness for spin echo sequences should be within +-15% of the prescribed thickness for 5 mm or greater slice thickness
4. High Contrast Spatial Resolution – Objects 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)
5. Low Contrast Detectability –
    a. For field strengths up to and including 1.0T, objects with a diameter of 4 mm or less with a contrast difference of 6% or less must be visualized. Additionally, objects with a diameter of 6 mm or less with a contrast difference of 4% or less must be visualized.
    b. For field strengths greater than 1.0T but 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.
    c. 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.
6. Slice Position Accuracy – The measured slice position should agree within +- 2 mm of the actual slice position.
7. Percent Intensity Uniformity (PIU) >= 88% for 2T or lower, >=82.5% for units higher than 2T.
8. Signal Ghosting Percentage (SGP) is evaluated for the *Phantom*: SGP must be less than 1.5%.
9. 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.

7.2.3 Nuclear Medicine Testing

7.2.3.1. *Gamma Camera* Imaging

A. Physics Testing

1. Annual Physics Evaluation of *Nuclear Medicine* modalities means testing that is performed on the *Nuclear Medicine* system by a qualified medical physicist and that includes at a minimum the following factors:
    a. Intrinsic Uniformity
    b. System Uniformity
    c. Intrinsic Spatial Resolution
    d. System Spatial Resolution
    e. Count Rate Sensitivity
    f. Visual Inspection of Camera
    g. Review of *Nuclear Medicine* Technologist's Quality Control Tests
2. The *Imaging providers* must submit the following to meet the *Gamma Camera* physics review requirements:
    a. Intrinsic Uniformity mission of the most recent Annual *Medical Physics* report
    b. The *Nuclear Medicine* system's Annual Physics Evaluation is performed by a qualified medical physicist.
    c. All *Sites* have completed the *Site's Nuclear Medicine* Protocol Review Sheet for the procedures specified.
    d. 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.

e. Intrinsic or extrinsic resolution images of 5 million counts utilizing a resolution *phantom*.
    i. If a four-quadrant bar *phantom* is utilized, the smallest bars must be less than 3 mm.
    ii. If utilizing a performance *phantom* with resolution rods, the *phantom* must contain a series of rods with diameters less than 8 mm.

B. The *imaging provider* shall submit all images in DICOM format via RadSite's upload utility, or compact disc (CD).The evaluation of submitted images shall include the imaging provider's *imaging system clinical images* and *phantom images*, if applicable, using the following parameters:
1. Uniformity
    a. 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.
    b. If Tl-201 is utilized, a review of the screen capture of the CFOV Integral Uniformity Percentages, if available, obtained from the intrinsic or extrinsic uniformity images for each camera head.
    c. 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.
2. Spatial Resolution
    a. 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.
        i. 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.
        ii. For extrinsic *phantom images* 8 mm diameter rods or smaller must be visualized.
3. The images are reviewed for artifacts. If an artifact is present, the artifact will be classified as:
    a. Minor = Artifacts present without inhibiting diagnostic interpretation; or
    b. Severe = Artifacts that degrade image quality and inhibit diagnostic interpretation.

C. 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.

7.2.3.2 *Single Photon Emission Computed Tomography (SPECT) Images*

A. Physics Testing
1. Annual Physics Evaluation of *Nuclear Medicine* modalities means testing that is performed on the Nuclear Medicine unit by a qualified medical physicist and that includes at a minimum the following factors:
    a. Intrinsic Uniformity

b. System Uniformity
c. Intrinsic Spatial Resolution
d. System Spatial Resolution
e. Count Rate Sensitivity
f. Visual Inspection of Camera
g. Center of Rotation
h. Review of *Nuclear Medicine* Technologist's *Quality Control* Tests

2. The *Imaging providers* must submit the following to meet the *SPECT* physics review requirements:
   a. Submission of the most recent Annual *Medical Physics* Report (must be within 12 months of submission)
   b. The *Nuclear Medicine* unit's Annual *Medical Physics* Evaluation is performed by a qualified medical physicist.
   c. All *Sites* have completed the *Site's Nuclear Medicine* Protocol Review Sheet for the procedures specified.
   d. *Phantom images* acquired as described in "*Nuclear Medicine/SPECT Phantom* Acquisition Instructions."

B. The *imaging provider* shall submit all images in digital electronic format or converted to compact disc (CD) or digital video disc (DVD) recordings. Each image must include:
   a. Region of Interests (ROIs) measurements placed where required for particular acquisitions, including mean ROIs and Standard deviation ROIs

C. The evaluation of submitted images shall include the imaging provider's *imaging system clinical images* and *phantom images*, if applicable, using the following parameters:
   a. 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)
      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. System Spatial Resolution
      i. 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. 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. The Tc-99m *SPECT* images will be evaluated for spatial resolution, uniformity and contrast resolution.
      i. *SPECT* Uniformity
         a) 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

a) For the Flanged and Flangeless Jaszczak *Phantom* series (excluding the small flangeless *phantom*), the 11.1 mm rods must be visible.
b) 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
a) For the Flanged and Flangeless Jaszczak *Phantom* series (excluding the small flangeless *phantom*), the 19.1 mm sphere must be visible.
b) For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom Inserts three spheres must be visible.

7.2.3.3 Positron Emission Tomography (PET) Images

A. Physics Testing
1. Annual *Medical Physics* Evaluation of *Nuclear Medicine* modalities means testing that is performed on the *PET* unit by a qualified medical physicist and that includes at a minimum the following factors:
a. Spatial Resolution
b. Uniformity
c. Contrast Resolution
d. SUV Evaluation
e. Review of *Nuclear Medicine* Technologist's Quality Control Tests
2. The *Imaging providers* must submit the following to meet the *PET* physics review requirements:
a. Submission of the most recent Annual *Medical Physics* Report (must be within 12 months of submission)
b. The *PET* unit's Annual *Medical Physics* Evaluation is performed by a qualified medical physicist.
c. All *sites* have completed the *Site's PET* Protocol Review Sheet for the procedures specified.
d. *Phantom images* acquired as described in "*PET Phantom* Acquisition Instructions."

B. The *imaging provider* shall submit all images in DICOM format via RadSite's upload utility, or compact disc (CD).

C. The *PET* images will be evaluated for uniformity and spatial resolution, and lesion detection under the following parameters:
1. *PET* Uniformity
a. 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.
2. *PET* Spatial Resolution
a. 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*. The 11.1 mm rods must be visible.
b. For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom Inserts the 11 mm rods must be visible.
c. All other *phantoms* must be approved and have a method of measuring spatial resolution to at least 11 mm.
3. *PET* Lesion Detection
a. 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."

b. For the NEMA NU-2 *PET phantom*, the 13 mm "hot" cylinder should be visualized
c. For the Jaszczak Deluxe *phantom*, the 12 mm "hot" cylinder should be visualized
d. For the Nuclear Associates PET/SPECT Phantom Source Tank, Phantom Inserts the 12 mm "hot" cylinder must be visible.
e. SUV will be measured for each "hot" cylinder and for the background to determine the accuracy of SUV measurements
    i. Mean SUV background values should be between 0.85 and 1.15.
    ii. 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.
f. 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. For each imaging system for which the applicant desires accreditation, the applicant must submit the most recent medical physicist report and corresponding phantom images. Submitted materials will be evaluated according to the sample physics quality scoring sheets listed in Appendix C.

7.3 Standard - Image Quality Evaluation

7.3.1 CT Summary

7.3.1.1 The CT Accreditation Program includes an assessment of the following elements for all CT scanners that are involved in *patient* care evaluations on any level:

A. Clinical images
B. Facility imaging protocols
C. Radiation exposure
D. Pediatric techniques designed to limit radiation exposure (for facilities performing pediatric CT studies)

7.3.1.2 The following CT examinations are available for accreditation:

A. Neurologic CT – Neuroimaging using CT includes evaluations of the brain, soft tissues of the neck, and the spine.
B. Musculoskeletal CT – This involves CT 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.
C. Body CT – This type of CT imaging includes the chest, abdomen and pelvis,
Cardiovascular – This imaging methodology involves imaging of the heart, pericardium, and aorta, and may include cardiac functional evaluations; and
CT Angiography (CTA) – The use of CTA in the evaluation 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, vessels of the abdomen and pelvis as well as of the extremities.

D. Pediatric CT – The use of CT scanning in children is of particular concern because children are more susceptible to the potential adverse effects of radiation than adults. Imaging facilities that provide CT imaging must demonstrate pediatric protocols to improve radiation protection for children.

