



RadSite™

Accreditation Reinvented

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

Version 1.3

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



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**Cone Beam CT
Advanced Diagnostic Imaging (ADI) Accreditation Program:
Standards and Guide v 1.3**

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Consolidated ADI Accreditation Program Standards and Guide

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Contents

<i>About RadSite</i>	3
RadSite’s ADI Accreditation Program	4
ADI Specialty Imaging.....	4
Why RadSite?.....	5
The Application Process.....	6
Appeals Process	12
Audits and Surveys	14
Notification Requirements	16
<i>Definitions</i>	17
<i>Section I: Imaging Supplier Information</i>	26
Standard 1.1 – Organizational Information	26
Standard 1.2 – Imaging Supplier Specialty	27
Standard 1.3 – Imaging Facility Requirements	28
Standard 1.4 – Non-Imaging System Requirements	28
Standard 1.5 – Mobile Imaging Requirements.....	29
<i>Section II: Imaging Systems</i>	31
Standard 2.1 – Imaging System Requirements.....	31
Standard 2.2 – Cone Beam CT Imaging System Requirements	31
Standard 2.3 – Regulatory Requirements and Testing Protocols	31
<i>Section III: Professional Qualifications</i>	34
Standard 3.1 – General Staffing Requirements	34
Standard 3.2 – Credentialing of Professional Licensure and Qualifications	35
Standard 3.3 – Medical/Clinical Director Qualifications	36
Standard 3.4 – Interpreting Practitioner Qualifications	40
Standard 3.5 – Imaging Technologist Qualifications	46
Standard 3.6 – Imaging Manager Qualifications.....	49
Standard 3.7 – Medical Physicist Qualifications.....	50
Standard 3.8 – Imaging Safety Officer Qualifications	50
<i>Section IV: Professional Oversight</i>	52
Standard 4.1 – Medical/Clinical Director Responsibilities	52
Standard 4.2 – Interpreting Practitioner Responsibilities	53
Standard 4.3 – Imaging Technologist Responsibilities	54
Standard 4.4 – Imaging Manager Responsibilities	55
Standard 4.5 – Medical Physicist Responsibilities	56
Standard 4.6 – Imaging Safety Officer Responsibilities	56
<i>Section V: Policies and Procedures</i>	59
Standard 5.1 – Policies and Procedures.....	59
Standard 5.2 – Regulatory Compliance Program	60
Standard 5.3 – Complaint Resolution Process	60
Standard 5.4 – Storage Requirements	61
<i>Section VI: Quality and Patient Safety</i>	63
Standard 6.1 – Quality Assurance Program	63
Standard 6.2 – Patient and Personnel Safety Program	66
Standard 6.3 – Medical Imaging Policies.....	70

Standard 6.4 – Patient Access	71
Standard 6.5 – Patient Confidentiality.....	71
Standard 6.6 – Financial Integrity	72
<i>Section VII: Technical Quality</i>	<i>73</i>
Standard 7.1 – General Requirements.....	73
Standard 7.2 – Cone Beam CT Physics Evaluation.....	76
Standard 7.3 – Cone Beam CT Image Quality Evaluation.....	78
Standard 7.4 – Corrective Action for Imaging System Deficiencies.....	81
<i>Appendix A: Acronyms</i>	<i>83</i>
<i>Appendix B: Time Frame Summary.....</i>	<i>85</i>
<i>Appendix C: On-Site Audit Checklist.....</i>	<i>87</i>
<i>Appendix D: Technical References.....</i>	<i>97</i>

About RadSite

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

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

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

RadSite’s offices are located in Annapolis, MD.

RadSite's ADI Accreditation Program

RadSite has earned the reputation of offering an innovative and cost-effective choice for imaging accreditation. RadSite's Advanced Diagnostic Imaging (ADI) Accreditation Programs are made up of six (6) different standards covering:

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

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

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

ADI Specialty Imaging

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

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

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

RadSite designates the following ADI clinical specialty modules as follows:

Table 1: RadSite ADI Clinical Specialty Modules
(Updated October 2024)

Computed Tomography	Magnetic Resonance Imaging	Nuclear Medicine
<p>Conventional CT</p> <ul style="list-style-type: none"> • Angiography • Body • Cardiac • Coronary Calcium Scoring • Maxillofacial • Musculoskeletal • Neurologic <p>CBCT</p> <ul style="list-style-type: none"> • Breast • Dental • ENT • Maxillofacial • Musculoskeletal <ul style="list-style-type: none"> ○ Chiropractic ○ Orthopedics ○ Podiatry 	<p>MRI</p> <ul style="list-style-type: none"> • Angiography • Body • Breast • Cardiac • Functional • Musculoskeletal • Neurologic 	<p>Planar, SPECT, or SPECT/CT</p> <ul style="list-style-type: none"> • Body • Cardiac <p>PET or PET/CT</p> <ul style="list-style-type: none"> • Cardiac • Inflammation (Infection) • Neurologic • Oncology

Why RadSite?

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

- Is governed by a volunteer committee system comprised of a wide range of stakeholder groups to promote accountability and transparency.
- Uses an evidence-based approach to promote best practices for imaging systems.
- Leverages an experienced leadership team that has brought to market over 25 healthcare accreditation programs during the past 25 years.
- Develops standards that are subject to external peer review, which includes a formal standards' review process, beta testing, and inter-rater reliability assessments.

- Streamlines the application process by using a secure online accreditation portal that can be configured to pre-populate fields for streamlined data entry.
- Offers a competitive pricing structure, with discounts available for multiple imaging systems and rural locations.
- Is approved by CMS and over 350 private payers for reimbursement purposes; and,
- Incorporates third-party feedback in the design and operations of its accreditation processes.

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

The Application Process

1. Steps Prior to Submitting the Application

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

2. Steps of the Application Process

- Fill out the online application.
- Collect additional information as requested via the online accreditation portal based on the ADI Standards.

- Submit clinical, phantom, and test-object images, along with other documents, via RadSite's upload utility.

Here are a couple additional helpful notes:

- If the operations of an applicant's imaging system or imaging facility do not apply to a particular standard, the applicant should record "N/A" for "not applicable."
- Each applicant must take precautions to safeguard any Protected Health Information (PHI) or other confidential information that is sent to RadSite. RadSite does not request PHI during the application process. For example, each applicant can use RadSite's cloud-based utility to anonymize its images when uploading. If they do not utilize this function, applicants should de-identify the images before submission. Applicants are encouraged to contact their account manager if they need additional information on recommended HIPAA and confidentiality protocols and how to best send information to RadSite.
- Throughout the application process, RadSite customer service representatives are available to assist with any questions. Representatives can be reached at [\(443\) 440-6007](tel:443-440-6007) from 8 a.m. to 4 p.m. ET.

3. Steps After Submission of the Application:

- a. A RadSite accreditation coordinator will contact the applicant to verify the scope of the applicant's imaging practice and review the process.
- b. Additional documents will be sent to the applicant to complete the application process.

4. Information to be Submitted with the Application

Image Study Submission Requirements:

- Each applicant must submit a minimum of three exams for each ADI system under review, and a fourth study if 2% or more of the total caseload of exams are pediatric. See Table 2 for the total number of exams that need to be submitted depending on the number of specialty modules that are part of the application. A complete explanation of the clinical image requirements is provided for each modality in Section VII.
- Each image study must be of an actual patient imaged on the applicable ADI system within six months prior to the submission of the accreditation application.
 - The image studies must include the facility's protocol for that examination and the corresponding clinical report.
 - The goal is to receive a representative sample of the types of exams the imaging supplier completes as part of its general practice, and if applicable, for each specialty module.

- For Cone Beam CT ADI accreditation:
 - Each applicant must submit three image exams for each ADI system under review for the first specialty area.
 - If 2% or more of the total caseload of exams are pediatric, one additional image study must be submitted with a patient who is between 0 and 15 years of age.
- For each additional clinical Cone Beam CT specialty designation for the same ADI imaging system:
 - The applicant must submit two image exams in that specialty area. Each study should be a different type of exam within the designated specialty.
 - If 2% or more of the total caseload of image exams are pediatric for each applicable specialty area, an additional image exam must be submitted with a patient who is between 0 and 15 years of age.
 - Note: For Cone Beam CT imaging systems, most are only used for one specialty area with the exception of Dental/Maxillofacial. So typically, each Cone Beam CT imaging system that is undergoing an accreditation review will need to submit three studies with the applicable reports. Check with RadSite to identify the scope of the accreditation application if more than one specialty area is covered by the Cone Beam imaging system.
- For any of the image reviews, RadSite reserves the right to have an applicant submit additional studies to ensure a representative sample is being scored pursuant to Section VII for Technical Quality. **Table 2** summarizes the study submission requirements:

Table 2: Study Submission Requirements (Revised October 2024)		
SPECIALTY AREAS	SUBMISSION REQUIREMENT DETAILS	
General		Total # of Studies
ADI Accreditation with No Specialties	Submit three studies which represent the scanning patterns for the imaging system	3
One Specialty Module	Submit two studies for the specialty module and one additional which represents the scanning patterns for the imaging system	3
Two Specialty Modules	Submit two studies for each specialty module	4

Three Specialty Modules	Submit one study for each specialty module and one additional which represents the scanning patterns for the imaging system	4
Four Specialty Modules	Submit one study for each specialty module	4
Five or more Specialty Modules	Submit one study for each additional specialty module	+1

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

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

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

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

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

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

6. **Request for More Information**

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

- If a request for more information is made, RadSite will have up to 90 days from the date of the request to make an accreditation decision.

7. Audit of Applicants

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

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

8. The Application Review Process

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

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

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

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

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

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

RadSite will notify each applicant in writing of its decision.

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

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

- CT ADI Accreditation
- MRI ADI Accreditation
- NucMed ADI Accreditation
- Dental Cone Beam CT ADI Accreditation
- Medical Cone Beam CT ADI Accreditation

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

9. Accreditation Determinations

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

- **Failure**
 - The applicant fails to meet the criteria to achieve full accreditation.
 - The applicant fails to improve its score sufficiently after a corrective action period.
 - The applicant will receive a written summary report and “Notice of Failure” statement that identifies the reasons for failure.

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

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

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

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

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

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

Appeals Process

Each applicant has two levels of appeal:

- **Reconsideration (level 1)**
 - The applicant can request a reconsideration of an initial adverse accreditation determination.
 - The applicant’s request for reconsideration must be made in writing and submitted within 30 days of the applicant’s receipt of the “Notice of Failure” or other adverse determination.
 - The applicant’s written request for reconsideration must include an explanation of the basis for the request and any relevant documentation that supports the request for reconsideration of the adverse decision.

- RadSite will rule on the applicant's requests for reconsideration within 30 days.
- **Appeal (level 2)**
 - If the applicant is not satisfied with the reconsideration decision made by the Accreditation Committee, the applicant may file an appeal.
 - The appeal can be filed with the RadSite Advisory Board within 45 days of the applicant's receipt of the adverse reconsideration decision.
 - RadSite's Advisory Board will rule on the appeal within 45 days.
 - The decision of the Advisory Board is the final determination and is not subject to further appeal within the RadSite organization.

