IAC Standards for MRI Image-Guided Prostate Biopsy Procedures Accreditation

Accreditation Standards

APRIL 2025

Introduction

The Intersocietal Accreditation Commission (IAC) accredits facilities performing image-guided procedures. IAC accreditation is a quality metric by which facilities can evaluate and improve the level of patient care they provide.

A facility (i.e., imaging center, physician office, hospital) performing MRI guided procedures may utilize both high and low field MRI units. Facilities performing high field biopsy and treatment procedures seeking accreditation must utilize the *IAC MRI Standards & Guidelines for Accreditation* as it relates to equipment and environmental safety. All facilities performing prostate biopsy procedures utilizing MRI technology must comply with the procedural and safety standards noted in this document.

The *IAC Standards for MRI Image-Guided Prostate Biopsy Procedures* are specific to facilities performing image-guided prostate biopsy and treatment procedures utilizing ultra-low field (<0.2T) MRI technology. All staff and operational aspects of the facility are under the supervision and the responsibility of the Medical Director. A Technical Manager appointed by the Medical Director is responsible for the oversight of the technical staff members and the daily operation of the facility.

The IAC accreditation program is an independent peer review designed as an educational tool to improve the overall quality of the facility leading to improved patient outcomes. Accreditation also serves as recognition of facilities that are committed to providing quality, safe, patient care in the performance of image guided procedures.

These accreditation Standards and Guidelines are the minimum standards for accreditation of facilities who perform ultra-low field MRI image-guided biopsy and treatment procedures.

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable. Facilities are encouraged to contact the IAC for guidance related to utilization of new technology not currently addressed in the IAC Standards.

These Standards were published and effective on January 1, 2025. Additional recommendations were published on April 1, 2025 to include an Artificial Intelligence (AI) Guidance Document.

The facility, including all staff, must comply at all times with all federal, state, and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

Part A: Organization

Section 1A: Staff Qualifications

The staff qualifications listed in this section refer to medical and technical staff that operate the ultra-low field (0.065T) Image-Guided MRI Prostate Biopsy. Refer to the *IAC MRI Standards & Guidelines for Accreditation* for the medical and technical staff pathways as applicable for MRI units equal to or greater than 0.065T.

STANDARD – Overview

1.1A The medical and technical staff training and experience requirements are specific to the operation of the ultra-low field (0.065T) FDA-approved/cleared MRI image-guided equipment for prostate biopsies/ treatment and the management of the patient throughout the biopsy procedure and post procedure care.

1.1.1A Operation of MRI equipment greater than 0.065T are required to comply with the *IAC MRI Standards & Guidelines for Accreditation*.

STANDARD – Medical Director and Medical Staff

1.2A The Medical Director and edical staff must be a licensed physician (MD or DO) in the state or jurisdiction where procedures are performed. The license must be current and unrestricted.

1.2.1A The Medical Director and medical staff must hold certifications by an American Board of Medical Specialties (ABMS) recognized relevant specialty board (e.g., American Board of Urology [ABU], American Board of Radiology [ABR]) or board certified in a relevant specialty recognized by the American Osteopathic Association, Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec.

1.2.2A Clinical Competency Training and Experience

1.2.2.1A The Medical Director and medical staff must have documented supervised image-guided procedural experience during which the physician performed and interpreted image-guided percutaneous biopsy procedures, serving as the primary operator, with outcomes within the quality improvement thresholds.

1.2.2.2A Performed a minimum of 30 biopsies during training and/or clinical practice.

1.2.3A Continuing Medical Education (CME) Requirements

1.2.3.1A The Medical Director and medical staff must obtain CME credit hours as required by license/certification and a minimum of one credit hour must be related to prostate diagnosis, treatment and management in the past three years.

1.2.3.2A Documentation of CME credits must be kept on file and available for inspection.

1.2.4A Medical Director Responsibilities

1.2.4.1A Implementing measures to achieve and maintain compliance with the *Standards* for all services provided, including compliance, outcomes, quality control and quality of care and appropriateness of care provided.

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1.2.4.2A May supervise all staff and operation of the facility or delegate specific operations but is responsible for assuring compliance of medical and other staff to the *Standards* outlined in this document.

1.2.4.3A Additional responsibilities include, but are not limited to:

i. ensuring patient and personnel safety;
ii. the review of quality improvement (QI) documentation that includes the requirements listed in Part 4C: Quality Improvement Documentation.
iii. the review and approval of policies (or appoint a designee) at least annually, and as new policies are introduced.
- Must be documented via signature (or initials) and date on the reviewed document or manual.