Image Selection

7.3.1.3 Clinical Image Submissions – For each *CT imaging system* a service provider is seeking accreditation, a minimum of three adult image case studies and protocols, as well as one pediatric, if applicable, must be submitted. An applicant must submit one adult imaging case study from each of the three main categories (i.e.: One neuroimaging, one musculoskeletal and one body scan.) The image case studies must be chosen from the following examination options:

Adult Examination Choices*		
Neuroimaging	**Musculoskeletal**	**Body**
• Brain • Soft tissue of the neck	• Spine Cervical Thoracic Lumbar Extremity/Joint	• Chest High Resolution Standard Resolution • Abdomen/Pelvis • Angiography**

Pediatric Examination Choices		
Neuroimaging	**Musculoskeletal**	**Body**
• Brain • Soft tissue of the neck	• Spine Cervical Thoracic Lumbar Extremity/Joint	• Chest • Abdomen/Pelvis

*At least one data set, in addition to the CT Angiography must be done with contrast.
**If cardiac exams are performed, a cardiac exam must be submitted.
Each data set must be from an actual *patient.*
If the image supplier is specialized the three data sets must be from three different protocols.
Note: For facilities performing only one type of imaging, at least two additional image sets must be submitted (one of three exams unless the facility performs pediatrics, in which case an additional pediatric study must be submitted).

Clinical Image Requirements

7.3.1.4 Each facility is required to submit an example 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 set of *clinical images* should include:

A. The clinical indications for the examination
B. All images obtained or post-processed including additional planes and/or 3D images
C. Images submitted must predate the application by at least 3 and no more than 6 months
   1. New technology must be represented in the images submitted and must reflect recent upgrades to all equipment
D. These images will be assessed for the following items:

1. Demographic Data
    a. *Patient*-identifying information (First & Last Names, Medical Record Number)
    b. *Patient* date of birth
    c. Gender of *patient*
    d. Name of institution
    e. Date and time of examination
    f. Equipment type
2. Diagnostic Data
    a. CT Number Accuracy
    b. Slice Thickness Accuracy
    c. Appropriate use of reconstruction
    d. CT Number Uniformity and Noise
    e. Artifact evaluation
3. Technical Data
4. High-Contrast Spatial Resolution Low-Contrast Detectability must be demonstrated
    a. Anatomic coverage display
    b. Anatomic orientation labels
    c. Field of View
    d. Radiation dose (mA & kVp)
    e. Scan time
    f. Image numbering system
5. Abnormality imaged adequately for diagnosis
    a. Appropriate use of contrast agents

Radiation Exposure

7.3.1.5 It is important to recognize that facility accreditation is in part based upon DIAGNOSTIC IMAGE QUALITY. Facilities should be aware of and actively participating in the principle of ALARA (As Low As Reasonably Achievable). It is important the facility 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 (*phantom* must be scanned at comparable dosage to demonstrate contrast at dose):

A. **75 mGy** or less for adult brain
B. **30 mGy** or less for adult chest (for single run)
C. **25 mGy** or less for adult abdomen
D. **25 mGy** or less for adult pelvis
E. **70 mGy** or less for pediatric brain must not exceed dose for age weight category (see Image Gently Chart in Appendix D)
F. **25 mGy** or less for pediatric chest must not exceed dose for age weight category (see Image Gently Chart in Appendix D)
G. **20 mGy** or less for pediatric abdomen must not exceed dose for age weight category (see Image Gently Chart in Appendix D)
H. **20 mGy** or less for pediatric pelvis must not exceed dose for age weight category (see Image Gently Chart in Appendix D)

Exam Protocols

7.3.1.6 The availability and common use of multi–detector row CT scanning has resulted in protocols that have become more complex because of a larger number of interacting operator-defined parameters. Each facility should submit the protocols they use on a regular basis. The protocol should include the following:

A. Indications for the examination
B. Necessity for the use of contrast (intravenous/intrathecal)
C. Slice thickness
D. Standard reconstruction images
E. Scan parameters

Scan Parameters

A. **Type of Exam:** Neurologic, Musculoskeletal, Body or Pediatric
B. **Anatomic Coverage:** Superior and inferior extent of the examination.
C. **Contrast:** Indications, dose, injection rate, and scan delay, if used.
D. **Effective Detector Row Thickness:** This parameter determines the reconstructed section thickness that cannot be smaller than the effective detector row thickness.
E. **Coverage:** Anatomical regions included in scan.
F. **Radiation Exposure:** mAs, and kVp with CT dose index volume ($CTDI_{vol}$) in mGy.
G. **Intravenous contrast:** Only non-ionic contrast agents should be used. Dose should be appropriate for the *patient.* (Pediatric doses should be calculated based on 2.0 ml/kg or less.)
H. **Injection rate:** No greater than 5 ml/second.
I. **Acquisitions:** Single phase, multi-phase, delay, equilibrium.
J. **Oral contrast:** To be used as needed for stomach and bowel opacification.
K. **Window and level:** Soft tissue, lung, liver, bone and 3D reconstruction.
L. **Slice thickness:** Appropriate to the study being performed.
M. **Reconstruction:** Should be performed when additional diagnostic benefit can be achieved.

Example Protocols:

7.3.1.7 Example protocols and pass/fail criteria for each can be found in Appendix D.

7.3.2 *MRI*

Summary

7.3.2.1 The MR Accreditation Program includes an assessment of the following elements for all MR scanners that are involved in *patient* care evaluations on any level.

A. Field Strength
B. Types of Imaging Examinations
C. Image Quality
D. Artifacts
E. Image Protocols

Field Strength

7.3.2.2 The strength of the magnetic field for an *MRI* scanner is most often reported in units of tesla (10,000 G = 1 T). Higher field strength MR scanners in general provide a more detailed image, allow for faster scan times, and have greater operating costs. Lower field strength scanners are particularly popular when they have an open configuration allowing for improved tolerance by claustrophobic and/or obese *patients.* In general MR systems with field strength of 0.5 T or higher are recommended for optimal *patient* care.

Types of Imaging Examinations

7.3.2.3 The following *MRI* examinations are available for accreditation:

A. Neurologic *MRI* – Neuroimaging using *MRI* includes evaluations of the brain, soft tissues of the neck, spine and peripheral nervous system including the brachial plexus and lumbar plexus. Neuroimaging may also include dynamic cerebrospinal fluid flow studies, diffusion weighted imaging, diffusion tensor imaging, and functional *magnetic resonance imaging*.
B. Musculoskeletal *MRI*: 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.
C. Body *MRI* – This type of *MRI* imaging includes the neck, chest, abdomen, and pelvis.
D. Cardiovascular *MRI* – This imaging methodology involves imaging of the heart, pericardium, aorta, and may include cardiac functional evaluations.
E. 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.
F. MR Angiography (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.
G. MR Spectroscopy – Magnetic Resonance Spectroscopy (MRS), also referred to as Nuclear magnetic resonance spectroscopy (NMR) or NMR spectroscopy is a method of determining the chemical composition of a region of brain tissue by observing the spectrum of electromagnetic energy released from that brain tissue. MRS is typically performed in one of two ways:
    1. Single-voxel spectroscopy (SVS), and
    2. Multi-voxel spectroscopy (MVS). SVS obtains a spectrum from a single sample volume of brain tissue whereas with MVS spectra are obtained from multiple voxels. Multi-voxel MRS offers the advantage of covering a much larger area of the brain decreasing the probability of sampling errors. The tradeoff is a weakening of the signal-to-noise ratio with a less robust spectrum unless compensated for by increased scan time.
        a. Single-voxel and multi-voxel spectroscopy typically employ one of two methodologies: 1) Point Resolved Excitation Spin-echo Sequence (PRESS), or 2) Stimulated Echo Acquisition Mode (STEAM). MRS in common clinical use typically evaluates for the following metabolites:
            i. N-Acetyl Aspartate (NAA) – An amino acid unique to neuronal tissue and is generally regarded as a marker of neuronal viability. The normal NAA concentration is in the range of 8-9 mmol/kg and is decreased in conditions leading to axonal injury with neuronal loss.
            ii. Choline (Cho) – A heterogeneous spectral peak that may contain a variety of choline-containing compounds including acetylcholine, phosphocholine (lecithin), and glycerophosphocholine. Cho is elevated in any condition affecting the white matter of the brain with elevated levels found after trauma, in demyelinating diseases, and neoplasms. Cho is often related to the Creatine peak in determining the degree of Cho abnormality.

iii. Creatine (Cr) – Reflects the energy potential available in brain tissue with a high concentration in normal brain because of the relative constant brain cell demand for energy. Creatine-Choline ratios are recognized as an important indicator of brain disease.

iv. Lactate (Lac) – Absent in normal brain tissue and elevated in ischemic conditions or metabolic disorders. This spectral peak is sensitive to the technique employed and is often inverted or bifid. (The TE of 144 being used indicates that the lactate peak will be inverted.)

v. Lipid – Absent in normal brain tissue and increases in tumors, infections and metabolic disorders.

vi. Myo-inositol (Ins) – A naturally occurring sugar that is decreased in stroke, tumors, lymphoma and some low-grade malignancies.