Audits and Surveys

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

Table 3: Accredited Supplier Audit Overview	
Audit Frequency	<p>RadSite will perform an unannounced audit of randomly selected accredited imaging suppliers during the three-year accreditation period to ensure compliance with RadSite Standards.</p> <p>The imaging suppliers to be audited each year are randomly selected.</p>
Types of Audits	<p>RadSite performs 3 types of audits of its accredited suppliers:</p> <ol style="list-style-type: none"> 1. Desk audits 2. Virtual audits 3. On-site audits
Desktop Audits	<p>A desktop audit consists of review of documents and imaging studies submitted to RadSite from randomly selected accredited imaging suppliers. Additional documentation typically is required to ensure certain elements of the RadSite standards are being implemented by the imaging supplier.</p> <p>Expenses: RadSite will cover the labor costs of any additional desktop audits. However, it is the responsibility of the imaging supplier to cover the costs of submitting any additional materials or information requested.</p>
Virtual Audits	<p>A virtual audit consists of a virtual meeting between the RadSite and imaging facility staff via means such as Zoom, GoToMeeting, or WebEx. During the virtual meeting, the RadSite staff will request documents for review and discuss issues with the facility.</p> <p>Virtual audits cannot be completely unannounced because arrangements must be made to set up the required technology. While the virtual audit call needs to be scheduled in advance, no agenda will be provided, and documents will not be requested until the time of the meeting.</p> <p>Expenses: RadSite will not charge an imaging supplier any additional fees for a virtual audit.</p>
On-site Audits	<p>An on-site audit consists of an unannounced visit to a randomly selected accredited imaging supplier. This means that RadSite will arrive at the selected imaging facility for an on-site audit without providing any prior notification to the imaging supplier.</p>

	<p>Expenses: RadSite will not charge an imaging supplier any additional fees for an on-site audit.</p>
<p>Complaint (For-Cause) Audits of Accredited Imaging Suppliers</p>	<p>Description: If a complaint against an accredited imaging supplier is filed with RadSite or referred by a regulator or other third party, and RadSite determines that the complaint merits further investigation, RadSite shall initiate a site audit of such accredited imaging supplier.</p> <p>If RadSite determines a complaint or issue involves a serious patient safety concern (including, but not limited to, situations where the safety concern poses an immediate jeopardy to the accredited imaging supplier’s patients or a hazard to the general public), RadSite is obligated to initiate an audit without providing any advance notification to the accredited imaging supplier.</p> <p>Expenses: If a complaint (for cause) on-site audit is conducted and the complaint against the accredited imaging supplier is validated, the accredited imaging supplier will pay RadSite fees of \$1,000 per diem charge plus reasonable travel costs, but no more than \$2,500.</p>
<p>Corrective Action Plan</p>	<p>Depending on the specific deficiencies (if any), that arise during an audit, RadSite reserves the right to:</p> <ol style="list-style-type: none"> 1. Create and enforce a Corrective Action Plan; and 2. Revoke or suspend the accreditation as it relates to the imaging supplier, a designated ADI service or imaging system. <p>Per the specifications of the Corrective Action Plan, RadSite will monitor the remediation efforts of the accredited imaging supplier.</p> <p>If the deficiencies continue, the RadSite Accreditation Committee may revoke or suspend the accreditation as it relates to the imaging supplier, a designated ADI service or imaging system.</p> <p>Accredited imaging suppliers retain the right to appeal any adverse determination under these circumstances.</p> <p>As appropriate, RadSite will notify CMS and other relevant state or federal agencies regarding the deficiencies and any changes in accreditation status.</p>
<p>Third-Party Notifications</p>	<p>RadSite reserves the right to notify federal, state and local authorities, at any time, if RadSite determines that a malfunctioning imaging system poses a serious patient safety concern (including, but not limited to, situations where the safety concern poses an immediate jeopardy to the accredited imaging supplier’s patients or a hazard to the general public).</p>

Notification Requirements

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

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

Applicants must notify RadSite:

- Within fourteen (14) days of any business operation “material” change to its business operations that impact the scope of the ADI accreditation, such as revisions or alterations in the company name, address, and ownership or the moving of a facility.
- Within two (2) days of any business operation “adverse change” to its business operations, such as filing for bankruptcy, loss or restriction of business license, no longer providing ADI radiological services, or being sued.
- Within two (2) days of any issues impacting patient safety such as where the safety concern poses an immediate jeopardy to the accredited imaging supplier’s patients or a hazard to the general public.

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

See also definition for medical director.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

See also definition for clinical director.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

See also definition for supervising practitioner.

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

- Dental Cone Beam CT ADI Accreditation, version 1.2; and
- Medical Cone Beam CT ADI Accreditation, version 1.2

(See also supervising physician)

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

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

- Referring patients to fill in the time slots without the appropriate medical necessity.
- Billing Medicare or another payer as if the provider “owns” the imaging equipment under the “Group Practice Exemption.”
- Any other use of a slot-leasing arrangement that is not in the patient’s best interest.

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

Section I: Imaging Supplier Information

Standard 1.1 – Organizational Information

- 1.1.1 **Background.** The imaging supplier shall provide background information including:
- A. Location of imaging supplier’s main office or corporate headquarters;
 - B. Location of all imaging facilities (and for the ADI mobile systems, identify the facilities serviced by each imaging system and list each facility that bills separately for the use of the mobile ADI system);
 - C. Identification of all imaging systems at each imaging facility;
 - D. Identification of all imaging systems that are being excluded from the ADI accreditation application; and
 - E. National provider identifier (NPI) numbers and other information for all healthcare providers who are using the imaging systems for ADI services at each location and are billing CMS for those services.
- 1.1.2 **Scope of Services.** The imaging supplier shall also provide additional background information regarding the imaging supplier’s scope of services in regard to:
- A. The clinical setting of each imaging facility, including:
 - i. Identification of key clinical personnel;
 - ii. A physician or practitioner’s specialty areas;
 - iii. Freestanding radiology facilities;
 - iv. Other practitioners that provide ADI service who are paid under the fee schedule established under section 1848(b) of the Social Security Act.
 - B. Patient and general populations served; and
 - C. Any additional imaging services that are not within the scope of ADI services, such as:
 - i. x-rays;
 - ii. fluoroscopy;
 - iii. ultrasounds;
 - iv. mammograms

Further Explanation

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

Document Submission

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

Standard 1.2 – Imaging Supplier Specialty

- 1.2.1 **Scope of Practice.** If the imaging supplier specializes in providing certain types of imaging services, the imaging supplier shall:
- A. Provide documentation demonstrating that its staff, physicians and non-physician practitioners follow evidence-based medical guidelines in the appropriate diagnostic uses of these services;
 - B. Describe the necessary expertise in administering these services and interpreting the images produced or have contracted with a third-party with the necessary expertise to do so; and
 - C. Ensure their scope of practice and imaging practices are permissible under federal, state and local regulations.
- 1.2.2 **Qualifications.** The imaging supplier shall comply with the experience and education requirements set forth in Section III and the exam submission requirements set forth in Section VII.

Further Explanation

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

Standard 1.3 – Imaging Facility Requirements

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

Further Explanation

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

Standard 1.4 – Non-Imaging System Requirements

- 1.4.1 The imaging supplier's non-imaging systems shall:
- A. Meet manufacturer's safety recommendations and procedures;
 - B. Meet all federal, state and local regulations;
 - C. Meet or exceed all non-safety manufacturer recommendations;
 - D. Conduct regular inspections which are scheduled and performed at least annually or per the manufacturer's specifications, whichever is shorter;
 - E. Keep service and maintenance records up to date; and
 - F. Perform periodic quality control testing.

Further Explanation

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

Standard 1.5 – Mobile Imaging Requirements

- 1.5.1 **General Requirements.** The imaging supplier shall provide information on all mobile imaging systems that demonstrate the proper installation, use and maintenance according to manufacturer recommendations, as well as compliance with all federal, state and local requirements.
- 1.5.2 **Leasing.** If the imaging supplier leases the mobile imaging system(s), the imaging supplier shall have a written agreement with the owner of the mobile imaging system(s) that:
- A. Sets the terms for use of the mobile imaging system(s) by the provider (Lessee);
 - B. Ensures continuity of services;
 - C. Permits all applicable standards and regulatory requirements to be met; and
 - D. Allows the imaging supplier to audit all aspects of the mobile imaging system operations in an appropriate and timely manner.
- 1.5.3 **Safety Protocols.** The imaging supplier shall follow the same safety procedures when using mobile imaging systems as it does with stationary imaging systems, as well as additional pertinent requirements associated with the mobile imaging system's relocation abilities and frequencies. This includes but is not limited to these items:
- A. Implementing quality control procedures at each new location to set up and run operations, including procedures to address safe power hook up, machine recalibration and temperature monitoring;
 - B. Using properly licensed and professional staff necessary to support proper use, as defined below in Sections III and IV;
 - C. Ensuring appropriate cleaning of the mobile imaging system including an infection control program;
 - D. Implementing patient safety policies and procedures for handling medical emergencies and urgencies along with necessary basic and advanced first aide equipment including immediate access to a crash/code cart, along with a direct communication link to handle resuscitations and other life-sustaining measures; and

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

Further Explanation

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

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

Section II: Imaging Systems

Standard 2.1 – Imaging System Requirements

- 2.1.1 For each ADI imaging system, the imaging supplier shall:
- A. Provide information which demonstrates the proper installation, calibration, use, maintenance and troubleshooting in accordance to manufacturer recommendations and in compliance with all federal, state and local requirements;
 - B. Demonstrate that the imaging supplier meets the applicable manufacturer’s recommendations for quality control testing as further defined in Section VII; and
 - C. Conduct regular inspections which are scheduled and performed at least annually or per the manufacturer’s specifications, whichever is shorter.

Standard 2.2 –Cone Beam CT Imaging System Requirements

- 2.2.1 **General System Requirements.** For Cone Beam CT imaging systems (if applicable), the imaging supplier shall monitor the following quality and performance control factors pursuant to Section VII:
- A. Quality control program (e.g., routine calibrations and service);
 - B. Reconstructed slice thickness;
 - C. High contrast (spatial) resolution;
 - D. Low contrast resolution;
 - E. Noise level;
 - F. Artifact-free status; and
 - G. CT number accuracy and linearity.

Standard 2.3 – Regulatory Requirements and Testing Protocols

- 2.5.1 **General Requirements.** The imaging supplier must ensure and demonstrate that all ADI imaging systems:
- A. Meet all federal, state and local requirements as required by law; and
 - B. Implement a routine maintenance and operation plan that includes:
 - i. Regularly scheduled annual inspections,

- ii. Appropriate cleaning and disinfecting of medical and imaging equipment after each patient,
- iii. Preventive maintenance in accordance with the manufacturer's recommendations or at least every 3 months (whichever is shorter),
- iv. Maintaining a record of all service performed on each ADI imaging system and its components
- v. Safe power hook-up,
- vi. Machine recalibration, and
- vii. Temperature monitoring.

Document Submission

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

- 1) A policy describing each facility's imaging system maintenance program.
- 2) A written narrative explaining the imaging supplier's existing approach to its quality control program. The purpose of this requirement is to ensure that imaging suppliers provide safe and appropriate Cone Beam CT services to their patients.

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

Further Explanation

The intent of this standard is to ensure imaging systems at each location are installed, operated, and maintained according to the requirements of the manufacturer as well as from federal, state and local government agencies. RadSite requests imaging suppliers to provide specific information related to each ADI imaging system at each site, including:

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

- The medical physicist report.
- Cone Beam CT additional requirements:
 - Presence of metal suppression capabilities.
 - The vendor specific QC or user manual which describes the expected QC and values.

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

Section III: Professional Qualifications

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

Standard 3.1 – General Staffing Requirements

3.1.1 The imaging supplier shall:

- A. Maintain an employee manual that is reviewed and updated at least annually and distributed to staff;
- B. Implement a grievance process for employees;
- C. Maintain written job descriptions for all staff members involved in the delivery of the technical component of ADI services, which, at a minimum, provides the following information:
 - i. Job title,
 - ii. Description of job responsibilities,
 - iii. Minimum qualifications for education, training and professional experience,
 - iv. Appropriate licensure or certification requirements, and
 - v. Identification of supervisor or otherwise reference reporting responsibilities; and
- D. Maintain personnel files for each employee and all applicable credentialing information for professional staff, with said files being kept in a secured location with restricted access to the appropriate management staff only.

Further Explanation

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

Standard 3.2 – Credentialing of Professional Licensure and Qualifications

- 3.2.1 **General Requirements.** The imaging supplier shall ensure that all imaging practitioners are qualified to carry out their respective job functions by verifying the current credentials of all imaging practitioners through primary and secondary source verification upon hire, including current license(s) or credentials and history of licensure in all jurisdictions in which the practitioners have credentials in addition to the other requirements detailed in this Standard.
- 3.2.2. **Credentialing Elements.** The imaging supplier’s credentialing verification program shall include the following elements:
- A. **General.** History of education, professional training, licensure, certifications, board certification status, and history of professional complaints, disciplinary actions, sanctions, and license suspensions;
 - B. **Primary Source.** Primary verification of credentials from granting institutions covering state licensing boards, specialty certification boards (if applicable), and the highest level of education; and
 - C. **Secondary Source.** Secondary verification of:
 - i. Credentials from societies, professional organizations, or trade organizations,
 - ii. Work history for a minimum of the last five years (or since last credentialed by the organization),
 - iii. Review of professional liability claims,
 - iv. Review of grievances history,
 - v. Review of history of disciplinary actions, sanctions, admonishments, and penalties imposed by any agencies such as, but not limited to, hospitals, licensing boards, and government entities,
 - vi. Valid and current Drug Enforcement Agency (DEA) certificate or state-controlled substance certificate, if applicable,
 - vii. Proof of professional liability insurance, ability to self-insure, or other coverage as required by the state, if applicable, and
 - viii. Current hospital affiliations or privileges, if applicable.