1.2.4.4A If the Medical Director is off-site, he/she must have a regular presence in the facility to participate in QI meetings and other facility operations.

STANDARD – Technical Manager / Supervising Staff

1.3A A technical manager or supervising staff must be delegated to coordinate the operations necessary for the procedure. The Medical Director or staff may serve in this role meeting the requirements outlined in Standard 1.2A.

1.3.1A The technical manager or supervising staff must be a licensed, board certified physician or a licensed non physician advanced practice provider, nurse, or ancillary personnel in compliance with all federal, state, regulations, including laws relating to licensed scope of practice.

STANDARD – Technical Staff

1.4A The technical staff (i.e., ARRT, (R) (CT) (MR) (RA) or other post primary certification, MA) must have appropriate training, technical certification and/or documented experience in an imaging with and patient care responsibilities.

1.4.1A Technical Staff Continuing Education (CE) Requirements

1.4.1.1A Technical staff must obtain CE credit hours as required by license/certification and a minimum of one credit hour must be related to prostate diagnosis, treatment and management in the past three years.

1.4.1.2A Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Advanced Practice Provider (APP)

1.5A Non-physician personnel within the facility must have a specific job description on file and must be evaluated annually for performance and competency.

1.5.1A Advanced Practice Providers (APP) work under the direction of the Medical Director or a medical staff member who is listed in the application.

1.5.2A The Medical Director is responsible for the APP's clinical assignments and determines the level of supervision required in reference to competency and in compliance with scope of practice and state regulations.

1.5.3A APP Required Training and Experience

1.5.3.1A The APP must meet one of the following criteria for required certification:

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i. Physician Assistant (PA)
ii. Nurse Practitioner (NP)

1.5.4A APP Continuing Medical Education (CME) Requirements

1.5.4.1A The APP must obtain CME credit hours as required by license/certification and a minimum of one credit hour must be related to prostate diagnosis, treatment and management in the past three years.

1.5.4.2A Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Nursing Staff

1.6A Nursing staff work under the direction of the Medical Director or a medical staff member who is listed in the application. The nurse must be a licensed registered nurse (RN) or licensed practical/vocational nurse (LPN/LVN) who possesses knowledge in the treatment of interventional procedures and meets the required license/certification and experience qualifications as outlined in this document.

1.6.1A The Medical Director is responsible for the nursing clinical assignments and determination of the level of supervision required in reference to competency and in compliance with scope of practice and state regulations.

1.6.2A Nursing Staff Continuing Medical Education (CME) Requirements

1.6.2.1A Nursing staff must obtain CME credit hours as required by license/certification and a minimum of one credit hour must be related to prostate diagnosis, treatment and management in the past three years.

1.6.2.2A Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Anesthesia Personnel

1.7A The facility must ensure that trained and experienced anesthesia personnel are available to perform safe and effective patient care appropriate for the level of service as designated by the Medical Director. The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as the facility configuration.

1.7.1A Anesthesia personnel qualifications:

1.7.1.1A Licensed physician, board certified by the American Board of Anesthesiology (ABA)

1.7.1.2A Certified Registered Nurse Anesthetist (CRNA)

1.7.2A Responsibilities may include, but not limited to:

1.7.2.1A administering and monitoring moderate sedation;

1.7.2.2A performing cardiovascular assessment;

1.7.2.3A monitoring and assessing clinical status of patient;

1.7.2.4A cardiovascular and hemodynamic monitoring and management;

1.7.2.5A advising patient care team and treating patient appropriately;

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1.7.2.6A demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the biopsy or interventional procedures performed in the facility; and

1.7.2.7A assisting with procedures under personal supervision of a qualified medical staff member.

1.7.3A Anesthesia assistants are permitted under the direct supervision of a board-certified anesthesiologist or a CRNA.[1]

STANDARD – Ancillary Personnel

1.8A All ancillary personnel within the facility must be supervised by the Medical Director or a qualified designee.

1.8.1A Ancillary personnel must be trained and experienced to perform responsibilities appropriate for the level of service as designated by the Medical Director or a qualified designee.

1.8.2A The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as the facility configuration.

1.8.3A Ancillary personnel may consist of, but are not limited to:

1.8.3.1A medical physicist;

1.8.3.2A technical assistants;

1.8.3.3A clerical and administrative assistants;

1.8.3.4A computer support staff; or

1.8.3.5A equipment support staff (i.e., biomedical, x-ray service).