Image Selection

7.3.2.4 For each *MRI* system that a service provider is seeking accreditation, a minimum of three image case studies and protocols must be submitted; one pediatric case study should be submitted if applicable. The image case studies must be chosen from the following examination options:

Adult/Pediatric Examination Choices		
Neuroimaging	**Musculoskeletal**	**Cardiovascular**
• Brain Headache Trauma Stroke/TIA Demyelinating Disease Hearing Loss Visual Disturbance(Orbit) • Soft tissue of the neck • Spine Cervical Thoracic Lumbar	• Joints Shoulder, Elbow, Knee, Ankle, Hand, Foot	• Heart • Pericardium • Aorta • Cardiac functional evaluations
Body	**Breast Imaging**	**Angiography**
• Neck • Chest • Abdomen • Pelvis		• Brain: Cerebral vasculature • Carotid • Arch and Carotid • Cardiac and chest vasculature • Vessels of the abdomen and pelvis as well as the extremities
Spectroscopy		
• Single-voxel spectroscopy • Multi-voxel spectroscopy		

Image Quality

7.3.2.5 In addition to the *MRI* systems undergoing a detailed physics review, each facility is required to submit an example 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:

A. The clinical indications for the examination
B. All sequences obtained on the *patient*
C. The radiology report provided for the examination
D. Images submitted must predate the application by at least three and no more than six months.
E. These images will be assessed for the following items:
    1. Demographic data
        a. *Patient*-identifying information (First & Last Names, Medical Record Number)
        b. *Patient* date of birth
        c. Gender of *patient*
        d. Name of institution
        e. Date and time of examination
        f. Equipment type
    2. Technical Data
        a. Geometric Accuracy
        b. High-Contrast Spatial Resolution
        c. Low-Contrast Detectability
        d. Existence of Artifacts
        e. Signal Uniformity
    1. Abnormality imaged adequately for diagnosis

Artifacts

7.3.2.6 Artifacts are relatively common during MR scanning and may interfere with image quality and interpretation. Some artifacts are unavoidable such as *patient* motion caused by breathing. Other artifacts may be limited by careful utilization of scanning methodologies. It is important to limit scan artifacts as much as possible. *MRI* examinations submitted or selected for review will be assessed for the following image artifacts potentially limiting image quality:

A. Aliasing – Also referred to as "wrap around: occurs when a body part exceeds the field of view, and the body part outside the field of view is wrapped into a more central part of the image
B. Black Boundary – Also referred to as "India Ink," represents contours outlining MR structures
C. Anatomy without corresponding anatomical structure
D. Truncation artifacts (Edge ringing) – Periodic parallel lines or ringing adjacent to borders or tissue discontinuity, in either the phase and/or frequency encoding directions. This is due to a small matrix.
E. Heterogeneous brightness (Shading) – This is due to RF heterogeneity, improper *patient* positioning, or metal in the magnet or on the *patient*
F. Heterogeneous fat suppression – Uneven darkening of the fat signal in different portions of the image set. This may be due to either a heterogeneous magnetic field or a heterogeneous RF field.
G. Susceptibility – Localized field distortion or non-uniformities produced by differing tissue magnetic susceptibility (especially at air-tissue interfaces)

H. Chemical shift – Occurs along the frequency encoding axis at fat/water soft tissue
I. Ghosting – Periodic replication of partial copies of images of the original structure along the phase encoding axis due to motion. It includes artifacts from swallowing (C-spine), respiration and peristalsis (L-spine), CSF pulsation (brain and spine), vascular pulsation (brain and knee) and cardiac motion (T-spine)
J. Geometric distortion – Size, orientation or shape is not accurately represented on the image.
K. Excessive filtering – Excessive smoothing using software to reduce apparent noise in the image. Excessive filtering or smoothing obscures the true anatomical structure and/or contrast.
L. Misregistration of 2D images – Consecutive 2D images do not line up so some anatomy is skipped and other regions are imaged twice. This can also be a particularly serious problem on 2D time-of-flight MRA MIPs.
M. Misregistration of subtracted images – On subtracted images, there is incomplete subtraction of the background tissue signal with prominent signal at edges that do not align properly.
N. Ringing – Accentuation of edges due to either under sampling of k-space (not enough phase encoding steps) or at the leading edge of the bolus on an enhanced 3D MRA study due to IV contrast being present during acquisition of peripheral k-space but not as much during acquisition of the center of k-space.
O. Stair step (Venetian blind artifact) – In MRA, a vessel goes obliquely through slices, due to slice thickness and vessel size. Venetian blind occurs on multi slab MRA (typically on reformations and MIPs), when the adjacent slabs are not properly and seamlessly overlapped.
P. Reformatting artifacts – Improper MIP and reformations may give the false appearance of vessel occlusion or stenosis when it is only partially included in the MIP volume. Superimposed vessels may falsely appear stenotic on MIP due to stealing of voxels at the vessel edges. Stair step artifact may occur on oblique reconstruction when the slices are too thick or there is insufficient zero filling.
Q. ECG lead artifacts – The ECG leads used for cardiac gating should not produce excessive artifacts that would interfere with the interpretation of the image.
R. RF leak or "zipper" artifact – Linear hyperintensity parallel to the phase encoding direction often caused by unwanted sources of RF signals originating within (e.g., light bulb failure) or outside (e.g. inadequate RF shielding) the scanner room.
S. Echo train blurring – Image blurring due to excessively long echo spacing and/or echo train length.

Example *MRI* Protocols

7.3.2.7 Example protocols and pass/fail criteria for each can be found in Appendix D.

7.3.3 Nuclear Medicine

Image Selection:

7.3.3.1 Service providers desiring accreditation for *Nuclear Medicine* must indicate each type of *Nuclear Medicine* examination for which they desire accreditation selecting from:

A. *Gamma Camera*/*Planar*(non-cardiac)
B. Cardiac (planar and SPECT)
C. SPECT
*D. PET/CT**

*Note: All PET/CT machines must undergo accreditation for both PET and CT criteria.

7.3.3.2 For each *Nuclear Medicine* system that a service provider is seeking accreditation, a minimum of three image case studies and protocols must be submitted; one pediatric case study should be submitted if applicable. The image case studies must be chosen from the following examination options, and chosen from each category if applicable:

A. One *Gamma Camera/Planar*
   1. Whole body bone scan
   2. Ventilation perfusion scan
   3. Hepatobiliary study

B. One *SPECT*
   1. Bone
   2. Liver/Spleen
   3. Gallium

C. Cardiology
   1. Myocardial Perfusion thallium or technetium based pharmaceutical
   2. MUGA Scan

7.3.3.3 In addition to the *Nuclear Medicine* systems undergoing a detailed physics review, each facility is required to submit an example set of *clinical images* with the accompanying clinical report for each type of *Nuclear Medicine* examination for which it is requesting accreditation. This set of *clinical images* should include:

A. The clinical indications for the examination
B. All images obtained including post-processing, fused and 3D images
C. The clinical report provided for the examination
D. Images submitted must predate the application by at least three and no more than six months
E. These images will be assessed for the following items:
   1. Demographic data
      a. *Patient*-identifying information (First & Last Names, Medical Record Number)
      b. *Patient* date of birth
      c. Gender of *patient*
      d. Name of institution
      e. Date and time of examination
      f. Equipment type
   2. Technical Data
      a. Extrinsic Uniformity
      b. Extrinsic Spatial Resolution
      c. System Alignment from the Center of Rotation
   1. Abnormality imaged adequately for diagnosis Diagnostic Adequacy

Image Analysis Examples

7.3.3.3 Example protocols and pass/fail criteria can be found in Appendix D.

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 case studies (including sample images and clinical reports) and corresponding protocols, as well as one additional pediatric case study if the imaging system is used on

pediatric patients. Submitted materials will be evaluated according to the sample image quality scoring sheets listed in Appendix E, and sample protocols listed in Appendix D.

7.4 Standard - Corrective Action for Imaging System Deficiencies

7.4.1 The *imaging provider* shall address any problems or substantive deficiencies with each *imaging system* by:

7.4.1.1 Reporting the issue to the *medical director/supervising physician* and *imaging manager*;

7.4.1.2 Providing updates on the issue to *imaging provider* staff as necessary to carry out their duties and to care for *patients*;

7.4.1.3 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;

7.4.1.4 Removing the *imaging system* from *patient* service if there is an identified *patient* safety issue until it meets or exceeds performance requirements; and

7.4.1.5 Documenting all key activities including the appropriate risk-related timeframes and reported to the appropriate agencies and individuals.

Further Explanation

The intent of this standard is to verify that the *imaging provider* has and implements a corrective action plan to address any *imaging system* deficiencies or issues that may arise. 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

ABMP – American Board of Medical Physics

ABR – American Board of Radiology

ABSNM – American Board of Science in Nuclear Medicine

ACR – American College of Radiology

ADI – Advanced Diagnostic Imaging

AEC – Automatic Exposure Controls

ALARA – As Low as Reasonably Achievable

ARMRIT – American Registry of Magnetic Resonance Imaging Technologists

ARRT – American Registry of Radiologic Technologists

ASRT – American Society of Radiologic Technologists

CAD – Computer-Aided Diagnosis

CD – Compact Disk

CMS – Center for Medicare and Medicaid Services

CT – Computed tomography

DEA – Drug Enforcement Agency

DICOM – Digital Imaging and Communications in Medicine

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

MRI – Magnetic resonance imaging

MITA – Medical Imaging & Technology Alliance

N/A – Not Applicable

NEMA – National Electrical Manufacturer Association

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

RAP – RadSite Assessment Program

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

SPECT – Single Photon Emission Computed tomography

SUV – Standardized Uptake Value

U.S. – United States

Appendix B: Timeframe Summary

Summary of Time Frames		
Issue	**Timeframe**	**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:	120 days	Once the application is completed in full, RadSite will make its initial determination in one hundred and twenty (120) days or less.
Full Accreditation:	3 years	Accreditation period is three (3) years from date of MAP 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 MAP Accreditation Program until: Ninety (90) days after the date of the first *Notice of Failure* notification.
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 MAP Accreditation Program until: 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 MAP Accreditation must be registered with and reviewed by RadSite within sixty (60) days of being brought online and before being used on any *patients.*
Appeals Process: First Level	30 days	The applicant can appeal in writing an *adverse decision* to the Accreditation Committee within thirty (30) days of the applicant's R*eceipt* 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 Board of Advisors within forty five (45) days of the applicant's R*eceipt* 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 Visits 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 visits for applicants and may audit these facilities at any time. Note: The Application still must be completed within the 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 MAP Accreditation.