- 3.2.3 **Ongoing and Re-Credentialing Requirements.** The imaging supplier shall include in its credentialing program:
- A. Review of the licenses and credentials of all imaging practitioners at least once every three years, or more often as appropriate;
 - B. Implementation of corrective actions in response to adverse changes in certification, licensure or status;
 - C. Notification of the applicable authorities of any material changes in licensure or certification status of all imaging personnel within 30 days of such changes; and
 - D. Notification to RadSite of any material changes in licensure or certification status of the medical/clinical director or supervising physician within 30 days of such changes.

Further Explanation

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

Document Submission

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

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

Standard 3.3 – Medical/Clinical Director Qualifications

- 3.3.1 **General Requirements.** The imaging supplier shall employ or contract with one or more medical/clinical directors who:
- A. Are responsible for the clinical oversight of the imaging supplier, its imaging facilities, and its Cone Beam CT imaging services;
 - B. Have a current, unrestricted license to practice medicine within the state in which the imaging facility is located;

- i. If working at imaging facilities in multiple states, the medical or clinical director is required to have multiple current, unrestricted licenses in each of those jurisdictions.
- ii. If the license of the medical or clinical director is restricted, the imaging supplier must have a process to ensure job functions do not violate the restrictions imposed by the applicable state board(s)];

C. Meet one of the following requirements:

- i. Board-certified or board-eligible in radiology by a recognized specialty group in radiology (e.g., American Board of Radiology and American Osteopathic Board of Radiology);
- ii. Board-certified or board-eligible in radiology by a recognized specialty group in radiology (e.g., American Board of Radiology in a related specialty with documentation of supervised training in the interpretation and reporting of imaging examinations; or
- iii. Completed a recognized training program in the interpretation and reporting of imaging examinations when using a third-party radiologist to interpret or complete overreads of the ADI studies.

D. Meet the following requirements:

- i. Meet the baseline education and experience requirements of an interpreting physician or practitioner for the applicable specialty areas of the imaging supplier practice,
- ii. Possess continuing experience as documented from interpretation and reporting of examinations, and
- iii. Maintain continuing education as required by medical licensing and board certification.

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

3.3.3 **Additional Professional Requirements for Cone Beam CT**

- A. **Professional Certification.** The imaging supplier shall employ or contract with one or more medical/clinical directors (or supervising physicians/practitioners) who maintain professional certifications as required by licensing bodies and specialty organizations. The medical/clinical director can meet this requirement by either being board certified or board eligible by the American Board of Radiology or the American Osteopathic Board of Radiology, or by meeting one of the following specialty certification organizations as applicable to the scope of practice:
 - i. Dental/maxillofacial specialty organizations: Dental certification may be obtained from one of the following: the American Dental Association (ADA), the American Board of Endodontics, American Association of Orthodontics, Academy of General Dentistry,

American Academy of Cosmetic Dentistry, American Academy of Oral Maxillofacial Radiology, American Association of Endodontists, American Academy of Periodontology, American Board of Pediatric Dentistry.

- ii. ENT specialty organizations: Board certification may be obtained from one of the following: (a) American Board of Medical Specialties (ABMS), or (b) American Osteopathic Association, or (c) American Board of Otolaryngology.
 - iii. Orthopedic specialty organizations: Board certification may be obtained from one of the following: (a) American Board of Medical Specialties (ABMS) or (b) American Osteopathic Association.
 - iv. Chiropractor specialty organizations: Board certification may be obtained from one of the following: (a) Academy of Chiropractic Orthopedists (ACO); (b) American Chiropractic Board of Diagnosis and Internal Disorders (ABCI); (c) American Chiropractic Board of Neurology (ACAN); (d) American Chiropractic Board of Radiology (ACBR); (e) American Chiropractic Board of Rehabilitation (ACBR); (F) American Board of Chiropractic Specialties (ABCS); and (g) National Board of Chiropractic Examiners (NBCE).
 - v. Podiatry specialty organizations: Board certification may be obtained from one of the following (a) American Board of Medical Specialties (ABMS), (b) American Board of Podiatric Medicine (ABPM), (c) American Board of Podiatric Surgery (ABPS) in a relevant specialty, (d) the American Podiatric Medical Association (APMA), (e) the American Board of Multiple Specialties in Podiatry (ABMSP) or (f) or another certification body recognized by RadSite.
 - vi. Breast imaging specialty organizations: Board certification may be obtained from the American Board of Medical Specialties (ABMS).
- B. *Additional Qualification Requirement.*** The medical/clinical director (or supervising physician/practitioner) shall meet one of the following requirements:
- i. Qualification by training: Completed training in a subspecialty of dentistry, or medicine which includes training in advanced diagnostic imaging and Cone Beam CT:
 - a) This training shall include participation in one or more training program(s) or courses provided by a professional society or a recognized vendor, and
 - b) Documentation of the required training must be provided to the imaging supplier's credentialing, human resources or other applicable department.
 - ii. Qualification by experience:
 - a) Be a physician with at least two years of experience in interpreting CT studies and at least 15 hours of continuing education training related to CT, including at least six hours of training in radiation safety, and

- b) Demonstrate interpretation of at least 120 Cone Beam CT studies.
 - iii. Qualification by board eligibility: Be board-certified or board-eligible in radiology by a recognized radiology specialty group (i.e., American Academy of Oral and Maxillofacial Radiology, American Board of Radiology, or American Osteopathic Board of Radiology).
- C. **Additional Training Parameters.** For purposes of meeting this standard, the training may include CME/CE/CDE courses and manufacturer-directed courses related to CT or Cone Beam CT imaging, which shall meet the following parameters:
- i. The CME/CE/CDE training must be from an organization recognized by RadSite,
 - ii. At least three hours of CME/CE/CDE training must be related to radiobiology/radiation safety,
 - iii. The minimum training requirement for each Cone Beam CT specialty for the interpretation of studies are as follows:
 - a) *Dental/maxillofacial requirements*: 12 hours of CE/CDE's from the American Dental Association Continuing Education Recognition Program (ADA CERP) or the Academy of General Dentistry Program for Continuing Education (AGD PACE).
 - b) *Chiropractor requirements*: 12 hours of Category I CME relative to chiropractic care.
 - c) *ENT requirements*: 12 hours of Category I CME relative to ENT.
 - d) *Orthopedic requirements*: 12 hours of Category I CME relative to orthopedics.
 - e) *Podiatry requirements*: 12 hours of Category I CME relative to podiatry.
 - f) *Breast imaging requirements*: 12 hours of Category I CME relative to breast imaging; and
 - iv. Training must be documented and available to RadSite on request.

Further Explanation

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

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

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

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

Notes:

- Dental Cone Beam CT only: If a dental provider does not have an option to become board certified in their field, they must qualify for an analogous specialty certification within their scope of practice.
- Contact RadSite for any new organizations that provide certifications or CME/CE/CDE instruction that are not referenced in the Standards to determine if they will be recognized by RadSite for meeting this or any other standard.

Document Submission

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

- Medical/clinical director credentials as validated by the applicant's internal credentialing program, demonstrating that the individual meets the requirements defined under Standard 3.3.
- Documentation of completion of the required continuing education studies by the medical/clinical director.

Standard 3.4 – Interpreting Practitioner Qualifications

- Cone Beam CT Imaging.** The Cone Beam CT imaging supplier shall employ or contract with one or more qualified interpreting practitioners that meet all of the following requirements:
 - Licensure.** Has a current, unrestricted license to practice dentistry or medicine for the applicable specialty areas within the state of the imaging supplier's location, or multiple current, unrestricted licenses if required by federal, state or local regulations or by other practice requirements (or if the license is restricted, the imaging supplier has a process to ensure job functions do not violate the restrictions imposed by the State Board);
 - Board Certification.** Meets the following requirements:

- i. Board certification or eligibility in radiology by a recognized specialty group in radiology (e.g., American Board of Radiology and American Osteopathic Board of Radiology), or Board certification or eligibility in an applicable specialty area with documentation of supervised training in the interpretation and reporting of imaging examinations,
 - ii. Has continuing, documented experience in the interpretation and reporting of examinations; and
 - iii. Maintains continuing education as required by licensing and board certification;
- C. **Residency.** Completion of an accredited residency program in the applicable specialty area;
- D. **Training/Experience.** The interpreting practitioner shall meet the following requirements:
- i. **Baseline Education Requirements:** Additional baseline education requirements for each Cone Beam CT specialty:
 - 1) Dental/maxillofacial requirements: A dentist, maxillofacial surgeon or medical provider who has acquired at least 150 hours of CME/CE/CDE's or the equivalent which track their imaging practice patterns,
 - 2) ENT, orthopedic, chiropractor, podiatry or breast imaging requirements: A practitioner who has acquired at least 150 hours of Category I CME/CE's or the equivalent which tracks their imaging practice patterns,
 - 3) In terms of IV contrast and conscious sedation of a patient, the interpreting practitioner must be properly trained and meet all state regulatory requirements, and
 - 4) Additional baseline training topics: Training shall include the following components as applied to the specific scope of practice:
 - 1) Normal CT anatomy,
 - 2) Review of common pathology on CT,
 - 3) Principles of CT image quality analysis,
 - 4) Radiation dose reduction strategies and impact on image quality,
 - 5) Instruction on protection of patients' eyes and other applicable anatomy,
 - 6) Requirements for a comprehensive CT report,
 - 7) Understanding CT artifacts,
 - 8) Patient communication requirements (including critical and unexpected results); and

- ii. Baseline Experience Requirement:
 - a) Interpreting at least 100 Cone Beam CT studies for each applicable specialty module within 24-months (where the candidate is physically present and involved in the acquisition of at least 35% of the exam studies),
 - b) Being supervised by a third-party interpreting physician (or dental radiologist) who meets the experience and training requirements of RadSite’s ADI Standards for CT imaging to complete overreads for the first 50 Cone Beam CT exams,
 - c) Interpretation by the imaging provider is limited to their area of training and experience:
 - 1) *Dental example:* A dentist with training in maxillofacial imaging can interpret CT images in that specialty but should not interpret in areas outside the maxillofacial region even though the CT may cover these areas. Those interpretations should be made by a qualified imaging expert such as a radiologist, dental radiologist or other specialist with expertise in that anatomic area. Examples of this include vascular calcification within the circle of Willis or pathology of the cervical spine, which are not emphasized in the training associated with maxillofacial image interpretation.
 - 2) *Medical example:* An orthopedist with training in extremity imaging can interpret CT images in that specialty but should not interpret in areas outside those for which they are trained, even though the CT may cover these areas. Those interpretations should be made by a qualified imaging expert such as a radiologist or other specialist with expertise in that anatomic area. Examples include abdominal or thoracic images, which are not emphasized in the training associated with orthopedic imaging interpretation.
- iii. Continuing Education Requirements: Interpretation of at least 250 Cone Beam CT studies within the past 36 months; and
- iv. Continuing Experience Requirements: The interpreting practitioner must meet the continuing education requirements as follows:
 - a) As required by the applicable state dental or practitioner licensing agencies and board certification/eligibility requirements,
 - b) Additional continuing education requirements for each Cone Beam CT specialty:
 - 1) *Dental/maxillofacial requirements:* A dentist, maxillofacial surgeon or other medical practitioner must complete 90 CME/CE/CDE hours every 36 months which track that dentist’s or medical practitioner’s imaging practice patterns, or

- 2) *ENT, orthopedic, chiropractic or podiatry or breast requirements:* A physician or practitioner must complete 60 Category I CME/CE hours every 36 months which track that physician/practitioner's imaging practice patterns.