1.8.4A Ancillary personnel must meet the CE/CME requirements of the licensing/credentialing body.

1.8.5A Documentation of the current license, credentials and CE/CME credits must be available for inspection.

1.8.6A Documented training, annual competence evaluation of ancillary personnel appropriate to the assigned duties must be available for inspection.

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Section 2A: Administrative

STANDARD – Patient Confidentiality

2.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

2.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the facility and how the facility handles complaints/grievances.

STANDARD – Primary Source Verification

2.3A There must be a policy in place identifying how the facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as the licensing, certification and training of all staff members and any other direct patient care providers.

STANDARD – Record Retention

2.4A All medical records must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years.

Sample documents are available for each of the required policies listed in Section 2A on the IAC website at intersocietal.org/helpful-resources/sample-documents-repository.

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Section 3A: Patient and Personnel Safety

STANDARD – Safety

3.1A Written policies and procedures must exist to ensure patient and personnel safety. Safety policies must be enforced, reviewed, and documented annually by the Quality Improvement (QI) committee or the Medical Director.

3.1.1A Patient Identification Policy – For all clinical procedures, there must be a current process that assures accurate patient identification immediately prior to initiating the procedure.

3.1.2A Infection Control Policy – Procedures and policies must exist to control the spread of infectious diseases and blood borne pathogens. The policy must include equipment cleaning, hand washing, glove use and universal precautions that are implemented in the facility.

3.1.3A Acute Medical Emergency Policy – In the event of a procedure-related emergency (i.e., respiratory arrest, cardiac arrest, severe agent reaction, etc.), there must be a written policy for patient management that includes rapid recognition of the symptoms, immediate and appropriate, response and safe removal of the patient from MRI system, and administration of emergency medical care.

3.1.3.1A For medical emergencies, equipment and supplies (i.e., defibrillator, oxygen tank, suction, monitoring device, etc.) must be accessible and used, as needed.

3.1.3.2A Licensed and/or qualified and trained personnel (i.e., BLS or ACLS certified) must be available to manage medical emergencies and handle critically ill or high-risk patients.

3.1.4A Incident Report/Adverse Events Policy – A policy for documentation of adverse events (i.e., medication reactions, patient incidents, patient falls, etc.) must be in place.

3.1.5A The administration of medications, sedation and anesthesia must comply at all times with all federal, state, and local laws and regulations and ASA guidelines where applicable.

STANDARD – Environmental Safety

3.2A Environmental Safety Policy – A policy must be established to ensure that the environment is equipped for patient, personnel, and visitor comfort, safety and privacy. The policy should include, but not limited to: education, training and screening of all patients, facility staff members and personnel that may be required to enter the procedure environment.

3.2.1A Safety policies must address possible contraindications and appropriate safeguards to ensure patient and personnel safety with regard to the presence of electrical, mechanical or magnetically activated devices including cardiac pacemakers, implantable cardioverter defibrillators, certain neuro stimulators, certain cochlear implants and other similar devices that may malfunction or have altered operation under conditions used for MRI procedures.

3.2.2A Safety policies must address possible contraindications to MRI procedures that include implants made from ferromagnetic or electrically conductive materials such as certain clips, stents, ocular implants, otologic implants, cardiovascular catheters and other similar devices that may be moved, dislodged or heat excessively during the MRI procedures.

3.2.3A A method for continuous visual, verbal and/or physiologic monitoring of the patient during the examination must be present.

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3.2.4A Physical space requirements include, but are not limited to:

3.2.4.1A reception and patient/staff bathroom;

3.2.4.2A handwashing/sanitation stations for staff;

3.2.4.3A private patient examination, consultation and procedural area(s);

3.2.4.4A adequate space for performing resuscitation;

3.2.4.5A configuration and doorways for the emergency transport of patients from patient care areas and kept clear from obstruction; and

3.2.4.6A marked emergency exits for patients, visitors and staff.

STANDARD – Storage

3.3A Adequate space must be provided for:

3.3.1A patient records, reports and digital data storage areas;

3.3.2A administration records and support areas;

3.3.3A equipment/supply storage areas.

Comment: The storage areas must ensure confidentiality of the data as appropriate according to HIPAA regulations and protected from fire/flood.

STANDARD – Personnel Safety

3.4A All personnel in the facility staff must adhere to national patient safety goals and standards set forth by the Occupational Safety Health Administration (OSHA), Centers for Disease Control (CDC) and other applicable agencies.