Appendix C: Sample Physics Quality Scoring Sheets (For Standard 7.2 – Physics Quality Review)

CT Physics Evaluation

Date: _____
Performed By: _____
Facility ID#: _____
Image ID# _____
Phantom Submitted _____

GAMMEX PHANTOM	CATPHAN PHANTOM	AAPM PHANTOM	Adult Head	Adult Abdomen	Peds Head	Peds Abdomen
Parameters on the submitted images do not match the protocols on Phantom Data Form (each box counts as one minor deficiency)	Parameters on the submitted images do not match the protocols on Phantom Data Form (each box counts as one minor deficiency)	Parameters on the submitted images do not match the protocols on Phantom Data Form (each box counts as one minor deficiency)				
kVp different (each box counts as one major deficiency)	kVp different (each box counts as one major deficiency)	kVp different (each box counts as one major deficiency)				
mAs more than 10% different (each box counts as one major deficiency)	mAs more than 10% different (each box counts as one major deficiency)	mAs more than 10% different (each box counts as one major deficiency)				
Pitch more than 10% different (each box counts as one major deficiency)	Pitch more than 10% different (each box counts as one major deficiency)	Pitch more than 10% different (each box counts as one major deficiency)				
ROI Measurements (any number outside the criteria is a minor deficiency)	ROI Measurements (any number outside the criteria is a minor deficiency)	ROI Measurements (any number outside the criteria is a minor deficiency)	2 or More Minors = Fail	2 or More Minors = Fail	2 or More Minors = Fail	2 or More Minors = Fail
Polyethylene HU (between -107 and -83)	Polyethylene HU (between -107 and -83)	Polyethylene HU (between -107 and -83)				
Water HU (between -5 and +5)	Water HU (between -5 and +5)	Water HU (between -5 and +5)				
Acrylic HU (between +110 and +134)	Acrylic HU (between +110 and +134)	Acrylic HU (between +110 and +134)				
Bone HU (between 850 and 970)	Teflon HU (between 890 and 1010)	Polystryene HU (between -25 and -42)				
Air HU (between -1050 and -950)	Air HU (between -1050 and -950)	Air HU (between -1050 and -950)				
		Pass/Fail				
Low contrast result (6 mm diameter or less objects visible)	Low contrast result (6 mm diameter or less objects visible)	Low contrast result (6 mm diameter or less objects visible)				NA
		Pass/Fail				
Uniformity (+-5 from center)	Uniformity (+-5 from center)	Uniformity (+-5 from center)				
Center ROI signal (HU)	Center ROI signal (HU)	Center ROI signal (HU)				
12:00 ROI signal (HU)	12:00 ROI signal (HU)	12:00 ROI signal (HU)				
3:00 ROI signal (HU)	3:00 ROI signal (HU)	3:00 ROI signal (HU)				
6:00 ROI signal (HU)	6:00 ROI signal (HU)	6:00 ROI signal (HU)				
9:00 ROI signal (HU)	9:00 ROI signal (HU)	9:00 ROI signal (HU)				
		Pass/Fail				
High Contrast Resolution (6 lp/cm)	High Contrast Resolution (6 lp/cm)	High Contrast Resolution (6 lp/cm)				
		Pass/Fail				
Artifacts	Artifacts	Artifacts	☐ None ☐ Minor ☐ Major	☐ None ☐ Minor ☐ Major	☐ None ☐ Minor ☐ Major	☐ None ☐ Minor ☐ Major
		Pass/Fail				
CTDIvol (mGy)						
		Pass/Fail				
Results (Pass/Fail)						

Comments: _____

MRI Physics Evaluation

Date: _____

Performed By: _____

Facility ID#: _____

Image ID# _____

Phantom Submitted _____

										Pass/Fail
MRI Magnetic Field Homogeneity (< 2.0 ppm)										
	Sagital Localizer			Site T1			Site T2			
Geometric Accuracy (±2% deviation)										
High Contrast Spatial Resolution (≤ 1 mm)										
Slice Thickness Accuracy (±0.5 mm)										
Slice Position Accuracy (±2 mm)										
Percent Intensity Uniformity (≥82.5% for ≥2T, ≥90.0% for ≤2T)										
Percent Signal Ghosting (≤1.0%)										
Low Contrast Object Detectability*										
Artifacts	☐	☐	☐	☐	☐	☐	☐	☐	☐	
	None	**Minor**	**Major**	**None**	**Minor**	**Major**	**None**	**Minor**	**Major**	

Comments: _____

* For field strengths up to and including 1.0T, objects with a diameter of 4 mm or less with a contrast difference of 6% or less must be visualized. Additionally, objects with a diameter of 6 mm or less with a contrast difference of 4% or less must be visualized.

* For field strengths greater than 1.0T but 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 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.

Nuclear Medicine Physics Evaluation

Date: _____

Performed By: _____

Facility ID#: _____

Image ID# _____

Phantom Submitted _____

Isotope 1 (Tc-99m)	Head 1	Head 2 (if Applicable)	Head 3 (if Applicable)
		Planar	
Uniformity*			
Spatial Resolution (≤8.0 mm diameter rods)			
Isotope 2			
Uniformity*			
Spatial Resolution (≤3.5 mm bars)			
		SPECT Images	
Uniformity			
Spatial Resolution (≤11.1 mm rods)			
Contrast (≤19.1 mm sphere)			
Artifacts	☐ ☐ ☐ **None Minor Major**	☐ ☐ ☐ **None Minor Major**	☐ ☐ ☐ **None Minor Major**

Comments: _____

*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. IF values are not available, the uniformity will be evaluated by overall appearance.

PET Physics Evaluation

Date: _____

Performed By: _____

Facility ID#: _____

Image ID# _____

Phantom Submitted _____

Visual Inspection	Value	Pass/Fail
Uniformity*		
Spatial Resolution (≤11.1 mm diameter rods)		
Lesion Detection (13 mm hot cylinder or less)		
SUV Measurement	**Measurement**	**Pass/Fail**
Background (0.85 - 1.15)		
Max SUV of Large Hot Cylinder (3.5 - 4.5)		
Artifacts		

Comments: _____

*If minor artifacts are visible in only a few slices, the uniformity is considered adequate.

Appendix D: Protocol Samples (For Standard 7.3 – Image Quality Review)

Example CT Protocols:

Adult Brain

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Gantry Tilt	Canthal-Meatal Line	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 75 mGy	Radiation dose > 75 mGy
mAs	80 – 800 mAs	Radiation dose > 75 mGy
kVp	100 – 140 kVp	Radiation dose > 75 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 to 1.5	Inappropriate pitch
Field of View (FOV)	FOV from 20 to 24	Inappropriate FOV
Intravenous Contrast	50 to 150 ml appropriate use	Inappropriate dose or use

Adult Temporal Bones

PARAMETER	PASS	FAIL
Coverage	Above IAC to mastoid tip	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 75 mGy	Radiation dose > 75 mGy
mAs	80 – 800 mAs	Radiation dose > 75 mGy
kVp	120 – 140 kVp	Radiation dose > 75 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 18 to 20	Inappropriate FOV
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Reconstruction	Coronal (Sagittal optional)	No coronal reconstruction

Adult Cervical Spine

PARAMETER	PASS	FAIL
Coverage	Foramen Magnum to T2	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 40mGy	Radiation dose > 40 mGy
mAs	80 – 800 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 to 1.5	Inappropriate pitch
Field of View (FOV)	FOV from 14 to 18	Inappropriate FOV
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Adult Thoracic Spine

PARAMETER	PASS	FAIL
Coverage	C7 through L1	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 40mGy	Radiation dose > 40 mGy
mAs	80 – 800 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 14 to 18	Inappropriate FOV
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Adult Lumbar Spine

PARAMETER	PASS	FAIL
Coverage	T12 through distal sacrum	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 40mGy	Radiation dose > 40 mGy
mAs	80 – 800 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 8 to 14	Inappropriate FOV
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Adult Chest