Table 4: Interpreting Cone Beam CT Interpreting Practitioner's Requirements

	Baseline Experience Requirements			Continuing Experience Requirements	
Subject Area	# of Studies	CE Hours	Certifications	# of Studies /months	CE Hours /months
General ADI Modality Requirements					
Dental	100 supervised cases within 24-month (being physically present for 35%) AND the first 50 cases must be overread by an interpreting physician (or dental radiologist) for each applicable ADI modality	150 CE/CDE/ CMEs or the equivalent tracking practice patterns	Board eligible	250/36	60/36 CE/CDE/CMEs tracking practice patterns
ENT		150 Category I CME or the equivalent tracking practice patterns	Board eligible	250/36	60/36 Category I CME tracking practice patterns
Maxillofacial		150 CE/CDE/ CMEs or the equivalent tracking practice patterns	Board eligible	250/36	60/36 CE/CDE/CMEs tracking practice patterns
Orthopedics		150 Category I CME or the equivalent tracking practice patterns	Board eligible	250/36	60/36 Category I CME tracking practice patterns
Chiropractic		150 CE/CDE/ CMEs or the equivalent tracking practice patterns	Board eligible	250/36	60/36 CE/CDE/CMEs tracking practice patterns
Podiatry		150 CE/CDE/ CMEs or the equivalent tracking practice patterns	Board eligible	250/36	90/36 CE/CDE/CMEs tracking practice patterns

Breast Imaging		150 CMEs or the equivalent tracking practice patterns	Board eligible	250/36	60/36 CE/CDE/CMEs tracking practice patterns
Note: Table 4 is not exhaustive. Read Standards for additional details.					

Further Explanation

The intent of this standard is to ensure appropriately trained, licensed, and experienced interpreting physicians / practitioners for Cone Beam CT exams are analyzing and reporting results of examinations.

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

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

To meet the traditional ADI requirements, all interpreting practitioners must be MD/DO professionals. However, some limited exceptions are allowed for non-MD/DO professionals. Pursuant to Standard 3.4.1, additional licensure, certification and education requirements are detailed to allow specific medical professionals such as a dentist, maxillofacial surgeon, chiropractor and podiatrist to read within a defined scope of practice. Any interpretation beyond the scope of practice must be read by a MD/DO professional (and for dental Cone Beam CT, a dental radiologist is also an option) that meets this Standard. All Cone Beam CT imaging suppliers are encouraged to have qualified MD/DO professionals (or dental radiologists) obtain secondary reviews of image exams as a best practice.

In terms of recent interpreting physician and practitioner graduates, they are exempt from the baseline CME/CDE/CE requirements if they have graduated in the past two years and are being actively supervised by a qualified interpreting physician (or dental radiologist).

In terms of any conscious sedation of a patient related to the dental, endodontal, maxillofacial or orthodontal imaging procedure, the attending physician or non-physician practitioner must be properly trained and meet all state regulatory requirements.

Document Submission

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

Standard 3.5 – Imaging Technologist Qualifications

3.5.1 **General Requirement.** The imaging supplier shall employ or contract with one or more Cone Beam CT imaging technologists to operate the facility's Cone Beam CT scanner.

3.5.2 **Medical Qualifications.** The Medical Cone Beam CT imaging technologist shall:

- A. Be qualified to operate a Cone Beam CT imaging system according to applicable federal, state and local regulations;
- B. Meet one of the following requirements:
 - i. Have a certification from the American Registry of Radiologic Technologists (ARRT); or
 - ii. Have completed training in a subspecialty in medicine which includes training in advanced diagnostic imaging and Cone Beam CT which shall include:
 - a) Participation in one or more training program(s) or courses provided by professional society or a recognized vendor,
 - b) Documentation of the required training must be provided to the imaging supplier's credentialing, human resource or other applicable department; and
- C. Have a current, unrestricted license, certification or registration from the state in which they practice.

3.5.3 **Dental Qualifications.** The Dental Cone Beam CT imaging technologist shall:

- A. Be qualified to operate a Cone Beam CT imaging system according to applicable federal, state and local regulations;
- B. Meet one of the following requirements:
 - i. Have a registration or certification from one of the following organizations:
 - a) The American Registry of Radiologic Technologists (ARRT),
 - b) Dental Assistant National Board (DANB)
 - c) Certified or Registered Dental Assistant (CDA/RDA),
 - d) Certified or Registered Orthodontic Assistant (COA/ROA),
- C. For dental assistants to qualify to operate a Cone Beam CT system they must satisfy the following conditions:

- i. Have a current, unrestricted license, certification or registration from the state in which they practice, or
- ii. If there is no license available for dental assistants in the state in which they practice, they must have one of the following certifications:
 - a) Dental Assisting National Board (DANB) Certification,
 - b) Certification as an orthodontic assistant with documentation of training from an accredited educational program; or
 - c) Certification as an Expanded Functional Dental Assistant; or
- iii. Have completed training in a subspecialty in medicine which includes training in advanced diagnostic imaging and Cone Beam CT:
 - a) This training shall include participation in one or more training program(s) or courses provided by a professional society or a recognized vendor, and
 - b) Documentation of the required training must be provided to the imaging supplier's credentialing, human resource or other applicable department; and
- iv. Must comply with dental board regulations for that state.

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

A. *Baseline Education Requirements*

- i. Education. Completion of at least 10 CE hours or the equivalent of education in the applicable specialty areas which includes dental, ENT, maxillofacial, musculoskeletal (including orthopedics, chiropractic and podiatry) and breast imaging (See Table 1);
- ii. Training Scope. Completed adequate training covering the CT technology and imagery which shall cover:
 - a) CT image acquisition and image processing,
 - b) Basic principles of CT technology and functionality,
 - c) Review of different CT imaging techniques,
 - d) Care for patients undergoing CT,
 - e) CT image quality analysis,
 - f) Implementation of a CT quality control program, and

- g) Knowledge of selection criteria for CT exams;
 - iii. Additional Course Work. Have completed a course in radiobiology (the branch of biology concerned with the effects of ionizing radiation on organisms) as a part of prior training, or separate from prior training, and shall supply documentation that the course has been completed;
- B. *Baseline Experience Requirements.* Performed a minimum of 25 Cone Beam CT scans within 12-months under the supervision of a person qualified to be an interpreting practitioner, or if a recent graduate, are working directly under the supervision of an experienced Cone Beam CT imaging technologist;
- C. *Continuing Education Requirements*
- i. Education. Complete 30 hours of continuing medical education every three years with a focus on radiation safety, which will cover the following topics:
 - (i) Radiation physics,
 - (ii) Radiation dose estimates and risks associated with radiation,
 - (iii) Radiation protection for staff and patients in CT practice,
 - (iv) Principles of radiation dose optimization for CT,
 - (v) CT equipment and apparatus,
 - (vi) Patient specific radiation risk factors, and
 - (vii) Radiation reporting requirements (including local, state and national mandates);and
 - ii. Vendor Education. Vendor provided education about their specific imaging systems and protocols; and
 - iii. Ongoing Mentoring. Ongoing supervision/mentoring by the clinical director or supervising physician/practitioner, and other qualified imaging technologists in order to demonstrate clinical and technical proficiency;
- D. *Continuing Experience Requirements.* Perform a minimum of 25 Cone Beam CT exams annually.

3.5.5 **Additional Specialty Requirements.**

- A. *Dental/maxillofacial requirements:* Any education taken to satisfy this requirement must be accredited by the American Dental Association Continuing Education Recognition Program (ADA CERP) or the Academy of General Dentistry Program for Continuing Education (AGD PACE), and shall cover dental/maxillofacial CT.

B. *ENT, orthopedic, chiropractic, podiatry or breast imaging requirements:* None.

Further Explanation

The intent of this standard is to ensure an appropriately trained, licensed and experienced Cone Beam CT imaging technologist is utilized for obtaining Cone Beam CT images from patients. This can be either a physician, dentist, dental assistant, medical assistant, mid-level practitioner, dental hygienist, or ARRT registered or certified Radiologic Technologist. The Cone Beam CT application also requests information regarding whether or not the imaging technologist is qualified to produce Cone Beam CT services.

Note: Imaging technologists, who are new to Cone Beam CT imaging systems, are not required to meet the baseline education or experience requirements for the first 3 months after they start working with the accredited Cone Beam CT imaging system, as long as they meet RadSite's other requirements. Under limited circumstances, an applicant (e.g., an imaging supplier with many imaging technologists) may request from RadSite an extension for up to 6 months to allow time to make sure all Cone Beam CT technologists are receiving the necessary training to meet the baseline education and experience requirements. In all cases, the Cone Beam CT imaging supplier will make a good faith effort to identify and train a lead Cone Beam CT technologist as soon as possible.

Document Submission

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

Standard 3.6 – Imaging Manager Qualifications

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

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

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

- i. American Registry of Radiologic Technologists (ARRT), an ARRT sub-certification, American Registry of Magnetic Resonance Imaging Technologists (ARMRIT), Nuclear Medicine Technology Certification Board (NMTCB) certification, or registered nurse license with relevant specialty certification, or sufficient requisite certification based on the jurisdiction where the imaging supplier is located,
- ii. Certified Radiology Administrator (CRA), or
- iii. At least two years of documented experience as an imaging manager; and

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

Further Explanation

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

Document Submission

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

Standard 3.7 – Medical Physicist Qualifications

3.7.1 **General Requirement.** The imaging supplier shall utilize one or more medical physicists to:

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

3.7.2 **Qualifications.** The imaging supplier shall contract or employ a medical physicist who has:

- A. A master's degree or higher in physics, physical science, or a closely related field;
- B. An active license to provide services as a medical physicist in the states where licensure is applicable; and
- C. The following additional experience:
 - i. A medical physicist shall have board certification or eligibility from the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP), the American Board of Health Physics (ABHP), or the American Board of Science in Nuclear Medicine (ABSNM) to practice independently in one or more of the subfields of medical physics.

Further Explanation

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

Standard 3.8 – Imaging Safety Officer Qualifications

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

- A. Is certified by a specialty organization recognized by RadSite or the Nuclear Regulatory Commission;
- B. Meets any additional federal, state or local safety requirements for each applicable advanced diagnostic system in use by the imaging supplier; and
- C. Has satisfactorily completed training in patient safety, radiation safety, regulatory issues related to radiation, and emergency procedures for the imaging systems in use in the imaging facility.

Further Explanation

The intent of this standard is to ensure properly qualified individuals help implement the patient and radiation safety program in the imaging facility. The imaging safety officer is responsible for protecting patients based on the type of imaging systems used.

For Dental Cone Beam CT Accreditation: an imaging safety officer can be a certified dental assistant, Dentist DDS, or Dentist DMD with documented radiation safety course hours as specified for dental technologists.

Document Submission

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

Section IV: Professional Oversight

Standard 4.1 – Medical/Clinical Director Responsibilities

- 4.1.1 The medical/clinical director (and if applicable the supervising physician/practitioner) shall carry out the following functions:
- A. Supervise and participate in the development and implementation of written policies and procedures regarding the work performed by the imaging supplier, and the operation of any applicable imaging systems;
 - B. Implement guidelines for safety of patients, including pediatric, and pregnant patients as well as medically compromised patients;
 - C. Ensure that only qualified practitioners are hired;
 - D. Ensure compliance with policies and procedures regarding (if applicable):
 - i. The appropriate and safe use of pharmacological agents for sedation, allergy or reaction suppression, contrast enhancement, and other applications, and
 - ii. The appropriate physician oversight as required by standards of practice and regulations regarding dispensing or administering such pharmacological agents;
 - E. Consult with and supervise senior managers who are affiliated with the imaging supplier;
 - F. Follow-up with medical physicist or medical physicist report recommendations;
 - G. Supervise the imaging supplier's risk management program to ensure optimal patient health and safety; and
 - H. Ensure that the facility is complying with the RadSite accreditation standards by doing the following:
 - i. Notifying RadSite within 14 days of any material or adverse change to its business operations that may directly impact the scope of the ADI accreditation,
 - ii. Providing immediate notification to RadSite of any outcomes of patient injury, untoward event, or death due to malfunction or improper use of radiology equipment, or due to lack of compliance with policies and procedures,
 - iii. Notifying RadSite promptly of complaints of any kind that are received about the ADI services provided, and
 - iv. Addressing any substantive deficiencies related to the RadSite Standards.

Further Explanation

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

Document Submission

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

Standard 4.2 – Interpreting Practitioner Responsibilities

- 4.2.1 The interpreting practitioner shall carry out the following functions:
- A. When applicable, observing, assisting and performing clinical examinations in compliance with the requirements established by the medical/clinical director;
 - B. Interpreting and reporting results of examinations;
 - C. Reporting any medical errors, mishaps, or near misses to the medical/clinical director stemming from any source including, but not limited to, personnel and equipment performance; and
 - D. Other duties assigned by the medical/clinical director (or supervising physician/practitioner) or other responsibilities required by the ADI Standards.