STANDARD – Supervision

3.5A All policies must be enforced by the Medical Director and reviewed by all staff. Training and documentation of the review must occur as appropriate but no less than annually.

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Part B: Equipment and Procedures

Section 1B: Equipment Safety

Operation of units equal to or greater than 0.2T are required to adhere to the *IAC Standards & Guidelines for MRI Accreditation*.

STANDARD – MRI-Guided System

The following *Standards* apply to MRI image guide equipment/system that is FDA approved for prostate biopsy and treatment procedures only. Personnel operating this equipment must do so in compliance with the required scope of practice and state and federal regulations as applicable.

1.1B The facility must have documented policies and procedures to address patient safety (refer to Section 3A: Patient and Personnel Safety) and safety of the equipment used in the performance of the procedure and equipment used to respond to a medical emergency.

STANDARD – Equipment Quality Control

1.2B MRI Equipment and Image Registration System

All equipment and instrumentation that may be used during the procedure must be routinely inspected for safety and proper functionality following the manufacturer's specifications and/or the medical physicist's recommendations for quality control and equipment safety.

1.2.1B Fusion imaging requirements:

1.2.1.1B Manufacturers specifications must be adhered to at all times.

1.2.1.2B A qualified medical physicist or service engineer is recommended to establish the quality control program.

1.2.2B The MRI equipment quality control (QC) documentation must consist of system installation/acceptance testing.

1.2.3B The manufacturer's representative, service engineer, qualified medical physicist or qualified expert must perform the acceptance testing.

1.2.4B The system parameters must be compared to the manufacturer's system specifications or industry standards and reviewed by appropriate staff, recommended to be a qualified medical physicist.

1.2.5B Routine (daily and periodic) quality control (QC) tests are to be conducted according to performance measurements as outlined by the manufacturer's system specifications and/or the medical physicist's recommendations.

1.2.5.1B Deviations from established thresholds must be documented and corrective action taken where appropriate.

1.2.5.2B Preventive maintenance (PM) service is required per the manufacturers' recommendations but not less than annually for the MRI image guide system.

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1.2.5.3B A manufacturer's service engineer and/or the site's personnel, who have been properly trained to maintain the equipment, must perform the preventive maintenance.

1.2.6B A written report of the acceptance tests must be maintained at the facility. The report must include the QC tests performed, the results as compared to manufacturers or industry guidelines, recommendations to the facility (if any) and must be signed and dated by the person performing the tests. The tests performed must also be archived on the system or a separate device for future reference.

1.2.7B A complete report of the installation, PM, quality control tests and service records must be maintained at the facility for the MRI image guide system. The reports must be signed and dated by the person(s) performing the tests.

1.2.8B A collaborative plan between the facility and manufacturer must be established to identify the process and timeline for training and transition from the manufacturer presence in the facility to relinquishment of operation of the scanner to the facility staff.

1.2.9B The facility must define who will be operating the equipment after manufacturer training is completed.

STANDARD – Emergency Equipment / Medication / Supplies

1.3B Site-specific, detailed protocols must be documented and be followed for routine inspection and quality control checks for emergency medical equipment, supplies and medications that may be used during the procedure. All equipment must be FDA-approved (as appropriate) and in accordance with federal and state regulations.

1.3.1B An emergency response cart, resuscitation supplies, equipment, medications and qualified trained staff (ACLS/BLS) to respond to a medical emergency must be present during the procedure.

1.3.2B There must be documentation that all emergency response equipment was checked for safety and that medications used are labeled and not expired.

1.3.3B All equipment, medications and supply inspections and the quality control (QC) results must be documented and reviewed by the Medical Director.

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Section 2B: Process and Procedure

STANDARD – Procedure Overview

2.1B These *Standards* include the minimum requirements for the performance of MRI image-guided prostate biopsy and treatment procedures. Facilities must have written policies and procedures to address patient safety pre-procedure, during the procedure and immediate post-procedure, and patient post-procedure follow up instructions. Specific biopsy and treatment protocols for the approach taken (i.e., transurethral, transrectal, transperineal), and the protocol specific to the MRI unit must be established.

2.1.1B The facility must utilize an accredited/certified pathology lab to evaluate the biopsy specimen(s). Pathology labs are regulated and certified based on the federal law, Clinical Laboratory Improvement Amendments (CLIA).

2.1.2B The facilities performing the biopsy must acquire/obtain the appropriate 1.5T or 3.0T MR diagnostic images of the prostate prior to or during the procedure to aid in the localization of the target biopsy areas.