PARAMETER	PASS	FAIL
Coverage	Lung apex through adrenals	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 30mGy	Radiation dose > 30 mGy
mAs	80 – 800 mAs	Radiation dose > 30 mGy
kVp	80 – 140 kVp	Radiation dose > 30 mGy
Tube Rotation Time	1 seconds or less	Greater than 2 seconds
Pitch	1.0 to 1.5	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast	50 to 150 ml appropriate use	Inappropriate dose or use
Injection rate	2 – 4 ml/sec	Injection rate slow or fast
Slice Thickness Routine Chest	5 mm or less	Slice thickness > 5 mm
Slice Thickness Aorta	3 mm or less	Slice thickness > 3 mm
Slice Thickness Pul. Embolus	2 mm or less	Slice Thickness > 2 mm
Reconstruction (optional)	Coronal and Sagittal	No sagittal or coronal

		reconstruction

Adult Neck

PARAMETER	PASS	FAIL
Coverage	Base of brain to apices	Incomplete Coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose (mGy)	($CTDI_{vol}$)determined <30 mGy	Radiation dose >30 mGy
mAs	80-800 mAs	Radiation dose >30 mGy
kVp	80-140 kVp	Radiation dose >30 mGy
Tube Rotation Time	1 second or less	Greater than 1 second
Pitch	1.0-1.5 seconds	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast (ml) (optional)	50-150 ml appropriate use	Inappropriate dose or use
Slice Thickness Routine Chest (mm)	5mm or less	Slice thickness > 5mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Adult Cardiac

PARAMETER	PASS	FAIL
Coverage	Total cardiac volume	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 50mGy	Radiation dose > 50 mGy
mAs	80 – 800 mAs	Radiation dose > 50 mGy
kVp	80 – 140 kVp	Radiation dose > 50 mGy
Tube Rotation Time	1 second or less	Greater than 1 second
Tube Rotation Time CTA	0.5 seconds or less	Greater than 0.5 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast	50 to 150 ml appropriate use	Inappropriate dose or use
Slice Thickness	1 mm or less	Slice thickness > 2 mm
Reconstruction	Coronal & Sagittal	Incomplete reconstruction

Adult Abdomen/Pelvis

PARAMETER	PASS	FAIL
Coverage	Diaphragm to pubic symphysis	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 50mGy	Radiation dose > 50 mGy
mAs	80 – 800 mAs	Radiation dose > 50 mGy
kVp	80 – 140 kVp	Radiation dose > 50 mGy
Tube Rotation Time	1 second or less	Greater than 1 seconds
Pitch	1.0 to 1.80	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast	50 to 150 ml appropriate use	Inappropriate dose or use

(optional)		
Injection Rate	2-4 ml/sec	Rate outside of range
Oral Contrast (optional)	Adequate - stomach & bowel	Inadequate opacification
Slice Thickness	5 mm or less	Slice thickness > 5 mm

Adult Abdomen

PARAMETER	PASS	FAIL
Coverage	Diaphragm to iliac crest	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 25mGy	Radiation dose > 25 mGy
mAs	80 – 800 mAs	Radiation dose > 25 mGy
kVp	80 – 140 kVp	Radiation dose > 25 mGy
Tube Rotation Time	1 second or less	Greater than 1 seconds
Pitch	1.5 or less	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast	50 to 150 ml appropriate use	Inappropriate dose or use
Injection Rate	2-5 ml/sec	Rate outside of range
Standard Delay Acquisition	60-75 seconds	Incorrect acquisition time
Multiphase Acquisitions	1)25-30 & 2) 45-65 seconds	Incomplete acquisitions/time
Additional Equilibrium Scan	4-10 minutes as needed	Inappropriate equilibrium scan
Oral and Intravenous Contrast optional	Optional	N/A
Slice Thickness	5 mm or less	Slice thickness > 5 mm

Adult Pelvis

PARAMETER	PASS	FAIL
Coverage	Iliac crest to pubic symphysis	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 25mGy	Radiation dose > 25 mGy
mAs	80 – 800 mAs	Radiation dose > 25 mGy
kVp	80 – 140 kVp	Radiation dose > 25 mGy
Tube Rotation Time	1 second or less	Greater than 1 second
Pitch	1.5 or less	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast	50 to 150 ml appropriate use	Inappropriate dose or use
Injection Rate	2-5 ml/sec	Rate outside of range
Standard Delay Acquisition	60-75 seconds	Incorrect acquisition time
Multiphase Acquisitions	1)25-30 & 2) 45-65 seconds	Incomplete acquisitions/time
Additional Equilibrium Scan	4-10 minutes as needed	Inappropriate equilibrium scan
Slice Thickness	5 mm or less	Slice thickness > 5 mm

Adult Extremity

PARAMETER	PASS	FAIL
Coverage	From proximal articular joint surface to distal articular joint surface	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose (mGy)	($CTDI_{vol}$)determined < <25 mGy	Radiation dose > 25 mGy
mAs	40-400 mAs	Radiation dose > 25 mGy
kVp	80-140 kVp	Radiation dose > 25 mGy
Tube Rotation Time	1 sec or less	Greater than 1 second
Pitch	1.5 or less	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Injection Rate (ml/sec) (optional)	2-5ml/sec	Rate outside of range
Slice Thickness (mm)	3mm or less	Slice thickness > 3mm

Pediatric Protocol:
(Worksheet for Pediatric CT available from Image Gently at:
http://pedrad.org/associations/5364/ig/index.cfm?page=368)

Table I: mAs Reduction Factors for the Pediatric Abdomen and Thorax

Abdomen Baseline:	kVp fill in	mA fill in	Time (sec) fill in	Pitch Abdomen fill in	Pitch Thorax fill in
PA Thickness (cm)	Approx Age	Abdomen mAs Reduction Factor (RF)	Estimated mAs = BL x RF	Thorax mAs Reduction Factor (RF)	Estimated mAs = BL x RF
9	newborn	0.43		0.42	
12	1 yr	0.51		0.49	
14	5 yr	0.59		0.57	
16	10 yr	0.66		0.64	
19	15 yr	0.76		0.73	
22	small adult	0.90		0.82	
25	med adult	1.0		0.91	
31	large adult	1.27		1.16	

1. Type in baseline abdomen techniques and mAs in yellow cells
2. Spreadsheet will calculate mAs estimated for pediatric patients of varying sizes (For interactive spreadsheet, please visit: http://pedrad.org/associations/5364/ig/index.cfm?page=368)

Pediatric Brain

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Gantry Tilt	Canthal-Meatal Line	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 70mGy	Radiation dose > 70 mGy

mAs	80 – 400 mAs	Radiation dose > 70 mGy
kVp	70 – 120 kVp	Radiation dose > 70 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 to 1.5	Inappropriate pitch
Field of View (FOV)	FOV from 20 to 24	Inappropriate FOV
Intravenous Contrast (optional)	2 ml/kg appropriate use	Inappropriate dose or use
Slice Thickness	5 mm or less	Slice thickness > 5mm

Pediatric Temporal Bones

PARAMETER	PASS	FAIL
Coverage	Above IAC to mastoid tip	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determined < 70mGy	Radiation dose > 70 mGy
mAs	80 – 400 mAs	Radiation dose > 70 mGy
kVp	80 – 140 kVp	Radiation dose > 70 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 18 to 20	Inappropriate FOV
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Reconstruction	Coronal (Sagittal optional)	No coronal reconstruction

Pediatric Cervical Spine

PARAMETER	PASS	FAIL
Coverage	Foramen Magnum to T2	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 40mGy	Radiation dose > 40 mGy
mAs	80 – 400 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 8 to 14	Inappropriate FOV
Slice Thickness	3 mm or less	Slice thickness > 3 mm
Reconstruction	Sagittal (coronal optional)	No sagittal reconstruction

Pediatric Thoracic Spine

PARAMETER	PASS	FAIL
Coverage	C7 through L1	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 40mGy	Radiation dose > 40 mGy
mAs	80 – 400 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 8 to 14	Inappropriate FOV

Slice Thickness	3 mm or less	Slice thickness > 3 mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Pediatric Lumbar Spine

PARAMETER	PASS	FAIL
Coverage	T12 through distal sacrum	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 40mGy	Radiation dose > 40 mGy
mAs	80 – 400 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 or less	Inappropriate pitch
Field of View (FOV)	FOV from 8 to 14	Inappropriate FOV
Slice Thickness	3 mm or less	Slice thickness > 3 mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Pediatric Chest

PARAMETER	PASS	FAIL
Coverage	Lung apex to lung base	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 25mGy	Radiation dose > 25 mGy
mAs	80 – 400 mAs	Radiation dose > 25 mGy
kVp	80 – 140 kVp	Radiation dose > 25 mGy
Tube Rotation Time	2 seconds or less	Greater than 2 seconds
Pitch	1.0 to 1.5	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast (optional)	2 ml/kg appropriate use	Inappropriate dose or use
Slice Thickness	4 mm or less	Slice thickness > 4 mm