Further Explanation

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

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

Document Submission

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

Standard 4.3 – Imaging Technologist Responsibilities

4.3.1 The imaging technologist shall carry out the following functions:

- A. Prepare and operate imaging systems appropriately;
- B. Properly position patients to effectively record the requested diagnostic images;
- C. Properly use protective coverings to protect patients and themselves from excess radiation exposure;
- D. Properly prepare and administer contrast media during the procedure (which includes but is not limited to double checking the physician's order, using the proper dosage and method of administration).
- E. Follow the policies, procedures, and safety protocols established by the medical/clinical director or generated by federal, state and local requirements, and by other oversight or accrediting agencies;
- F. Report any medical errors, mishaps, or near misses stemming from any source including but not limited to personnel and equipment performance, to the medical/clinical director (and if applicable to the supervising physician/practitioner);
- G. Implement the quality control processes required by the RadSite Standards;
- H. Educate patients about safety concerns inherent to ionizing radiation and contrast administration;
- I. Comply with all applicable federal, state and local regulations regarding the operation of the applicable imaging systems;
- J. Maintain the current credentials necessary to operate the applicable imaging systems; and
- K. Maintain the necessary experience or training as set forth above in standard 3.5.

Further Explanation

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

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

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

Document Submission

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

Standard 4.4 – Imaging Manager Responsibilities

4.4.1 The imaging manager shall:

- A. Have a comprehensive understanding of the principles of imaging system safety for each of the ADI modality used by the imaging supplier, and which the imaging manager oversees;
- B. Ensure compliance with the policies and procedures pertaining to imaging system safety;
- C. Have reporting accountability to the medical/clinical director (or supervising physician/practitioner);
- D. Know and follow the priority reporting procedures for any equipment malfunctions, mishaps, and medical errors to the appropriate entities, including the medical/clinical (or supervising physician/practitioner); and
- E. Help implement or maintain a quality control program.

Further Explanation

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

Document Submission

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

Standard 4.5 – Medical Physicist Responsibilities

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

- A. Be familiar with and apply equipment manufacturer specifications and patient safety requirements;
- B. Perform periodic evaluations of the imaging systems by using phantoms or test-objects;
- C. Monitor the provision of patient specific dose measurements, patient radiation doses, and equipment performance, through periodic inspections and evaluations;
- D. Produce comprehensive medical physicist reports;
- E. Provide consulting support to the imaging supplier;
- F. Report any equipment malfunctions, mishaps, safety breeches, and concerns to the medical director and any other designated staff member;
- G. Assist in the creation of patient and staff education and training programs related to radiation safety; and
- H. Conduct the following survey:
 - i. For CT a radiation protection survey documenting that there is an appropriate shielding plan, that the shielding is in place in accordance with the shielding plan, and that the shielding plan has been properly modified if any significant changes have occurred at the practice since the plan was developed, or

Further Explanation

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

Document Submission

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

Standard 4.6 – Imaging Safety Officer Responsibilities

4.6.1 **General Requirement.** The imaging supplier shall appoint an imaging safety officer to oversee and implement a Patient and Personnel Safety Program. This position can be served by a radiation safety officer (RSO).

- 4.6.2 **Job Responsibilities.** Each imaging safety officer as applicable to each type of ADI system shall:
- A. Establish written policies and procedures covering the Patient and Personnel Safety Program;
 - B. Serve on the imaging safety committee;
 - C. Provide annual training in radiation safety to meet ALARA (As Low As Reasonably Available) practices;
 - D. Ensure the facility is following all federal and state regulations, including the maintenance of a radioactive materials (RAM) license;
 - E. Monitor all activities that involve the use of radioactive materials, ionizing radiation, MRI magnets or other imaging related activities;
 - F. Supervise quality control (QC) of nuclear equipment;
 - G. Monitor radiation personnel exposure records;
 - H. Maintain an inventory of all radioactive materials; and
 - I. Review and modify imaging exam protocols for radiation dose optimization in accordance with industry and societal standards.
- 4.6.3 **Policy Requirements.** The imaging safety officer shall ensure that policies and procedures are established and enforced that address the following as appropriate for the type of ADI system:
- A. For CT:
 - i. Implement dosimetry monitoring, with reporting of cumulative radiation exposure, in accordance with the frequency requirements of the local jurisdiction (if required locally);
 - ii. Require protective shielding to be used, as appropriate, by staff members to protect themselves, fellow staff members throughout the facility, patients, and the public from radiation exposure;
 - iii. Ensure that imaging equipment shall be installed in an appropriately shielded enclosure in order to promote adequate radiation protection to staff and designate this enclosure as a controlled (staff-only) area;
 - iv. Automatically record radiation dose calculations by the imaging system and present to the imaging technologist as a digital readout in any standardized format, and automatically incorporate into the electronic record in a manner in which it is instantly and machine-readably accessible to both clinicians and physicists for future review;

- v. Require the calculated patient radiation dose to be inclusive of all acquired images, including repeats;
- vi. When the radiation dose read out is presented to the imaging technologist, ensure that the calculated radiation dose is appropriate for the exam being performed;

 - a) In the event that the calculated radiation dose exceeds a predefined reference threshold, additional documentation and investigation is required (including consultation with a medical physicist), and
 - b) When practical, consider thyroid shielding to reduce patient radiation, without obscuring relevant anatomy (For example: this can be effective for CT scans of the brain).

4.6.4 **Cone Beam CT Requirement.** A formal retrospective audit analyzing Cone Beam CT radiation data should be performed every 6 months for inter and intra-analysis of recorded Cone Beam CT radiation dose metrics; these comparative radiation data analytics should be incorporated into the annual medical physicist review; any modifications and/or interventions performed as a result of radiation data analysis should be formally recorded for future review (if applicable).

Further Explanation

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

Document Submission

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

Section V: Policies and Procedures

Standard 5.1 – Policies and Procedures

- 5.1.1 **General Requirement.** The imaging supplier shall maintain and comply with written policies and procedures that govern the key elements of its clinical and business operations.
- 5.1.2 **Specific Requirements.** The imaging supplier shall perform the following activities related to its written policies and procedures (hereinafter referred to as the “policies”):
- A. *Scope and Documentation.*
 - i. Draft and maintain all policies covering key business operations such as human resource protocols and other requirements included in the RadSite Standards,
 - ii. Draft and maintain all policies covering key clinical workflows such as scan protocols and other requirements included in the RadSite Standards,
 - iii. Document and maintain policies electronically or on paper,
 - iv. Document the original effective date and the most recent revision dates of each policy, and
 - v. View all policies through a master list;
 - B. *Updates.* Review, update and document all changes to the policies at least annually;
 - C. *Peer Review.* Have all policies reviewed and signed off by the medical/clinical director(s) and imaging manager(s);
 - D. *Staff Requirements.*
 - i. Notify all staff impacted by any new or revised policies,
 - ii. Hold staff training meetings at least quarterly, and
 - iii. Document staff attendance at training sessions.

Further Explanation

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

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

Document Submission

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

Standard 5.2 – Regulatory Compliance Program

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

Further Explanation

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

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

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

Standard 5.3 – Complaint Resolution Process

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

- A. Review, investigate, resolve and respond to all complaints involving patient or staff safety in an expedited manner, typically within 24 hours, or by the next working day;
- B. Respond to non-urgent complaints within thirty (30) days;
- C. Report any sentinel event to the proper authorities (Note: A sentinel event is defined as any medical error or event in a healthcare setting that result in serious injury or death to a patient or a hazard to the general public, which is not related to the natural course of the patient’s illness);
- D. Report all sentinel events to RadSite;

- E. Must document details of the investigation findings, remediation efforts taken and communication with the complainant and the senior management team of the imaging supplier about the complaint;
- F. Inform patients of their rights to submit a complaint and the process for doing so;
- G. Respond to complaints in a time frame indicative of the seriousness of the issue;
- H. Address any compliance issues such as privacy; and
- I. Create staff education and training programs based upon patient safety complaints and concerns.

Further Explanation

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

Standard 5.4 – Storage Requirements

- 5.4.1 **General Requirement.** The imaging supplier shall store diagnostic images and other patient-specific information in a confidential and secure manner to allow appropriate retrieval of the files for subsequent review.
- 5.4.2 **Specific Requirements.** Specifically, the imaging supplier shall undertake the following safeguards:
 - A. Store a hard copy or use a digital storage system for images;
 - B. Provide appropriate long-term storage for more than 98% of primary images archived for at least seven years;
 - C. Provide appropriate long-term storage for more than 98% of primary images archived for minors until patient has reached adulthood; and
 - D. Use and update periodically an image retention policy or manual.
- 1.
 - 5.5.2.
- 5.4.3 **Privacy/Security of Stored Records.** Storage adequacy is defined through HIPAA and HITECH unless the State in which the Facility operates requires more stringent methods.

Further Explanation

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

Section VI: Quality and Patient Safety

Standard 6.1 – Quality Assurance Program

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

A. *General Requirements*

- i. Is overseen by a quality assurance committee or another formal panel established by the imaging supplier that includes participation by the medical/clinical director,
- ii. Tracks, analyzes, and remediates complaints, grievances, concerns, and errors,
- iii. Monitors the manufacturer requirement notices for non-imaging and imaging systems,
- iv. Implements a clinical peer review program for assessment of diagnostic accuracy in medical imaging reporting,
- v. Establishes and maintains a medical outcomes audit program to follow-up on positive and negative results, which includes correlating those results with the interpreting physician's findings;

B. *Policies*

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

C. *Clinical Protocols*

- i. Incorporates established clinical standards for imaging appropriateness in accordance with recommendations and guidelines of the peer review literature and professional societies and/or organizations, and are updated annually, with notations regarding the sources being used and the changes to department policy,
- ii. Identifies, implements, and benchmarks clinical policies,
- iii. Requires that all imaging exam protocols should be created in accordance with established professional standards, technology guidelines (based on the recommendations of the imaging manufacturer), clinical indication for the exam, and individual patient attributes,

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

(Note: This provision is not required for Cone Beam CT dental/maxillofacial providers);

D. Additional Requirements

- i. Requires that all communications between the imaging supplier and the patient (or their legal guardian) should be formally documented in the patient's clinical record;
- ii. Creates staff education and training programs, which shall include imaging systems requirements and the analysis of measured QA deficiencies, and
- iii. Helps ensure compliance with other quality requirements pursuant to the RadSite Standards.

6.1.2 **Cone Beam CT QA Requirements.** In addition, Cone Beam CT imaging supplier shall also fulfill the following functions as part of its QA program:

A. Implementation of an image exam audit program which requires:

- i. Prospective and retrospective image quality analysis, with prospective image quality analysis including formal documentation of all rejected images and retakes,
- ii. Image retake data to include: the date and time of the exam performed, the identity of the Cone Beam CT imaging technologist, patient identity, clinical indication for exam, technology in use, descriptive data related to image quality deficiencies and cause, and comparative radiation dose measurements,
- iii. Supervisory Cone Beam CT personnel to formally review all prospective image quality/retake data on a routine basis (at a minimum of monthly intervals) and document any actions and/or interventions taken, and
- iv. If image retake analysis reveals an image retake rate exceeding 5% (for any individual exam type, clinical indication, or Cone Beam CT imaging technologist), intervention is required; which may take the form of remedial staff education/training, technology quality control, or protocol adjustment; and

B. Oversees quality control (QC) program, including appropriate remediation procedures for any known substantive deficiencies, which shall contain the following elements:

- i. A documented time stamped record (preferably electronically stored, although signing and dating is sufficient) of all equipment testing and calibration, along with the identity of the responsible party shall be maintained,

- ii. All quality control test results should be documented and stored for periodic review by an independent expert (e.g., medical physicist, accreditation organization) and correlated with comparable performance guidelines from comparable Cone Beam CT imaging technologists,
 - iii. Quality control testing should include the use of the manufacturer's recommended Cone Beam CT phantom, which should have compatible software allowing for automated recording and analysis of phantom quality control data,
 - iv. Formal and comprehensive quality control testing should be done:
 - a) At least annually by a medical physicist,
 - b) Daily by the imaging technologist or other appropriate staff, and
 - c) At other routine intervals as recommended by Cone Beam CT manufacturers,
 - v. Testing of Cone Beam CT should include detailed acceptance testing at the time of implementation along with routine periodic testing of equipment functionality and safety (performed at a minimum of annually), throughout the lifetime of the equipment, and
 - vi. In the event that quality control performance testing documents insufficient test results, more rigorous testing and oversight (under the supervision of a medical physicist) is required until the results have normalized; and
- C. All QC test results should be fully documented and generate exportable reports.