2.1.3B Facilities must adhere to the American Society of Anesthesiologists (ASA) and state regulations regarding sedation requirements and scope of practice.

STANDARD – Biopsy Procedure and Treatment Requirements

2.2B Pre-Procedure

2.2.1B Clinical Indication/Appropriateness: A clinical evaluation of each patient being considered for treatment must be performed and documented in the medical record.

2.2.2B The physician or care team must determine the necessity of the prostate biopsy utilizing American Urological Association (AUA), Society of Interventional Radiology (SIR) or other medical professional societal practice guidelines.

2.2.3B Indications for the biopsy may include, but are not limited to:

2.2.3.1B PSA level warranting the biopsy;

2.2.3.2B clinical presentation during a digital rectal exam;

2.2.3.3B a previous biopsy with a normal result, continued elevated PSA levels;

2.2.3.4B a previous biopsy that revealed prostate tissue cells that were abnormal, but not cancerous;

2.2.3.5B suspicious/inconclusive imaging findings;

2.2.3.6B Determination of biopsy/treatment technique and protocol must be established.

i. Transrectal method
   - Procedure through the rectum and is the most common.

ii. Transperineal method
   - Procedure through the skin between the scrotum and the rectum.

iii. Transurethral method
   - Procedure through the urethra using a cystoscope (a flexible tube and viewing device).

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2.2.3.7B Documentation of deviance from the protocol must be discussed and a process improvement plan implemented.

2.2.4B Diagnostic MR Images

2.2.4.1B Diagnostic MR images (1.5T or 3.0T) and the radiology report of the prostate must be performed and obtained prior to the procedure. These images will be used for the fusion registration to perform the biopsy.

2.2.4.2B The facility must ensure the quality of the diagnostic MRI images are sufficient to perform the procedure.

2.2.4.3B The radiology report must be interpreted by a radiologist and include Prostate Imaging Reporting and Data Systems (PI-RADS®) description.

2.2.4.4B It is recommended that the images obtained are from a CMS-recognized Advanced Diagnostic Imaging (ADI) accredited facility.

2.2.5B Appropriate pre-procedure protocol must be documented in the medical record.

2.2.6B **Prior to Performance of the Procedure:**

2.2.6.1B Appropriate patient identification with explanation of the procedure and consent must be obtained.

2.2.6.2B Administration of local or general sedation as determined by the facility policy, qualified health care provider, ASA guidelines and state regulations.

2.2.6.3B Appropriate supplies needed for the procedure and patient management must be present.

2.2.6.4B A safety check or time-out by all staff involved prior to the procedure is required.

2.2.6.5B Patient preparation of the biopsy site using sterile technique is required.

2.2.7B **During the Procedure:**

2.2.7.1B The patient must be monitored as defined by the facility's protocol.

2.2.7.2B Strict adherence to sterile technique.

2.2.7.3B If anesthesia is administered, monitoring of the patient must be in compliance with the facility policy, ASA guidelines and state regulations.

2.2.7.4B Biopsy/treatment technique should follow published medical professional societal practice guidelines (i.e., AUA, SIR).

2.2.7.5B Determination of target selection/biopsy sites using facility protocol.

i. After the biopsy, samples are individually marked and fixed in specimen vial. The specimens are sent to the Clinical Laboratory Improvement Amendments (CLIA) certified lab for processing and evaluation.

ii. A comprehensive report containing the locations, the target images and biopsy sites of the prostate, is documented.

2.2.7.6B If applicable, determination of treatment type and process.

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i. A comprehensive report including the type and process for the treatment given should be documented.

2.2.8B **Post-Procedure, Patient Instructions and Follow Up**

2.2.8.1B The facility must have a policy in place to assess the patient's condition immediately post-procedure, provide post-procedure care instructions and follow up procedure must contain, but is not limited to:

i. documentation of vital signs;

ii. If general anesthesia is administered, immediate post-procedure assessment in compliance with American Society of Anesthesiologists (ASA) guidelines and state regulations;

iii. assessment of the biopsy site and proper dressing;

iv. management of post-procedure pain;

v. contact information to access the health care team;

vi. patient activity restrictions ambulation, travel and exercise;

vii. follow-up appointment, as appropriate:

- A follow-up appointment (as required by the facility's protocol) either in person, by telephone, or electronic communication with a medical staff member, advanced practice provider, or nursing staff member must be documented.

viii. Complications assessment (i.e., bleeding, infection, pain, etc.); and

ix. a pathology report must be sent to the referring physician and appropriate care team in a timely manner for patient management and treatment.