Pediatric Neck

PARAMETER	PASS	FAIL
Coverage	Base of brain to apices	Incomplete Coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose (mGy)	<25 mGy	Radiation dose >25 mGy
mAs	80-800 mAs	Radiation dose >25 mGy
kVp	80-140 kVp	Radiation dose >25 mGy
Tube Rotation Time	1 second or less	Greater than 1 second
Pitch	1.0-1.5	Inappropriate pitch
Field of View (FOV)	Fit to patient	Inappropriate FOV
Intravenous Contrast (ml) (optional)	50-150 ml appropriate use	Inappropriate dose or use
Injection rate	2-4 ml/sec	Rate outside of range
Slice Thickness Routine Chest (mm)	5mm	Slice thickness > 5mm

Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

Pediatric Cardiac

PARAMETER	PASS	FAIL
Coverage	Total cardiac volume	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 25mGy	Radiation dose > 25 mGy
mAs	80 – 400 mAs	Radiation dose > 25 mGy
kVp	80 – 140 kVp	Radiation dose > 25 mGy
Tube Rotation Time	1 second or less	Greater than 1 seconds
Pitch	1.0 to 1.5	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast	2 ml/kg appropriate use	Inappropriate dose or use
Slice Thickness	2 mm or less	Slice thickness > 2 mm

Pediatric Abdomen/Pelvis

PARAMETER	PASS	FAIL
Coverage	Diaphragm to pubic symphysis	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 40mGy	Radiation dose > 40 mGy
mAs	80 – 400 mAs	Radiation dose > 40 mGy
kVp	80 – 140 kVp	Radiation dose > 40 mGy
Tube Rotation Time	1 second or less	Greater than 1 seconds
Pitch	1.0 to 1.80	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast (optional)	2 ml/kg appropriate use	Inappropriate dose or use
Oral Contrast (optional)	Adequate - stomach & bowel	Inadequate opacification
Slice Thickness	5 mm or less	Slice thickness > 5 mm

Pediatric Abdomen

PARAMETER	PASS	FAIL
Coverage	Diaphragm to Iliac crest	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 20mGy	Radiation dose > 20 mGy
mAs	80 – 400 mAs	Radiation dose > 20 mGy
kVp	80 – 140 kVp	Radiation dose > 20 mGy
Tube Rotation Time	1 second or less	Greater than 1 seconds
Pitch	1.0 to 1.80	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast (optional)	2 ml/kg appropriate use	Inappropriate dose or use
Oral Contrast (optional)	Adequate - stomach & bowel	Inadequate opacification
Slice Thickness	5 mm or less	Slice thickness > 5 mm

Pediatric Pelvis

PARAMETER	PASS	FAIL
Coverage	Iliac crest to pubic symphysis	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose	($CTDI_{vol}$)determine < 20mGy	Radiation dose > 20 mGy
mAs	80 – 400 mAs	Radiation dose > 20 mGy
kVp	80 – 140 kVp	Radiation dose > 20 mGy
Tube Rotation Time	1 second or less	Greater than 1 seconds
Pitch	1.0 to 1.80	Inappropriate pitch
Field of View (FOV)	FOV fit to patient	Inappropriate FOV
Intravenous Contrast (optional)	2 ml/kg appropriate use	Inappropriate dose or use
Oral Contrast (optional)	Adequate – stomach & bowel	Inadequate opacification
Slice Thickness	5 mm or less	Slice thickness > 5 mm

Pediatric Extremity

PARAMETER	PASS	FAIL
Coverage	From proximal articular joint surface to distal articular joint surface	Incomplete coverage
Gantry Tilt	0	Insufficient or over angled
Radiation Dose (mGy)	< 20	Radiation dose > 20 mGy
mAs	40-400	Radiation dose > 20 mGy
kVp	80-140	Radiation dose > 20 mGy
Tube Rotation Time	1 sec or less	Greater than 1 second
Pitch	1.5	Inappropriate pitch
Field of View (FOV)	Fit to patient	Inappropriate FOV
Slice Thickness (mm)	3mm or less	Slice thickness > 3mm
Reconstruction	Sagittal and coronal	No sagittal or coronal reconstruction

*For CT Angiography studies that include pre and post-contrast exams, the total allowable radiation dose is twice that listed in the protocol examples above.

Example MRI Protocols

Brain for Headache

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	5 mm or less	Slice thickness > 5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1 or FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial T2	CSF hyperintense to brain	CSF hypointense to brain
Axial T1 (optional if T1 sag)	CSF hypointense to brain	Required if no T1 sagittal
Axial Diffusion (optional)	B value > 800	N/A

Brain for Trauma

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	5 mm or less	Slice thickness > 5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1 or FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial T2	CSF hyperintense to brain	CSF hypointense to brain
Axial T1 (optional if T1 sag)	CSF hypointense to brain	Required if no T1 sagittal
Axial Diffusion (optional)	B value > 800	N/A
Axial/Coronal susceptibility	Axial or Coronal sequences	No susceptibility imaging

Brain for Stroke/TIA

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	5 mm or less	Slice thickness > 5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1 or FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial T2	CSF hyperintense to brain	CSF hypointense to brain
Axial T1 (optional if T1 sag)	CSF hypointense to brain	Required if no T1 sagittal
Axial Diffusion	B value > 800	No diffusion imaging
Axial/Coronal susceptibility	Axial or Coronal sequences	No susceptibility imaging

Brain for Demyelinating Disease

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	5 mm or less	Slice thickness > 5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial T2	CSF hyperintense to brain	CSF hypointense to brain
Axial T1	CSF hypointense to brain	CSF hyperintense to brain

Axial Diffusion (optional)	B value > 800	N/A

Brain for Hearing Loss (IAC)

PARAMETER	PASS	FAIL
Coverage	Above to below IACs	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Axial or Coronal T1	CSF hypointense to brain	CSF hypertense to brain
Axial FLAIR	CSF hypointense to brain	CSF hypertense to brain
Axial T2	CSF hyperintense to brain	CSF hypointense to brain

Brain for Visual Disturbance (Orbit)

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	3 mm or less	Slice thickness > 3 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Coronal T1 or FLAIR (orbits)	CSF hypointense to brain	CSF hypertense to brain
Axial T1 or FLAIR (orbits)	CSF hypointense to brain	CSF hypertense to brain
Coronal T2 (orbits)	CSF hyperintense to brain	CSF hypointense to brain
Axial T2 (orbits)	CSF hyperintense to brain	CSF hypointense to brain
Sagittal T2 (orbits - optional)	CSF hyperintense to brain	N/A
Sagittal T1 (orbits - optional)	CSF hypointense to brain	N/A

Generic Brain

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	5 mm or less	Slice thickness > 5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1 or FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial FLAIR	CSF hypointense to brain	CSF hyperintense to brain
Axial T2	CSF hyperintense to brain	CSF hypointense to brain
Axial T1 (optional if T1 sag)	CSF hypointense to brain	Required if no T1 sagittal

Pituitary

PARAMETER	PASS	FAIL
Coverage	Vertex to skull base	Incomplete coverage
Slice Thickness	3 mm or less	Slice thickness > 3 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Coronal T1 (sella)	CSF hypointense to brain	CSF hypertense to brain
Sagittal T1 (sella)	CSF hypointense to brain	CSF hypertense to brain
Post contrast T1 Coronal	Obtained	Unless contraindicated
Post contrast T1 Sagittal	Obtained	Unless contraindicated
Contrast dynamic (optional)	20 sec or less dynamic	N/A
Coronal T2 - optional	CSF hyperintense to brain	N/A
Sagittal FLAIR - optional	CSF hypointense to brain	N/A
Coronal FLAIR – optional	CSF hypointense to brain	N/A

MRA Brain

PARAMETER	PASS	FAIL
Coverage	Vertebral-Anterior Cerebral	Incomplete coverage
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
3D Time of Flight	Multi-slab images	No multi-slab images

MRA Carotid

PARAMETER	PASS	FAIL
Coverage	Bilateral carotid bifurcations	Incomplete coverage
Slice Thickness	2 mm or less	Slice thickness > 2 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
3D Time of Flight	Multi-slab images	No multi-slab images
2 D Time of Flight	Multi-slab images	No multi-slab images

MRA Arch and Carotid

PARAMETER	PASS	FAIL
Coverage	Arch to Circle of Willis	Incomplete coverage
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Intravenous Contrast	0.1 ml/kg or less	No contrast
3D Contrast imaging	Multi-slab images	No multi-slab images

Cervical Spine

PARAMETER	PASS	FAIL
Coverage	Foramen Magnum to T2	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1	CSF hypointense to cord	CSF hyperintense to cord
Sagittal T2	CSF hyperintense to cord	CSF hypointense to cord
Axial T2	CSF hyperintense to cord	CSF hypointense to cord
Axial T1 (optional)	CSF hypointense to cord	N/A
Sagittal STIR (optional)	CSF hyperintense to cord	N/A

Thoracic Spine

PARAMETER	PASS	FAIL
Coverage	C7 through L1	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1	CSF hypointense to cord	CSF hyperintense to cord
Sagittal T2	CSF hyperintense to cord	CSF hypointense to cord
Axial T2	CSF hyperintense to cord	CSF hypointense to cord
Axial T1 (optional)	CSF hypointense to cord	N/A
Sagittal STIR (optional)	CSF hyperintense to cord	N/A