6.1.3 Peer Review Requirements When Using a Single Interpreting Practitioner.

- A. When a practice contains a single interpreting physician or practitioner, the QA program shall be conducted by a qualified, independent third party, which shall be a peer familiar with these requirements and be affiliated with an accredited facility.
- B. The third party shall annually review a random sample of studies. The sample size shall be at least the smaller of 5% of studies or 20 studies. It must contain at least one example of each anatomical area that the facility images (e.g., a facility imaging hands, knees, and feet must include all three).
- C. Cone Beam CT specialty requirements:
 - i. Dental/maxillofacial requirements: The third party shall be a dental peer.
 - ii. ENT/orthopedic/chiropractic/podiatry/breast imaging requirements: The third party shall be board-certified in radiology or any applicable radiological subspecialty.

Further Explanation

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

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

Since quite a great deal of variability currently exists in Cone Beam CT technologies, benchmarks specific to each individual Cone Beam CT technology should be established and measured against the individual Cone Beam CT supplier's data.

Document Submission

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

Standard 6.2 – Patient and Personnel Safety Program

- 6.2.1 **General Requirements.** The imaging supplier shall implement a patient and personnel safety program, conduct training at least annually, and document staff attendance at training. The imaging supplier must also document that the patient and personnel safety program meets the following requirements:
- A. Operates in accordance with written policies and procedures;
 - B. Is updated annually;
 - C. Includes the assignment of an imaging safety officer or radiation safety officer (RSO) to each imaging facility (this individual may hold other roles, particularly in small practices);
 - D. Monitors all staff for occupational radiation exposure as required by federal and state regulations;
 - E. Promotes proper radiation utilization, in accordance with ALARA (As Low As Reasonably Achievable) and other radiation safety principles;
 - F. Compliance with [Image Wisely](#) guidelines (for CT and NM imaging suppliers) and signing the pledge annually;
 - G. Compliance with [Image Gently](#) guidelines (for CT and NM imaging suppliers who are scanning pediatric patients) and signing the pledge;

- H. Reliance on [Choosing Wisely](#) recommendations to avoid unnecessary medical tests, treatments and procedures;
- I. Implements patient identification procedures;
- J. Implements safeguards for radiation and contrast media dosage;
- K. Implements pregnancy and pediatric screening procedures and protocols;
- L. Annually educates and trains staff on radiation safety and use of imaging medicine and equipment;
- M. Relies on medication adherence guidelines;
- N. Addresses safety concerns which pose an immediate jeopardy to the accredited imaging supplier's patients or a hazard to the general public;
- O. Posts radiation safety standards in each imaging facility;
- P. Requires the use of dosimeter devices by staff to monitor radiation exposure;
- Q. Ensures access to emergency equipment, supplies, and personnel in accordance with federal, state and local regulations;
- R. If applicable, requires a BLS, ACLS or ARLS certified licensed practitioner to be present and continuously monitor a patient undergoing IV contrast, along with the procedure being supervised by a qualified physician or non-physician practitioner in close proximity to the patient and immediately available [see direct supervision as defined by CFR §410.32(b)(3)(ii)], with immediate access to a crash cart and other life-sustaining measures;
- S. If applicable, requires an ACLS or ARLS certified licensed practitioner to be present and continuously monitor, including an electrocardiogram (ECG), a patient undergoing conscious sedation, along with the procedure being supervised by a qualified physician (or a qualified dentist) [see personal supervision as defined by CFR §410.32(b)(3)(iii)], with immediate access to a crash cart and other life-sustaining measures;
- T. Has access to spill confinement and decontamination resources;
- U. Establishes annual image volume thresholds for each imaging system;
- V. Requires the timely reporting of a sentinel event to the proper authorities, as required by law and applicable professional society standards, along with following all internal reporting directives; and
- W. Creation of a patient educational program related to medical imaging quality and safety.

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

- A. The imaging supplier shall:
 - i. Provide written Patient and Personnel Safety Program manuals,
 - ii. Conduct safety program training at least annually,
 - iii. Document staff attendance at safety program training sessions, and
 - iv. Document on-going compliance with the safety program.
- B. The Patient and Personnel Safety Program must include following issues and Occupational Safety and Health Administration (OSHA) topics:
 - i. Adverse drug reactions;
 - ii. OSHA: Blood pathogens and exposure control;
 - iii. OSHA: Infection control;
 - iv. OSHA: Safety standards;
 - v. Medical practice standards supported by training and certification requirements such as Advanced Cardiovascular Life Support;
 - vi. Evacuation plans that cover both facility-wide and locally-contained emergencies; and
 - vii. Issues associated with radiation safety.

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

- A. The facility's written policy regarding a drug-free workplace;
- B. Supervisor training empowering supervisors to police and enforce the policy;
- C. Employee training informing employees of this policy;
- D. Employee assistance for substance abuse;
- E. Substance abuse testing; and
- F. Sanctions for employees or contractors failing to comply with these requirements.

- 6.2.3 **Mentally Healthy Workplace.** The imaging supplier shall maintain a healthy workplace and demonstrate compliance with a mentally healthy workforce policy covering all employees and contractors.
- A. The program shall include, at minimum:
- i. A written policy regarding a mentally healthy workforce,
 - ii. Supervisor training empowering supervisors to police and enforce the policy,
 - iii. Employee training informing employees of this policy, and
 - iv. Remedies for employees or contractors failing to comply with the mentally healthy workforce program.
- B. The program may include an Employee Assistance Program (EAP) that provides for optional testing for mental health issues and referrals for mental health counseling and treatment as necessary.

Further Explanation

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

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

- Information regarding Image Wisely, an initiative of the ACR, AAPM, RSNA and ASRT for radiation safety in adult medical imaging, is available at <http://www.imagewisely.org>. At a minimum, the medical/clinical director or supervising physician/practitioner shall submit a pledge annually for each location.
- Information regarding Image Gently, an initiative of the Alliance for Safety in Pediatric Imaging, is available at <http://www.pedrad.org/associations/5364/ig/>. If the imaging supplier does pediatric imaging, the medical/clinical director or supervising physician/practitioner must have filled out the pledge.
- Information regarding Choosing Wisely, an initiative of the ABIM Foundation's goal to advance a national dialogue on avoiding unnecessary medical tests, treatments, and procedures, is available at <http://www.choosingwisely.org/>.

Under Standard 6.2.1 (O) related to the wearing of dosimeters, RadSite is currently defaulting to state regulations regarding the use of dosimeters for Cone Beam CT imaging systems.

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

Document Submission

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

- Patient and personnel safety program, addressing the elements listed above in Standard 6.2.1;
- OSHA requirements listed above in Standard 6.2.2; and
- Healthy workforce or substance abuse policy for its personnel, addressing the elements listed above in Standard 6.2.3 and Standard 6.2.4.

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

- A current Imaging Wisely email verification, certificate or [Honor Roll](#) screen shot; and
- A recent Image Gently certification document for imaging suppliers who see pediatric patients.

Standard 6.3 – Medical Imaging Policies

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

- A. The actual presence of a qualified medical physician or practitioner pursuant to Standard 6.2 when a contrast medium is used or sedation is required for a patient with immediate access to a supervising physician/practitioner;
- B. Interpretation of all studies on an appropriate computer or electronic communication device that provides the image quality necessary for proper interpretation;
- C. File maintenance of a formal final written or electronic report for each and all imaging studies performed; and
- D. Formal documentation of all final image examinations by an interpreting physician or practitioner, especially when the final report is dictated and translated by a transcriptionist.

Further Explanation

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

Document Submission

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

Standard 6.4 – Patient Access

- 6.4.1 The imaging supplier shall implement patient access policies and procedures that are documented in writing or electronic form and require:
- A. Obtaining imaging services in a timely manner at a reasonably convenient location;
 - B. Providing reasonable access to patients for their health information including imaging records in accordance with the organization’s medical record policy; and
 - C. Establishing a patient notification system for emergencies.

Further Explanation

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

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

Standard 6.5 – Patient Confidentiality

- 6.5.1 The imaging supplier shall implement patient confidentiality policies and procedures for responding to requests by patients, payers, and other third parties for records that are documented and require:
- A. Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and
 - B. Ensure that Protected Health Information (PHI) is only:
 - i. Made accessible to authorized personnel, such as those involved in the diagnosis and treatment of the patient, and
 - ii. Disclosed to others as permitted by federal and state regulations.

Further Explanation

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

Standard 6.6 – Financial Integrity

- 6.6.1 **General Requirement.** The imaging supplier shall not promote any:
- A. Financial conflicts that jeopardize the patient’s best interests and welfare; and
 - B. Inappropriate incentives or kickbacks associated with patient referrals.
- 6.6.2 **Regulatory Compliance.** The imaging supplier must comply with any federal and state regulations concerning financial integrity, including the Stark Law.
- 6.6.3 **Financial Policies.** The imaging supplier shall establish financial integrity policies that are documented in writing or electronic form that prohibit:
- A. Financial conflicts that jeopardize the patient’s best interests and welfare;
 - B. Any inappropriate incentives or kickbacks associated with patient referrals;
 - C. Financial incentives to refer patients for more procedures or specific facilities, including incentives to referring providers, any referring provider’s employees, relatives, or associates;
 - D. Any contracts or agreements such as time slot-leasing arrangements for the equipment that has the potential to produce a negative impact on the patient’s best interests and welfare;
 - E. The use of improper incentives such as ones to encourage the premature or preferential use of a new machine or contrast agent; and
 - F. Paying compensation based on the number of imaging services a provider refers to an imaging facility.

Further Explanation

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

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

Section VII: Technical Quality

Standard 7.1 – General Requirements

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

A. *Physics Report and Phantom Image Requirements.*

- i. The most recent annual medical physics report, which must be dated within 12 months of the application submission date for each imaging system, and
- ii. Phantom testing details for image quality and dose (for both adults and children) for each imaging system;

B. *Image Study Submission Requirements.*

- i. Image studies of:
 - a) Actual patients imaged by the imaging system within six months prior to the submission of the application,
 - b) The protocol and corresponding clinical reports for each individual imaging examination performed and submitted, and
 - c) The best work of as many current staff members as possible.
- ii. For Cone Beam CT ADI accreditation:
 - a) Three image exams for each ADI system under review,
 - b) One additional pediatric image study must be submitted if the imaging supplier does pediatric imaging (i.e., a patient who is between 0 and 15 years of age) if 2% or more of the total caseload of exams are pediatric, and
 - c) One image shall include the use of IV contrast, if applicable to the imaging supplier;
- iii. For each additional clinical specialty designation:
 - a) Submit two or more exams for each imaging specialty area, with each study representing a different type of exam within the designated specialty,
 - b) One additional pediatric image study must be submitted for the additional specialty area(s) if the imaging supplier does pediatric imaging and (i.e., a patient who is between 0 and 15 years of age) 2% or more of the total caseload of exams are pediatric, and

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

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

i. Demographics

- a) Facility name and address,
- b) Patient identifiers:
 - 1) Name
 - 2) Date of birth
 - 3) Gender
 - 4) Medical record number,
- c) Name of ordering physician,
- d) Name or type of exam,
- e) Date and time of exam,
- f) Date and time of dictation,
- g) Date and time of transcription,
- h) Name of interpreting physician, and
- i) Signature of the interpreting physician.

ii. Report elements/descriptions

- a) Clinical history,
- b) All techniques and procedures used to obtain the images,
- c) Use of contrast and/or radiopharmaceuticals including method of administration and volume,
- d) Any known patient reactions,
- e) Possible limitation(s),
- f) Specific clinical questions,
- g) Comparison with relevant studies or reports,
- h) Key findings,
- i) Medical observations/conclusions:
 - (i) Specific diagnosis when possible
 - (ii) Differential diagnosis when appropriate

- (iii) Note follow up or additional exams when appropriate
- (iv) Note any significant patient reactions as applicable.

- 7.1.2 **Uploading.** All images shall be submitted in DICOM format (or through a DICOM wrapper) via RadSite's upload utility.
- 7.1.3 **Cone Beam CT Specific Requirements.** Reporting and communication procedures shall include the following stipulations:
- A. Each Cone Beam CT exam performed should have an accompanying written report, which may consist of a note in the patient's chart or a separate document;
 - B. All discernable abnormalities associated with the anatomy and pathology found within the reconstructed volume of the Cone Beam CT exam which shall be described and accounted for in the accompanying report;
 - C. In addition to itemized anatomy and pathology, the following additional items should be incorporated into the Cone Beam CT report or accompanying file:
 - i. Clinical indication (reason for the exam to be performed),
 - ii. Technical information regarding the CT scan protocol,
 - iii. Correlating clinical and/or historical imaging data (if applicable),
 - iv. Detail all of the clinically significant findings found, and
 - v. Describe the specific follow-up recommendations (if applicable);
 - D. In the event that an unusual and/or uncertain finding is observed in the Cone Beam CT exam or report, subspecialty consultation should be requested for definitive evaluation;
 - E. All clinically unexpected and/or emergent Cone Beam CT report findings require direct communication between the interpreting and referring clinicians; when applicable, these findings should also be directly communicated between the interpreting clinician and patient/legal guardian; and
 - F. All communications of emergent and/or clinically unexpected report findings should be formally documented in the Cone Beam CT report.