2.2.9B **Procedure Report**

2.2.9.1B The report must include, but is not limited to:

i. name of the provider(s) performing the procedure, as well as the supervising provider, if applicable;

ii. number and location of the biopsy specimens, complications/adverse events as appropriate;

iii. patient condition during and post-procedure;

iv. sedation information;

v. monitoring information; and

vi. transition of care information (provider or covering medical team at any hour).

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Part C: Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

1.1C The facility must have a written Quality Improvement (QI) Program to evaluate all types of procedures performed in the facility on an ongoing basis. Use of the AUA registry, SIR registry and other medical professional quality metrics is recommended (as applicable) as part of the overall QI program.

1.1.1C The QI program must include the QI measures outlined below to include, but may not be limited to the evaluation and review of:

1.1.1.1C procedure appropriateness;

1.1.1.2C technical performance of the procedure;

1.1.1.3C patient safety and infection control;

1.1.1.4C procedure outcomes including complications and any adverse events; and

1.1.1.5C medical record (inclusive of procedure report) completeness and timeliness.

1.1.2C The Medical Director, staff and/or an appointed QI committee must provide oversight to the QI program including but not limited to review of the reports of QI evaluations and documented corrective actions taken to address any deficiencies and quality gaps.

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Section 2C: Quality Improvement Measures

STANDARD – General QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in this section. All measures described are to be evaluated for a minimum of 30 cases annually.

2.1.1C Procedure Appropriateness

2.1.1.1C The facility must evaluate the appropriateness of the procedures performed using published societal guidelines (where available) for each procedure reviewed. The categories include:

i. appropriate;
ii. may be appropriate;
iii. rarely appropriate;
iv. not appropriate.

2.1.2C Technical Performance of the Procedure:

2.1.2.1C completeness of the procedure;

2.1.2.2C documentation of adverse technical events such as equipment or device failure;

2.1.2.3C failure to perform the procedure;

2.1.2.4C quality of the diagnostic MRI images;

2.1.2.5C quality of the co-registration of the MRI images;

2.1.2.6C confirmation that the targeted lesion (s) was biopsied; and

2.1.2.7C adherence to the facility policies, procedure and infection control protocols.

2.1.3C Patient Safety and Infection Control

2.1.3.1C Review records to ensure protocols for the following were followed according to the facility policies and procedures:

i. pre-procedure;
ii. during the procedure;
iii. immediate post procedure;
iv. post procedure and patient follow up;
v. pathology transfer, documentation and reporting.

2.1.4C Procedure Outcomes

2.1.4.1C The facility must have a written policy and process to track and document the outcomes of all patients evaluated and/or treated;

2.1.4.2C All procedural outcomes must be documented in the patient medical record pre-procedure, during the procedure, immediate post-procedure and patient follow up care.

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2.1.4.3C All adverse events that occur within post-procedure must be documented in patient medical record per the facility protocol.

2.1.5C Medical Record (inclusive of procedure report) Completeness and Timeliness:

2.1.5.1C Time from completion of procedure to signature of final documentation inclusive of the biopsy report findings completed per the facility protocol.

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Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

3.1C The facility must have a minimum of two Quality Improvement (QI) meetings per year.

3.1.1C Every significant complication must be reviewed (e.g., safety issues, adverse events, etc.).

3.1.2C All cases categorized as rarely or never appropriate must be documented and discussed.

3.1.3C Review of the data for required QI measures must be documented and discussed.

3.1.4C Educational updates must be documented and discussed.

3.2C All clinical staff must participate in at least one QI meeting per year.

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Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation and Record Retention

4.1C The facility QI documentation must include, but is not limited to:

4.1.1C the data for all of the QI measures above;

4.1.2C changes in procedures or policies as a result of the QI review;

4.1.3C minutes from the QI meetings; and

4.1.4C participant list (may include remote participation and/or review of minutes).

4.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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Artificial Intelligence (AI) Guidance Document

To assure the quality and safety of care delivery when using AI applications for direct-patient care (clinical*) purposes, each facility should create and follow policies and procedures that address:

1. Training for personnel who use AI;
2. Security of AI software, updates, HIPAA considerations, etc.;
3. AI for Quality Improvement (if applicable);
4. Appropriate use for each AI application; and
5. Governance (authority to make decisions regarding AI implementation).

*Clinical use of AI includes image acquisition, image processing/enhancement, image interpretation, report generation, risk assessment of prognosis, patient history, identification of critical values/results and equipment quality control.

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