Lumbar Spine

PARAMETER	PASS	FAIL
Coverage	T12 through Sacrum	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T1	CSF hypointense to cord	CSF hyperintense to cord
Sagittal T2	CSF hyperintense to cord	CSF hypointense to cord
Axial T2	CSF hyperintense to cord	CSF hypointense to cord
Axial T1 (optional)	CSF hypointense to cord	N/A
Sagittal STIR (optional)	CSF hyperintense to cord	N/A

Knee

PARAMETER	PASS	FAIL
Coverage	Full knee joint	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T2	Hyperintense joint fluid	Hypointense joint fluid
Axial T2	Hyperintense joint fluid	Hypointense joint fluid
Coronal T2	Hyperintense joint fluid	Hypointense joint fluid
Sagittal T1 (optional)	Hypointense joint fluid	N/A
Axial T1 (optional)	Hypointense joint fluid	N/A
Coronal T1 (optional)	Hypointense joint fluid	N/A

Shoulder

PARAMETER	PASS	FAIL
Coverage	Full shoulder joint	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T2 (oblique)	Hyperintense joint fluid	Hypointense joint fluid
Axial T2	Hyperintense joint fluid	Hypointense joint fluid
Coronal T2 (oblique)	Hyperintense joint fluid	Hypointense joint fluid
Coronal T1 (oblique)	Hypointense joint fluid	Hyperintense joint fluid
Sagittal T1 (optional)	Hypointense joint fluid	N/A
Axial T1 (optional)	Hypointense joint fluid	N/A

Elbow

PARAMETER	PASS	FAIL
Coverage	Full elbow joint	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T2 or STIR	Hyperintense joint fluid	Hypointense joint fluid
Axial T2 or STIR	Hyperintense joint fluid	Hypointense joint fluid
Coronal T2 or STIR	Hyperintense joint fluid	Hypointense joint fluid
Axial T1	Hypointense joint fluid	Hyperintense joint fluid
Coronal T1	Hypointense joint fluid	Hyperintense joint fluid
Sagittal T1 (optional)	Hypointense joint fluid	N/A

Wrist

PARAMETER	PASS	FAIL
Coverage	Full wrist joint	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 4 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T2	Hyperintense joint fluid	Hypointense joint fluid
Axial T2	Hyperintense joint fluid	Hypointense joint fluid
Coronal T2 (oblique)	Hyperintense joint fluid	Hypointense joint fluid
Coronal T1 (oblique)	Hypointense joint fluid	Hyperintense joint fluid
Axial T1	Hypointense joint fluid	N/A
Sagittal T1 (optional)	Hypointense joint fluid	N/A

Abdomen

PARAMETER	PASS	FAIL
Coverage	At least complete liver	Incomplete coverage
Slice Thickness	10 mm or less	Slice thickness > 10 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
MRCP 2D or 3D	Hyperintense fluid	Poorly visualized fluid
Axial T2	Hyperintense fluid	Hypointense fluid
Axial T1	Hypointense fluid	Hyperintense fluid
Coronal T2 (optional)	Hyperintense fluid	N/A

Pelvis

PARAMETER	PASS	FAIL
Coverage	Iliac crest to pubic symphisis	Incomplete coverage
Slice Thickness	4 mm or less	Slice thickness > 5 mm
Intravenous Contrast	0.1 ml/kg or less	Inappropriate dose or use
Sagittal T2	Hyperintense fluid	Hypointense fluid
Axial T2	Hyperintense fluid	Hypointense fluid
Axial T1	Hypointense fluid	Hyperintense fluid
Sagittal T1	Hypointense fluid	Hyperintense fluid

MRA Thoracic Aorta

PARAMETER	PASS	FAIL
Coverage	Thoracic Aorta	Incomplete coverage
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Intravenous Contrast	0.1 ml/kg or less	No contrast
3D Contrast imaging	Multi-slab images	No multi-slab images
Reconstruction images	Multi-planar	Insufficient to evaluate

MRA Runoff

PARAMETER	PASS	FAIL
Coverage	Distal Aorta to distal feet	Incomplete coverage
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Intravenous Contrast	0.1 ml/kg or less	No contrast

3D Contrast imaging	Multi-slab images	No multi-slab images
Reconstruction images	Multi-planar	Insufficient to evaluate
Multi-station imaging	Femoral 18-30 seconds	No contrast
Multi-station imaging	Popliteal 33-37 seconds	No contrast
Multi-station imaging	Calf 35-60 seconds	No contrast

Cardiac

PARAMETER	PASS	FAIL
Coverage	Total cardiac volume	Incomplete coverage
Slice Thickness	1.5 mm or less	Slice thickness > 1.5 mm
Intravenous Contrast	0.1 ml/kg or less	No contrast
Cardiac Gating	No significant arrhythmia	Significant arrhythmia
Long Axis	Left atrium & ventricle	Inadequate positioning
Long Axis Cine	Left atrium & ventricle	Inadequate processing
Short Axis Cine	Include left ventricle	Inadequate coverage

Example Nuclear Medicine Protocols (Gamma camera, cardiac, SPECT and PET)

General Protocol Criteria

PARAMETER	PASS	FAIL
Coverage	Appropriate to scan	Incomplete coverage
Date & Time of Exam	Included	No date and/or time record
Radioactive agent given	Include agent	No report of agent used
Dose of radioactive agent	Dose provided	No dose provided
Camera uniformity	Demonstrated	Insufficient uniformity
Pathology Imaged	Adequate pathology imaging	Inadequate pathology

Bone Scintigraphy

PARAMETER	PASS	FAIL
Coverage	Whole body with spot images as appropriate based on clinical indication	Incomplete coverage
Date & Time of Exam	Included	No date and/or time record
Radioactive agent given	^{99m}Tc-phosphates and phosphonates	No report of agent used
Dose of radioactive agent	15-30 mCi	No dose provided
Time for Imaging	1-3s/frame angio, less than 10 minutes blood pool, delayed (skeletal) 2-5 h	No time provided or outside of those parameters. Delayed images only acceptable for many clinical indications
Examination performed for appropriate indication	Neoplastic disease, occult fracture, osteomyelitis, stress fracture, avascular necrosis, arthridities, RSD, bone infarcts, bone graft viability,	Exam is not appropriate given clinical indication

	bone pain	

Hepatobiliary Scan

PARAMETER	PASS	FAIL
Coverage	Abdomen including liver, gallbladder (if visualized) and proximal small bowel anterior or LAO	Incomplete coverage
Date & Time of Exam	Included	No date and/or time record
Radioactive agent given	^{99m}Tc-disofenin or ^{99m}Tc-mebrofenin	No report of agent used or non "iminodiacetic acid" agent used
Dose of radioactive agent	3-7 mCi adults	No dose provided
Time for Imaging	Continuous dynamic 1 frame/minute continuing for 60 minutes or when GB visualized; if not seen then image at 3-4 hours or administer morphine	No time provided or outside of those parameters. Delayed images only acceptable for many clinical indications
Examination performed for appropriate indication	Acute cholecystitis, functional biliary pain syndrome, right upper quadrant pain, biliary system patency, bile leakage, neonatal hyperbilirubinemia, assessment of biliary enteric bypass procedure, assessment of liver transplant, afferent loop syndrome, choledochal cysts, calculation of gallbladder ejection fraction, prior to partial hepatectomy, anomalous liver lobulation, enterogastric reflux assessment, Sphincter of Oddi Dysfunction	Exam is not appropriate given clinical indication

Myocardial Perfusion Imaging SPECT

PARAMETER	PASS	FAIL
Coverage	Images of the heart with the heart occupying 35% to 50% of usable field of view approximately	Incomplete coverage
Date & Time of Exam	Included	No date and/or time record
Radioactive agent given	^{201}Tl-chloride, ^{99m}Tc-sestamibi, ^{99m}Tc-tetrofosmin	No report of agent used or none of the above

Dose of radioactive agent	2-4 mCi Thallium or total of 20-40 mCi ^{99m}Technetium labeled radiopharmaceuticals	No dose provided or outside of these parameters
Time for Imaging	Varies with radiopharmaceutical: 5-10 minutes for Thallium for stress and 3-24 hours for rest 15-30 minutes after stress injection and 45-60 minutes after rest injection for Tc agents and 3-24 hours after injection of thallium for redistribution	No time provided or outside of those parameters.
Examination performed for appropriate indication	Myocardial ischemia or viability determination	Exam is not appropriate for the given clinical indication

Gated Equilibrium Radionuclide Ventriculography (MUGA – Multiple Gated Acquisition)

PARAMETER	PASS	FAIL
Coverage	Images of the heart with the heart occupying approximately 50% of the usable field of view approximately	Incomplete coverage
Date & Time of Exam	Included	No date and/or time record
Radioactive agent given	^{99m}Tc-pertechnetate labeled in vivo, modified in vivo, or in vitro	No report of agent used or agent other than ^{99m}Tc-pertechnetate
Dose of radioactive agent	15 to 35 mCi for adult	No dose provided or dose outside that parameter
Frames obtained	At least 16 frames per R-R interval	No frame rate provided or less than 16 frames per R-R interval
Examination performed for appropriate indication	Known or suspected coronary artery disease or MI, to distinguish between systolic or diastolic causes or CHF or to assess for cardiac function in patient with suspected CHF, assessment of cardiac function in patients undergoing chemotherapy, assessment of ventricular function in patients with suspected valvular heart	Exam is not appropriate given clinical indication

	disease	

Appendix E: Sample Image Quality Scoring Sheets (For Standard 7.3 – Image Quality Review)