Further Explanation

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

- **Physics Review:**

- Medical physics report.
- Phantom image sets (using approved or recognized phantoms).
- Patient radiation dose structured reports from the sample image studies submitted.
- Statement from the medical physicist assessing the extent to which the ALARA principle has been followed during the prior year.
- **Image Quality Review:**
 - Sample clinical images.
 - Corresponding clinical reports.
 - Corresponding protocols (procedures; including exam parameters).
 - Computer-generated, standardized report format.

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

Standard 7.2 – Cone Beam CT Physics Evaluation

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

- A. The annual physics testing must meet the following minimum requirements:
 - i. Number accuracy.
 - ii. Number uniformity.
 - iii. Geometry test (i.e., distance accuracy or eccentricity).
 - iv. Spatial resolution (i.e., high contrast).
 - v. Low contrast detectability (if applicable).
 - vi. Review of the site's Cone Beam CT quality assurance program which would include both the imaging system and the acquisition monitor if it is used for interpretation.
 - vii. Radiation output measurements that characterize the x-ray beam's conformance with manufacturers' specifications.

- viii. Imaging time accuracy.
 - ix. Where appropriate and implementable, the exposure as a function of output (mR/mAs) measured at the middle of the axis of rotation (Note: the exposure for a typical scan should be extracted using the average mAs of the scan. The anatomical area used to define a “typical scan” shall be reported. This will not be used as a pass or fail indicator but will be used to create a standard in the future).
 - x. Documentation of the age of the Cone Beam CT imaging system, when the last upgrade to the system occurred, and whether the manufacturer’s upgrade recommendations are being followed.
- B. The annual physics testing must be performed within 12 months of the application submission date.
- C. The annual physics testing must be performed by a qualified medical physicist.

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

- A. Vendor-specific QC/user manual which discusses the QC requirements (Note: The manual should be provided in its entirety, and should ideally be provided digitally);
- B. Complete site-specific Cone Beam CT protocol data for each system for the procedures specified, containing all appropriate radiation dose information, necessary for medical physicist’s dose evaluation of the site’s protocols;
- C. The medical physicist report will be evaluated based on meeting manufacturer specifications and must include results for the testing protocols referenced in this Standard; and
- D. The vendor supplied phantoms should be utilized to measure these parameters in order to ensure the Cone Beam CT is performing according to the manufacturer’s specifications:
 - i. Cone Beam CT number uniformity of water equivalent material: The Cone Beam CT number should remain within the manufacturer’s limit for five locations (center, 12 o’clock, 3 o’clock, 6 o’clock, and 9 o’clock).
 - ii. Cone Beam CT number accuracy is evaluated for the phantom – using a test object that has at least four materials with different Cone Beam CT values. 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 the manufacturer’s specifications. If the Cone Beam CT number falls outside of a model-specific specified range, a minor deficiency will be noted. For vendor phantoms or other commercially available phantoms that have additional material present, the Cone Beam CT number

accuracy will be evaluated based on vendor parameters. The measured value should be +/- 20% of the stated value of the material.

- iii. High contrast spatial resolution. The high contrast resolution for the site's QC protocol shall be greater than 8 lp/cm or equivalent.
- iv. Geometric accuracy is determined in various methods depending on the particular vendor (e.g., +/- 2 mm).

Further Explanation

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

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

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

Document Submission

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

Standard 7.3 – Cone Beam CT Image Quality Evaluation

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

- A. Clinical images including quality and specialty protocols;
- B. Facility imaging policies;
- C. Radiation exposure; and
- D. Specialty imaging guidelines including pediatric protocols (if applicable).

7.3.2 Specialty Examinations

- A. The following Cone Beam CT examinations qualify for specialty certification:
 - i. Dental and Maxillofacial – Dental imaging may include evaluation of the oral cavity including mandible, maxilla, teeth, and depending on the field of view, soft tissues of the neck, branches of the carotid artery, the spine and sinuses. Maxillofacial imaging may

include imaging of the skull, including the base of the skull, upper airway, and paranasal sinuses.

- ii. ENT – This involves imaging of the paranasal sinuses including the maxillary, frontal, ethmoid, and sphenoid sinuses and the external auditory canal, middle and inner ear and base of the skull.
 - iii. Orthopedic – This involves imaging of the musculoskeletal system and extremities.
 - iv. Chiropractic/Podiatry – This involves imaging of the musculoskeletal system and extremities.
 - v. Breast Imaging – This involves imaging only of the breast either unilateral or bilateral with or without contrast.
- B. Facilities performing Cone Beam CT examinations on children must demonstrate pediatric protocols to improve radiation protection for children.

7.3.3 Clinical Image Requirements

- A. Each imaging supplier is required to submit a sample set of clinical images with the accompanying clinical report and protocols for each type of Cone Beam CT imaging system for which they are requesting accreditation. Each set of clinical images should include:
- i. The clinical indications for the examination,
 - ii. All images obtained or post-processed including additional planes and/or 3D images,
 - iii. Image exams submitted must have occurred within the past six months prior to the application (unless the Cone Beam CT imaging system is a new install, and images were not previously available. In this scenario, images may be submitted upon acquisition in tandem with the accreditation application),
 - iv. If the imaging system has been upgraded or modified, the images submitted cannot predate any upgrade or modification, and
 - v. The imaging study clinical interpretation (clinical report of the study),
- B. These images will be assessed for the following items:
- i. Demographic Data
 - a) Patient-identifying information:
 - 1) Full name
 - 2) Date of birth
 - 3) Gender

- 4) Medical record number,
- b) Name of institution,
- c) Date and time of examination,
- d) Equipment type;
- ii. Image Characteristics:
 - a) Slice thickness appropriateness,
 - b) Appropriate use of reconstruction,
 - c) CT noise,
 - d) Artifact evaluation,
 - e) Anatomic coverage,
 - f) Anatomic orientation labels,
 - g) Field of View,
 - h) Radiation exposure (mAs & kVp),
 - i) Scan time (x-ray exposure time);
- iii. Appropriate use or non-use of contrast agents when these are utilized (if applicable to the imaging supplier's scope of practice).

7.3.4 Scan Parameters. The Cone Beam CT imaging system scan parameters include the following:

- A. *Type of Exam:* (e.g., Dental);
- B. *Anatomic Coverage:* Superior and inferior extent of the examination;
- C. *Field of View Size:* Anatomical regions included in scan;
- D. *Resolution:* Matrix size dependent on the type of scan;
- E. *Radiation Exposure:* Reported in the appropriate exposure measurement (e.g., mGy, mR or other accepted dose indicator);
- F. *Reconstructed Slice Thickness or Delivered Voxel Dimensions:* Appropriate to the study being performed (post scan analysis); and
- G. *Reconstruction:* Should be performed when additional diagnostic benefit can be achieved.

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

Cone Beam CT Adult and Pediatric Examination Choices		
Dental and Maxillofacial	ENT	Orthopedic / Chiropractic / Podiatry
<ul style="list-style-type: none"> • Oral cavity/teeth • Soft tissue of the neck • Paranasal sinuses • Upper airway • TMJ • Base of the skull • Skull 	<ul style="list-style-type: none"> • Paranasal sinuses • Upper airway • TMJ • Base of the skull • Skull • Temporal bones • External auditory canal • Middle ear • Inner ear 	<ul style="list-style-type: none"> • Musculoskeletal system • Extremities

Further Explanation

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

Standard 7.4 – Corrective Action for Imaging System Deficiencies

- 7.4.1 The imaging supplier shall address any problems or substantive deficiencies with each imaging system by:
- Reporting the issue to the medical/clinical director, along with any supervising physician and imaging managers;
 - Providing updates on the issue to imaging supplier staff as necessary to carry out their duties and to care for patients;

- C. Implementing corrective actions if the imaging system is not performing within manufacturer's specifications or according to evidence-based guidelines as appropriate to the seriousness of the deficiency or problem;
- D. Removing the imaging system from patient service if there is an identified patient safety issue until it meets or exceeds performance requirements; and
- E. Documenting all key activities including the appropriate risk-related time frames and reported to the appropriate agencies and individuals.

Further Explanation

The intent of this standard is to verify that the imaging supplier has and implements a corrective action plan to address any imaging system deficiencies or issues that may arise. The site shall maintain a logbook tracking issues, actions taken, changes to the equipment, and service calls. During a random on-site audit of the facility, RadSite may request to see a corrective action policy, logs of deficiency reports, and any other documentation of corrective action activities as related to this standard.

Appendix A: Acronyms

AAHP – American Academy of Health Physics	AOBR – American Osteopathic Board of Radiology
AAPM – American Association of Physicists in Medicine	ARMRIT – American Registry of Magnetic Resonance Imaging Technologists
ABIM – American Board of Internal Medicine	ARRT – American Registry of Radiologic Technologists
ABMP – American Board of Medical Physics	ASRT – American Society of Radiologic Technologists
ABR – American Board of Radiology	BLS – Basic Life Support
ABSNM – American Board of Science in Nuclear Medicine	CAD – Computer-Aided Diagnosis
ACC – American College of Cardiology	CBCT – Cone Beam Computed Tomography
ACCF – American College of Cardiology Foundation	CBNC – Certification Board of Nuclear Cardiology
ACGME -- Accreditation Council for Graduate Medical Education	CCTA – Coronary CT Angiography
ACLS -- Advanced Cardiac Life Support	CD – Compact Disk
ACFME – Accreditation Council for Graduate Medical Education	CDE – Continuing Dental Education
ACP – American College of Physicians	CE – Continuing Education
ACR – American College of Radiology	CME – Continuing Medical Education
ADI – Advanced Diagnostic Imaging	CMS – Center for Medicare and Medicaid Services
AHA – American Heart Association	COCATS – Core Cardiovascular Training Statement
ARLS -- Advanced Radiology Life Support	CT – Computed Tomography
AEC – Automatic Exposure Controls	DEA – Drug Enforcement Agency
ALARA – As Low as Reasonably Achievable	DICOM – Digital Imaging and Communications in Medicine
AO – Accreditation Organization	
AOBIM -- American Osteopathic Board of Internal Medicine	

DOB – Date of Birth

DVD – Digital Video Disc

FAIUM – Fellow of the American Institute of
Ultrasound in Medicine

FSRU – Fellow of the Society of Radiologists,
Ultrasound

HIPAA – The Health Insurance Portability and
Accountability Act

HR – Human Resource(s)

MAP – MIPPA Accreditation Program

MIPPA – Medicare Improvements for Patients
and Providers Act of 2008

MR – Magnetic Resonance

MRI – Magnetic Resonance Imaging

MRSO – Magnetic Resonance Safety Officer

MITA – Medical Imaging & Technology
Alliance

N/A – Not Applicable

NEMA – National Electrical Manufacturer
Association

NM – Nuclear Medicine

NMTCB - Nuclear Medicine Technology
Certification Board

NPI – National Provider Identifier

NPPES – National Plan and Provider
Enumeration System

NRC – Nuclear Regulatory Commission

OSHA – Occupational Safety and Health
Administration

PACS – Picture Archiving and Communication
System

PET – Positron Emission Tomography

PHI – Protected Health Information

QA – Quality Assurance

QC – Quality Control

RCVT – Registered Cardiovascular
Technologist

RDCS – Registered Diagnostic Cardiac
Sonographer

RDMS – Registry of Diagnostic Medical
Sonographer

RSNA – Radiological Society of North America

RSO – Radiation Safety Officer

RVS – Registered Vascular Specialist

RVT – Registered Vascular Technologist

SCCT – Society of Cardiovascular Computed
Tomography

SSN – Social Security Number

SPECT – Single Photon Emission Computed
Tomography

SUV – Standardized Uptake Value

U.S. – United States

Appendix B: Time Frame Summary

Summary of Time Frames		
Issue	Time Frame	Description
Application Timeline	120 days	Upon RadSite’s receipt of signed Application Agreement and payment, the applicant has 120 days or three months (whichever is longer) to complete the application.
Request for More Information	30 days	The applicant will have thirty (30) days from receipt of RadSite’s “Request for More Information” to respond.
Corrective Action Period	60 days	The applicant will have sixty (60) days from the date that a corrective action period notification is received to remedy the deficiencies and resubmit materials to RadSite for re-examination and re-scoring.
Incomplete Application	90 days	Applicant does not sufficiently complete the application process within ninety (90) days of RadSite’s receipt of signed application agreement and cleared payment. In some instances, this time period may be longer if the applicant has received an extension pursuant to RadSite policy.
Initial Determination	90 days	Once the application is completed in full, RadSite will make its initial determination in ninety (90) days or less.
Full Accreditation	3 years	The accreditation period is three (3) years from date of ADI accreditation achievement.
Waiting Period: First Failure	90 days	If the applicant does not receive full accreditation due to a failure or persistence of an incomplete application: the applicant cannot apply again for RadSite’s ADI Accreditation Program until ninety (90) days after the date of the first “Notice of Failure”.
Waiting Period: Second Failure	180 days	If the applicant does not receive full accreditation due to a failure or persistence of an incomplete application: the applicant cannot apply again for RadSite’s ADI Accreditation Program until one hundred eighty (180) days after the date of the second failure.

Out of Service Notification	90 days	In the event that one or more imaging systems are taken out of service, the applicant must provide RadSite with updated information within Ninety (90) days of the equipment's out-of-service date.
New Equipment	60 days	New imaging system equipment brought online during the ADI accreditation must be registered with and reviewed by RadSite within sixty (60) days of being brought online and before being used on any patients.
Reconsider: First Level	30 days	The applicant can request a reconsideration of an adverse decision to the Accreditation Committee within thirty (30) days of the applicant's receipt of the "Notice of Failure" or other adverse determination impacting the applicant's accreditation status.
Appeals Process: Second Level	45 days	The second appeal can be filed with the RadSite Advisory board within forty-five (45) days of the applicant's receipt of the adverse determination to the Level 1 reconsideration appeal.
Random On-Site Audits for Applicants and Accredited Organizations	None	RadSite is under no obligation to provide notice for random on-site audits for applicants or accredited organizations and may audit these facilities at any time.
On-Site Audits for Applicants	None required	RadSite will perform an on-site visit of all applicants and will make a reasonable effort to schedule the visit at a time that is convenient for the facility. However, RadSite is under no obligation to provide notice for such on-site audits for applicants and may audit these facilities at any time. Note: The Application still must be completed within the ninety (90) day window granted to all applicants.
For Cause On-Site Audits	None or 24 hours	If a complaint or issue involves a serious patient safety concern, RadSite is obligated to initiate a for-cause audit with no prior announcement. If the complaint or issue involves an important but less serious concern, RadSite is not obligated to provide any notice regarding the impending for-cause audit.
Notice of Material or Adverse Change	14 days	Notify RadSite within fourteen (14) days of any material or adverse change to its business operations that may directly impact the scope of the ADI accreditation.

Appendix C: On-Site Audit Checklist

General Description	Sample Site Audit Checklist Items	Score
General Facility Information	<ul style="list-style-type: none"> • Name • Address 	
ADI Information	<p>Accredited Modalities/Serial Numbers (Console and Gantry)</p> <ul style="list-style-type: none"> • CT • MRI • PET • SPECT 	
Regulatory	<p>Compliance program that monitors federal and state regulations</p> <ul style="list-style-type: none"> • RC license, if applicable • State inspection 	
Personnel	<p>Credentialing Program</p> <ul style="list-style-type: none"> • Review policies • Pull sample credentialing files to check for complete primary and secondary verification • Check re-credentialing every three years 	

	<p>Medical Director Qualifications</p> <ul style="list-style-type: none"> • State license • Copy of board certification(s) • Proof of qualification by training or experience • Proof of satisfaction of supervision requirements • Proof of continuing education • Job description <ul style="list-style-type: none"> ○ Job title ○ Description of job responsibilities ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements 	
	<p>Interpreting Physician Qualifications</p> <ul style="list-style-type: none"> • State license • Copy of board certification(s) or eligibility • Proof of continuing education • Job description <ul style="list-style-type: none"> ○ Job title ○ Description of job responsibilities ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements 	
	<p>Imaging Technologist Qualifications</p> <ul style="list-style-type: none"> • ARRT, ARMRT or NMTCB certification 	

	<ul style="list-style-type: none"> • Copy of BCLS/ACLS certification (if applicable) • Copy of state license (if applicable) • Job description <ul style="list-style-type: none"> ○ Job title ○ Description of job responsibilities ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements 	
	<p>Imaging Manager Qualifications</p> <ul style="list-style-type: none"> • Job description <ul style="list-style-type: none"> ○ Job title ○ Description of job responsibilities ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements • Copy of CV or resume • Copy of licenses or certifications (if applicable) • Materials to demonstrate that the imaging manager requirements have been satisfied 	
	<p>Medical Physicist (MR Scientist) Qualifications</p> <ul style="list-style-type: none"> • Evidence of relationship with facility (e.g., contract) • Job description <ul style="list-style-type: none"> ○ Job title ○ Description of job responsibilities 	

	<ul style="list-style-type: none"> ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements ● If available: <ul style="list-style-type: none"> ○ Copy of board certification (if applicable) ○ State license (if required) 	
	<p>Imaging Safety Officer (aka Radiation Safety Officer) Qualifications</p> <ul style="list-style-type: none"> ● Job description <ul style="list-style-type: none"> ○ Job title ○ Description of job responsibilities ○ Minimum qualifications of education, training, and professional experience ○ Appropriate licensure or certification requirements ● Review documents establishing active imaging safety program 	
<p>Policies</p>	<p>General Requirements</p> <ul style="list-style-type: none"> ● Maintain a master list of all policies and procedures and document all major clinical workflows in writing or electronically ● Annual review, and as appropriate updating, all clinical policies, procedures, and scan protocols under the medical director’s supervision ● Review policies and procedures to review for effective dates, including the date of the most recent revision, while documenting all changes ● Ensure clinical policies and procedures reviewed and signed off by both the medical director and imaging manager at least annually ● Documentation of staff training and attendance at least annually 	

	<p>Imaging System Policies</p> <ul style="list-style-type: none"> • Any policy describing imaging supplier’s imaging system maintenance program or a written narrative describing the provider’s existing approach to its program • QC logs of all imaging systems • Verify policies are reviewed at least annually and more frequently if needed 	
	<p>Clinical Policies</p> <ul style="list-style-type: none"> • Review samples of current clinical policies used by the imaging provider • Verify policies are reviewed at least annually and more frequently if needed • Interview staff to test knowledge base • The actual presence of qualified medical staff when a contrast medium is used, or sedation is required for a patient (if applicable) • Interpretation of all studies on an appropriate computer or electronic communication device that provides the image quality necessary for proper interpretation • File maintenance of a formal final written or electronic report for each and all imaging studies performed and • Formal documentation of all final image examinations by an interpreting physician, especially when the final report is dictated and translated by a transcriptionist • Satisfaction of applicable additional requirements (see sections). 	
<p>Quality Assurance</p>	<p>Quality Assurance Program</p> <ul style="list-style-type: none"> • Any QA policy and procedure which demonstrates the imaging supplier: 	

	<ul style="list-style-type: none"> ○ Operates according to written policies and procedures that are reviewed annually by the medical director ○ Be overseen by a quality assurance committee or another formal committee of the imaging supplier that includes participation by the medical director and if applicable one or more supervising medical providers ○ Track, analyze, and remediate complaints, grievances, concerns, and errors ○ Oversee quality control (QC) program, including appropriate remediation protocols for any known substantive deficiencies ○ Oversee imaging system training and other relevant educational programs ○ Help monitor manufacturer requirement notices for non-imaging and imaging systems (stationary and mobile) and update policies and procedures ○ Help identify, implement, and benchmark clinical policies and ○ Help ensure compliance with other quality requirements including the RadSite Standards. 	
<p>Safety Program</p>	<p>Patient and Personnel Safety Program</p> <ul style="list-style-type: none"> ● Any patient and personnel safety policies demonstrating that the imaging provider addresses the following: <ul style="list-style-type: none"> ○ Operates in accordance with written policies and procedures ○ Ensures that the patient and personnel safety program is updated at least annually ○ Includes the assignment of an imaging safety officer to each imaging facility ○ Monitors all staff for occupational radiation exposure as required by federal and state requirements 	

	<ul style="list-style-type: none"> ○ Promotes the proper use of radiation shielding in accordance with ALARA (As Low As Reasonably Achievable) and other radiation safety principles ○ Implements patient and procedure identification protocols ○ Implements safeguards for radiation and contrast media dosage ○ Implements pregnancy and pediatric screening protocols ○ Annually educates and trains staff on radiation safety and use of imaging medicine and equipment ○ Relies on medication adherence guidelines ○ Posts radiation safety standards in each imaging facility ○ Requires the use of dosimeter devices by staff to monitor radiation exposure ○ Ensures access to emergency equipment, supplies and personnel ○ Requires an ACLS or BLS certified medical professional to be at the facility when a patient is undergoing IV contrast with immediate access to a licensed physician ○ Requires an ACLS certified physician to supervise the procedure when a patient is undergoing conscious sedation ○ Has access to spill confinement and decontamination resources ○ Establishes annual image volume thresholds for each imaging system and ○ Requires the timely reporting of a sentinel event to the proper authorities – along with following all internal reporting directives. 	
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	<ul style="list-style-type: none"> • OSHA Polices: <ul style="list-style-type: none"> ○ Adverse drug reactions ○ OSHA: Blood pathogens and exposure control ○ OSHA: Infection control ○ OSHA: Safety standards ○ Advanced Cardiovascular Life Support ○ Evacuation plans that cover both facility-wide and locally contained emergencies and ○ Other specialty issues associated with radiation safety. 	
Drug Abuse Prevention	Drug Abuse Policy <ul style="list-style-type: none"> • The imaging supplier’s written policy regarding a drug-free workplace • Supervisor training empowering supervisors to police and enforce the policy • Employee training empowering employees to comply with the policy • Employee assistance for substance abuse • Substance abuse testing and • Sanctions for employees or contractors failing to comply with these requirements 	
Mental Health Policy	Mental Health Policy <ul style="list-style-type: none"> • The imaging suppliers written policy regarding mental health support • Supervisor training empowering supervisors to implement resources to support employees • Employee training empowering employees to take advantage of resources when dealing with depression, anxiety and other 	

	mental health conditions	
Logs	Documentation <ul style="list-style-type: none"> • Training logs for all staff members • Log of complaints/grievances and resolution 	
Storage	Storage Policies <ul style="list-style-type: none"> • Store a hard copy or electronic filing system for images • Provide appropriate long-term storage for more than 98% of primary images archived for at least seven years • Provide appropriate long-term storage for more than 98% of primary images archived for minors until patient has reached adulthood • Use and update periodically an image retention manual • Proper PHI handling 	
Equipment	Imaging System Performance <ul style="list-style-type: none"> • Provide a vendor specific QC/user manual which discusses the QC requirements for all ADI systems used • Regular QC for each imaging system • Current third-party physics report 	
Exams	Protocols <ul style="list-style-type: none"> • Following evidence-based pathway such as ACR • Copies of all protocols used on a regular basis • Detailed reports 	

Personnel	Credentialing Program <ul style="list-style-type: none">• Review policies• Pull sample credentialing files to check for complete primary and secondary verification• Check re-credentialing every three years	
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Appendix D: Technical References

All of the technical requirements set forth in Section VII of the Standards have undergone a rigorous review process to ensure that each standard is consistent with industry best-practice and requires a high level of quality from all successfully accredited imaging suppliers. Several RadSite Standards Committees, made up of a team of national experts in their respective fields, meet regularly to review current best-practices, analyze the most recent literature, and discuss requirements set by other nationally recognized standards-setting organizations in order to determine the appropriate values for each technical component requirement. For the convenience of its applicants, RadSite has compiled a list of third-party references that support and validate the values defined in the RadSite accreditation standards. In some instances, RadSite requirements may be more stringent than those set by other organizations.

CT

- **AAPM Report #100**
Available at: http://www.aapm.org/pubs/reports/RPT_100.pdf
- **CATPHAN 500-600 manual**
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