Adult CT Image Assessment							
	Reviewer Initials	_____	**Date**	_____	**Click for Protocol drop down list**		
	Facility ID #	_____	**Image ID#**	_____		**Pass**	**Fail**
						Yes	**No**
	1. Image Data Set Appropriate?						
	2. Are Patient Identifying Informations Adequate?						
	Medical Record Number						
	Date of Birth						
	Gender of Patient						
	Name of Institution						
	Date and Time of Examination						
	Equipment Type						
	3. Is Data Set From an Actual Patient?						
	4. Diagnostic Data						
	CT Number Accuracy						
	Slice Thickness Accuracy						
	Appropriate Use of Reconstruction						
	CT Number Uniformity and Noise						
	Artifact Evaluation						
	5. High-Contrast Spatial Resolution - Low-Contrast Detectability						
	Anatomic Coverage Display						
	Anatomic Orientation Labels						
	Field Of View						
	Radiation Dose						
	Scan Time						
	Image Numbering System						
	6. Abnormality Imaged Adequately for Diagnosis						
	Appropriate Use of Contrast Agents						
	Sufficient Diagnostic Notes Included to Determine Diagnostic Adequacy?						
	7. Does Image Predate Review by at least 3, but no more than 6-months?						
	8. Do Images Represent Adequate Post Processing?						
	9. Do Imaging Protocols Meet All Criteria Outlined In The Matching Protocol Tab?						

Pediatric CT Image Assessment								
		Reviewer Initials	_____	Date	_____	Click for Protocol drop down list		
		Facility ID#	_____	Image ID#	_____		Pass	Fail
							Yes	No
		1. Image Data Set Appropriate?						
		2. Are Patient Identifying Informations Adequate?						
		Medical Record Number						
		Date of Birth						
		Gender of Patient						
		Name of Institution						
		Date and Time of Examination						
		Equipment Type						
		3. Is Data Set From an Actual Patient?						
		4. Diagnostic Data						
		CT Number Accuracy						
		Slice Thickness Accuracy						
		Appropriate Use of Reconstruction						
		CT Number Uniformity and Noise						
		Artifact Evaluation						
		5. High-Contrast Spatial Resolution - Low-Contrast Detectability						
		Anatomic Coverage Display						
		Anatomic Orientation Labels						
		Field Of View						
		Radiation Dose						
		Scan Time						
		Image Numbering System						
		6. Abnormality Imaged Adequately for Diagnosis						
		Appropriate Use of Contrast Agents						
		Sufficient Diagnostic Notes Included to Determine Diagnostic Adequacy?						
		7. Does Image Predate Review by at least 3, but no more than 6-months?						
		8. Do Images Represent Adequate Post Processing?						
		9. Do Imaging Protocols Meet All Criteria Outlined In The Matching Protocol Tab?						

MRI Image Assessment						
Reviewer Initials	_____	**Date**	_____	**Click for Protocol drop down list**		
Facility ID#	_____	**Image ID#**	_____		**Pass**	**Fail**
					Yes	**No**
1. Image Data Set Appropriate?						
2. Are Patient Identifying Informations Adequate?						
Medical Record Number						
Date of Birth						
Gender of Patient						
Name of Institution						
Date and Time of Examination						
Equipment Type						
3. Is Data Set From an Actual Patient?						
4. Geometric Accuracy						
5. High-Contrast Spatial Resolution						
6. Low-Contrast Detectability						
7. Existence of Artifacts						
8. Signal Uniformity						
9. Abnormality Imaged Adequately for Diagnosis						
10. Sufficient Diagnostic Notes Included to Determine Diagnostic Adequacy?						
11. Does Image Predate Review by at least 3, but no more than 6-months?						
12. Do Images Represent Adequate Post Processing?						
13. Do Imaging Protocols Meet All Criteria Outlined In The Matching Protocol Tab?						

Nuclear Medicine Image Assessment							
	Reviewer Initials	_____	**Date**	_____	**Click for Protocol drop down list**		
	Facility ID#	_____	**Image ID#**	_____		**Pass**	**Fail**
						Yes	**No**
	1. Image Data Set Appropriate?						
	2. Are Patient Identifying Informations Adequate?						
	Medical Record Number						
	Date of Birth						
	Gender of Patient						
	Name of Institution						
	Date and Time of Examination						
	Equipment Type						
	3. Is Data Set From an Actual Patient?						
	4. Extrinsic Uniformity						
	5. Extrinsic Spatial Resolution						
	6. System Alignment from the Center of Rotation						
	7. Abnormality Imaged Adequately for Diagnosis						
	8. Sufficient Diagnostic Notes Included to Determine Diagnostic Adequacy?						
	9. Does Image Predate Review by at least 3, but no more than 6-months?						
	10. Do Images Represent Adequate Post Processing?						
	11. Do Imaging Protocols Meet All Criteria Outlined In The Matching Protocol Tab?						

Appendix F: On- Site Audit Checklist

General Facility information	Name Address	
	Accredited Modalities /Serial Numbers (Console and Gantry) CT MRI PET SPECT	
Regulatory	**5.3.1 Compliance program** that monitors federal and state regulatory requirements. NRC license, if applicable	
	State inspection	
Personnel	**3.2.5 The *imaging provider*** must submit policies and procedures supporting its credentialing policies, addressing all of the elements listed above in Standard 3.2	

	Medical Director Qualifications
	- State license
	- Copy of Board Certification
	- 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
	- 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	

	Medical Imaging Technologist Qualifications
	- ARRT, ARMRIT or NMTCB Certification
	- Copy of state license (if applicable)
	- Copy of BCLS/ACLS certification (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 and/or certifications (if applicable)	
	Medical Physicist Qualifications - Evidence of relationship with facility (ie: 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)	
	Radiation Safety Officer (RSO) - Job description - Job title - Description of job responsibilities - Minimum qualifications of education, training and professional experience - Appropriate licensure or certification requirements	
Policies	5.1.3 **The *imaging provider*** shall maintain and comply with written policies and procedures that govern the key elements of its clinical and business operations. 5.1.4 **Specifically, the *imaging provider* shall**: 5.1.2.4 Maintain a master list of all policies and procedures; 5.1.2.5 Update all policies and procedures with effective dates, including the date of the most recent revision; and 5.1.2.6 Have all clinical policies and procedures reviewed and signed off by both the *medical director* and *imaging manager* at least annually.	

	2.1.5 Imaging Systems Policy - Any policy describing Imaging Provider's Imaging System maintenance program - QC logs of all imaging systems - Verify policies are reviewed at least annually and more frequently if needed	
	5.2.1 Clinical Policies - A clinical policy is any document that describes in detail the process for performing an imaging scan on a patient. These documents may include step by step instructions or a general policy and procedure to be followed by the imaging provider while conducting a scan. - Samples of current Clinical Policies used by the Imaging Provider - Verify policies are reviewed at least annually and more frequently if needed - Documentation of peer review of policies	
	6.1.1 Quality Assurance Program – a program/policy that ensures each *imaging provider* has a structured approach to reviewing its processes so its business and clinical decisions promote operational integrity, clinical efficacy, and *patient* safety. - Any QA policy and procedure. This may include policies that require the imaging provider to: - Operates according to written policies and procedures that are reviewed annually by the *medical director/supervising physician*; - Be overseen by a quality assurance committee or another formal committee of the *imaging provider* that includes participation by the *medical director/supervising physician*; - 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/or mobile) and updates policies and procedures; - Help identify, implement and benchmark clinical policies; and - Help ensure compliance with other quality requirements including the MAP Standards.	
	6.2.1 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 a *radiation safety officer (RSO)* 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 including a crash cart or other life-sustaining measures; - Requires an ACLS certified individual to be present, and continuously monitor a patient undergoing IV contrast or 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.	

	6.2.2 Mental Health Policy - The Facilities 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 **6.2.3 Drug abuse Policy** - The Facilities 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	
	3.2.1 Credentialing Policy - Any Policy Verifying the current credentials of all *imaging practitioners* through primary and secondary source verification upon hire and reviewed at least annually, including current *license*(s) or *credentials*, and history of licensure in all jurisdictions in which the practitioners has credentials;	
	6.3.1 Medical Imaging Policy includes the following - The actual presence of qualified medical staff when a contrast medium is used or sedation is required for a *patient*; - 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.	
	Logs - 5.2.1 and 6.2.1 Training logs for all staff members - 5.4.1 Log of complaints/grievances and resolution	

	5.5.1 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; and - Use and update periodically an image retention manual	

Appendix G: 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 providers. The RadSite Standards Committee, a team of national experts in their respective fields, meets regularly to review current best-practice, 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